REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# 200606050489		
3. Entity address (NOT a post office address): 1500 Research Parkway, Suite B150 TAMU 1186	4. City: College Station		5. State:	6. Zip Code: 77843-1186
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: 979 847-9362	9. FAX: 979 862-3176		10. E-mail: araines@vprmail.tamu.ed
11. RO or facility director address (NOT a post office address): 1500 Research Parkway, Suite B150	12. City: College Station		13. State:	14. Zip Code: 77843-1186
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 07/02/2007	18. Type of immediate notification: ☐ E-mail ☐ Fax ☑ Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)				

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 07/02/2007	28. Date of last inventory:	29. Name of principal investigator for laboratory with select agents and toxins First: N/A MI: Last: N/A	
30. Location of incident (building and room #): N/A	31. Location of incident (within room (e.g., freezer, incubator)): N/A		32. Biosafety level of laboratory where incident occurred: BSL3
33. Name and telephone number of agencies or local authorities notified: Health Dept. 512 458-7318	34. Symbols or markings on vials (if any):		35. Agent was recovered (theft/loss): ☐ No ☐ Yes

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): see below

37. Provide a detailed summary of events (attach additional sheets if necessary):

Attached is a follow up report on an elevated titer reported to you on 5/11/07. Although the report indicates a reduction in ratio, the titer is still elevated. The person has not had access to the agent since coming to Texas A&M but previously worked in a Veterinary Diagnostic Clinic. While we continue to seek your guidance, we believe using elevated titers as a sole indicator of an occupational exposure is not adequate. Texas A&M has developed a new definition for occupational exposure and will apply it as we are monitoring labs for safety until we get guidance from CDC. Occupational exposures are now defined as "clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been released outside of the primary bio-containment barrier." Titers will still be collected as part of our medical surveillance program. Elevated titers will be investigated and if the investigation determines that an occupational exposure occurred.

If there are any concerns regarding Texas A&M's definition, please let us know immediately.

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION

38. APHIS authorization number from transfer form:	39. CDC authorization number from transfer form:
40. Name of carrier:	41. Airway bill number/bill of lading number/tracking number:
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):	

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
52. Sender was contacted regarding incident: ☐ No ☐ Yes	53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS

54. Hazards posed by release: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

55. Exposures: ☐ No ☑ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)

1 employee showed evidence of prior exposure.

56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)

The chamber is now flushed with a disinfectant rather than using manual cleaning methods. In addition, personnel are now using positive air displacement respirators instead of the N95 face mask.

57. Medical treatment was provided: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)

The employee had previously been treated by a private physician and is currently being monitored.

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED

	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^8 pfu/ml)
1	Coxiella burnetii						
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: _____ Typed or printed name of Respondent: Angelia Raines

Title: ARO, Director of Research Compliance Date: 07/09/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

TEXAS Department of State Health Services

Texas Department of State Health Services

1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-3194
(512) 458-7318

LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Submitter copy to:

Date: 6/8/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #:
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Addr

DOB: 4/26/1981

Date Rcvd: 6/5/2007
Spec Type: SERUM

Test Reas: DIAGNOSIS

To all providers: IF you have not reported your NPI to DSHS, please call 1-888-963-7111, ext. 6030.

Final Results

Specimen Numbers:
Date Collected: 6/1/2007

BRUCELLA AGGLUTINATION	(1:40

An agglutination titer of (1:40 is considered to be negative.
This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

Q FEVER IFA	**PHASE I	(1:64
	PHASE II	1:512

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

(continued)

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Texas Department of State Health Services

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AUSTIN, TEXAS 78756-3194
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CLIA #45D0660644

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attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec
Subm #:
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Tel #: (512)458-7578

Patient

Patient Address:

DOB: 4/26/1981

((Q FEVER IFA is Reportable to Health Dept))

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

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Division of Select Agents and Toxins
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1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# 200606050489		
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7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: 979 847-9362	9. FAX: 979 862-3176	10. E-mail: araines@vprmail.tamu.ed	
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19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)				

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27. Date and time of incident: 07/02/2007	28. Date of last inventory:	29. Name of principal investigator for laboratory with select agents and toxins First: N/A MI: Last: N/A	
30. Location of incident (building and room #): N/A	31. Location of incident (within room (e.g., freezer, incubator)): N/A		32. Biosafety level of laboratory where incident occurred: BSL3
33. Name and telephone number of agencies or local authorities notified: Health Dept. 512 458-7318	34. Symbols or markings on vials (if any):		35. Agent was recovered (theft/loss): ☐ No ☐ Yes

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): see below

37. Provide a detailed summary of events (attach additional sheets if necessary):

Attached is a follow up report of an elevated titer previously reported to you on 4/24/07. Although the report indicates a reduction in ratio, the titer is still elevated. The person was exposed prior to joining Texas A&M and has since continued to have elevated titers. While we continue to seek your guidance, we believe using elevated titers as a sole indicator of an occupational exposure is not adequate. Texas A&M has developed a new definition for occupational exposure and will apply it as we are monitoring labs for safety until we get guidance from CDC. Occupational exposures are now defined as "clinical symptoms confirmed by laboratory evidence
or an abnormal event in which the agent could have been released outside of the primary bio-containment barrier." Titers will still be collected as part of our medical surveillance program. Elevated titers will be investigated and if the investigation determines that an occupational exposure occurred.
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42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):	

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
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1 employee showed evidence of prior exposure.
56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)
The chamber is now flushed with a disinfectant rather than using manual cleaning methods. In addition, personnel are now using positive air displacement respirators instead of the N95 face mask.
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1	Coxiella burnetii						
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: [redacted] Typed or printed name of Respondent: Angelia Raines

Title: ARO, Director of Research Compliance Date: 07/09/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

TEXAS Department of State Health Services

Texas Department of State Health Services

1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-3194
(512) 458-7318

LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Submitter copy to:

Date: 6/20/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #:
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:) COLLEGE STATION, TX 77840

DOB: 10/26/1972

Date Rcvd: 6/15/2007
Spec Type: SERUM

Test Reas: DIAGNOSIS

To all providers: If you have not reported your NPI to DSHS, please call 1-888-963-7111, ext. 6030.

Final Results

Specimen Numbers:
Date Collected: 6/14/2007

Q FEVER IFA	**PHASE I	(1:64
	PHASE II	1:128

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

(continued)

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1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-3194
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CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

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Date: 6/20/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #:
Subm
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient _____

Patient Address. _____

DOB: 10/26/1972

((Q FEVER IFA is Reportable to Health Dept))

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

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☐ Called police department (case #) ☑ Other (explain): see below

37. Provide a detailed summary of events (attach additional sheets if necessary):

We received baseline titers for 4 people. We now require blood draw before a person can enter a lab. The reports indicated an elevated titer. While we do not believe these represent a release at a Texas A&M facility since none of the individuals have had access to the Coxiella agent, we are submitting the reports for your review. As we continue to investigate the labs, we will provide you with follow up information. While we continue to seek your guidance, we believe using elevated titers as a sole indicator of an occupational exposure is not adequate. Texas A&M has developed a new definition for occupational exposure and will apply it as we are monitoring labs for safety until we get we get guidance from CDC. Occupational exposures are now defined as "clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been released outside of the primary bio-containment barrier." Titers will still be collected as part of our medical surveillance program. Elevated titers will be investigated and if the investigation determines that an occupational exposure occurred,
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1	Coxiella burnetii						1 x 10
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
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attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

DOB: 12/29/1963

Date Rcvd: 5/23/2007
Spec Type: SERUM

Test Reas: DIAGNOSIS

Please fax your NPI to 512.458.7533 by May 23, 2007. Delay in sending the NPI risks reimbursement as well as the reimbursement of your health care partners. Federal Regulation (Health Insurance Portability and Accountability Act of 1996 (HIPAA)) outlines you must share your NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes.

Final Results

Specimen Numbers:
Date Collected: 5/22/2007

BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.
This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

Q FEVER IFA	**PHASE I	<1:64
	PHASE II	1:128

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum and a convalescent serum. Reactions to both phase I and phase II antibody are often seen in test sera. However, in acute Q fever the phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

(continued)

TEXAS Department of State Health Services

Texas Department of State Health Services

1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-319
(512) 458-7318

LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Submitter copy to:

Date: 6/1/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

DOB: 12/29/1963

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

((Q FEVER IFA is Reportable to Health Dept))

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

SCOTT & WHITE HOSPITAL AND CLINIC
DIVISION OF CLINICAL PATHOLOGY

Name: [redacted]
MRN: [redacted] Loc: BCS CLIN
Age: 43 Sex: M
DOB: 12/29/1963
Ad[redacted]

FINAL REPORT
FINAL

Phone:

PHYSICIAN INFORMATION

Ordered by: WELCH, THOMAS, MD

Deliver to: WELCH, THOMAS, MD

Order Date&Time: 05/22/2007 14:5
Print Date&Time: 06/21/2007 06:3
Lab Order #: A1223548

REFERENCE LABS

TEST-NAME	RESULTS	AB	REF-RANGE	UNITS	SITE
BRUCELLA AGGLUTINATION					
COLLECTED 05/22/07 14:46					
BRUCELLA AGGLUTINATION	<1:40		<1:40		

ALL ORIGINAL REPORTS OF ABNORMAL RESULTS WILL BE SCANNED INTO SEQUOIA.
*
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

REFERENCE LABS

TEST-NAME	RESULTS	AB	REF-RANGE	UNITS	SITE
Q-FEVER IFA					
COLLECTED 05/22/07 14:46					
Q FEVER PHASE I	<1:64				
Q FEVER PHASE II	1:128				

A Q FEVER IFA TITER OF <1:64 IS CONSIDERED TO BE NEGATIVE.
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

Reviewing Physician: [redacted]

SCOTT & WHITE HOSPITAL AND CLINIC
DIVISION OF CLINICAL PATHOLOGY

Name:
MRN:
Age: 53 Sex: F
DOB: 08/14/1953
Add:

C: BCS CLIN

Phone:

FINAL REPORT
FINAL

PHYSICIAN INFORMATION

Ordered by: WELCH, THOMAS, MD

Deliver to: WELCH, THOMAS, MD

Order Date&Time: 05/15/2007 13:
Print Date&Time: 06/05/2007 06:
Lab Order #: A1153424

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
BRUCELLA AGGLUTINATION				
COLLECTED 05/15/07 10:10				
BRUCELLA AGGLUTINATION	<1:40	<1:40		

ALL ORIGINAL REPORTS OF ABNORMAL RESULTS WILL BE SCANNED INTO SEQUOIA.
*
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
Q-FEVER IFA				
COLLECTED 05/15/07 10:10				
Q FEVER PHASE I	<1:64			
Q FEVER PHASE II	1:128			

A Q FEVER IFA TITER OF <1:64 IS CONSIDERED TO BE NEGATIVE.
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

Reviewing Physician: TW.

SCOTT & WHITE HOSPITAL AND CLINIC
DIVISION OF CLINICAL PATHOLOGY

Name:
MRN: Loc: BCS CLIN
Age: 23 Sex: M
DOB: 10/19/1983
Add:

Phone:

FINAL REPORT
FINAL

PHYSICIAN INFORMATION

Ordered by: WELCH, THOMAS, MD

Deliver to: WELCH, THOMAS, MD

Order Date&Time: 05/15/2007 13:00
Print Date&Time: 06/05/2007 06:30
Lab Order #: A1153401

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
BRUCELLA AGGLUTINATION				
COLLECTED 05/15/07 10:20				
BRUCELLA AGGLUTINATION	<1:40	<1:40		

ALL ORIGINAL REPORTS OF ABNORMAL RESULTS WILL BE SCANNED INTO SEQUOIA.
*
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
Q-FEVER IFA				
COLLECTED 05/15/07 10:20				
Q FEVER PHASE I	<1:64			
Q FEVER PHASE II	1:128			

A Q FEVER IFA TITER OF <1:64 IS CONSIDERED TO BE NEGATIVE.
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

Reviewing Physician: TW

SCOTT & WHITE HOSPITAL AND CLINIC
DIVISION OF CLINICAL PATHOLOGY

Name
MRN: [redacted] : BCS CLIN
Age: 31 Sex: M
DOB: 04/09/1976
Add: [redacted]

Phone:

FINAL REPORT
FINAL

PHYSICIAN INFORMATION

Ordered by: WELCH, THOMAS, MD

Deliver to: WELCH, THOMAS, MD

Order Date&Time: 05/15/2007 12:5
Print Date&Time: 06/05/2007 06:3
Lab Order #: A1153389

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
BRUCELLA AGGLUTINATION				
COLLECTED 05/15/07 11:00				
BRUCELLA AGGLUTINATION	<1:40	<1:40		

ALL ORIGINAL REPORTS OF ABNORMAL RESULTS WILL BE SCANNED INTO SEQUOIA.
*
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

REFERENCE LABS

TEST-NAME	RESULTS	AB REF-RANGE	UNITS	SITE
Q-FEVER IFA				
COLLECTED 05/15/07 11:00				
Q FEVER PHASE I	<1:64			
Q FEVER PHASE II	1:128			

A Q FEVER IFA TITER OF <1:64 IS CONSIDERED TO BE NEGATIVE.
PERFORMED BY
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W 49TH ST
AUSTIN, TX 78756

Reviewing Physician: TCW

VPR
Office of the Vice President for Research
Texas A&M University

Office of Research Compliance

Academy for Advanced Telecommunication and Learning Technologies

Center for Information Assurance and Security

Comparative Medicine Program

Institute for Scientific Computation

Integrative Center for Homeland Security

Microscopy Imaging Center

National Center for Foreign Animal and Zoonotic Disease Defense

Office of Distance Education

Office of Graduate Studies

Office of Proposal Development

Office of Sponsored Projects

Professional Development Group

Technology Commercialization Center

Texas A&M University Research Park

Texas A&M University

[illegible]

July 9, 2007

Mr. James F. McGee
Centers for Disease Control & Prevention
Division of Select Agents & Toxins
1600 Clifton Rd, NE., Mailstop A46
Atlanta, GA 30333

Mr. McGee:

The attached form-3s represent the most recent reports of elevated titers. As you know, in April, 2007, Texas A&M has been reporting any elevation, while we wait to receive your guidance on the definition of an occupation exposure. We have sent reports on any elevation in titer received from 2006, to date.

Two of the elevated titers we are reporting are follow up to based on previous reports submitted. The titers are now lower for both individuals but are still above the normal ratio.

Since we now require baselines on anyone before entering a laboratory, the other reports represent initial baselines.

While we continue to seek your guidance, we believe using elevated titers as a sole indicator of an occupational exposure is not adequate. For instance, since adopting the new reporting requirement, Texas A&M has notified you of 4 individuals with elevated titers for Q-fever. Two of the four were exposed to the agent prior to coming to Texas A&M and have continued to have elevated titers since. One person previously worked in a veterinary diagnostic lab before joining Texas A&M but had not been exposed to the agent since coming here. The 4th person had an elevated titer but there were no clinical symptoms and we could not determine that there was ever any access to the agent beyond the bio-containment barrier. There was evidence that the person had access to the antigen which although not a select agent, can cause an elevated titer.

Based on this information, Texas A&M has developed a new definition for occupational exposure and will apply it as we are monitoring labs for safety until

Mr. James F. McGee
Centers for Disease Control & Prevention

we get guidance from CDC. Occupational exposures are now defined as "clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been released outside of the primary bio-containment barrier." Titers will still be collected as part of our medical surveillance program. Elevated titers will be investigated and if the investigation determines that an occupational exposure occurred, we will report the information to you immediately. If there are any concerns regarding Texas A&M's definition, please let us know immediately.

Thank you in advance for your consideration and we look forward to receiving your input.

Sincerely,

Angelia Raines
ARO/Director, Office of Research Compliance

Cc: Richard Ewing, RO
Fuller Bazer, ARO
Brent Mattox, ARO
SBAT File
IBC
SBAT PI/LDs

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# C2006-06050489	
3. Entity address (NOT a post office address): TAMU 1112	4. City: College Station	5. State:	6. Zip Code: 77843-1186
7. Responsible Official (RO) or facility director First: Richard MI: I Last: Ewing	8. Telephone: (979) 845-8585	9. FAX: (979) 862-3176	10. E-mail: r.ewing@tamu.edu
11. RO or facility director address (NOT a post office address): Same as Entity (listed above)	12. City:	13. State:	14. Zip Code:
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 05/11/2007	18. Type of immediate notification: ☐ E-mail ☐ Fax ☑ Telephone
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☐ Yes (If yes, please provide additional details in an attachment.)			

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 05/11/2007 9:00 am	28. Date of last inventory: 12/11/2006	29. Name of principal investigator for laboratory with select agents and toxins First: James MI: Last: Samuel	
30. Location of incident (building and room #):	31. Location of incident (within room (e.g., freezer, incubator)): N/A	32. Biosafety level of laboratory where incident occurred: ABSL3	
33. Name and telephone number of agencies or local authorities notified: CDC and Brazos County Health Department	34. Symbols or markings on vials (if any): N/A	35. Agent was recovered (theft/loss): ☐ No ☐ Yes	

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): See detailed summary below

37. Provide a detailed summary of events (attach additional sheets if necessary):

On 5/11/07, the BSO/ARO received a baseline report that indicated that indicated a higher than normal titer for Q fever (Phase I = <1:64) (Phase II=1:1024).

The employee was DSAT approved on 1/5/07. Prior to that date, the employee was escorted in the lab on 4 separate occasions. However, he was only allowed to observe blood draws of infected animals and did not have access to the agent. After further review of the employee's work, we found that he had been working with Coxiella antigens but also had possible previous possible exposure while working with cow serum in a veterinary diagnostic lab in China.

Also, in reviewing the information, we found that the PI failed to follow his written protocol regarding baseline blood draws prior to lab access. All lab personnel will be required to receive refresher training on this requirement prior to June 1, 2007. In reviewing the Plans (security, incident response, safety) no changes were required, however all lab personnel will be required to receive refresher training in June.

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION	
38. APHIS authorization number from transfer form:	39. CDC authorization number from transfer form:
40. Name of carrier:	41. Airway bill number/bill of lading number/tracking number:
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):	

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
52. Sender was contacted regarding incident: ☐ No ☐ Yes	53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS
54. Hazards posed by release: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)
55. Exposures: ☑ No ☐ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)
56. Area was decontaminated: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)
57. Medical treatment was provided: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES							
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED							
	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^8 pfu/ml)
1	Coxiella burnetii						1 x 10
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: _____ Typed or printed name of Respondent: Angelia Raines

Title: Director, Office of Research Compliance Date: 05/18/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

To: Angelia Raines
Director of the Office of Research Compliance

Institutional Biosafety Committee

From: Brent S. Mattox, CIH
Institutional Biosafety Officer

Date: May 15, 2007, With May 18, 2007 Addendum

Subject: Investigative Report on Elevated Q Fever Titer

The following paragraphs contain the investigative report summarized in an email to your office on May 15, 2007.

On late afternoon of 5/10/2007, Scott and White called to inform Occupational Health that a high titer for Q Fever (Phase II 1:1024) was received on a new addition (baseline titer) to the Occupational Health Surveillance Program. Due to issues with obtaining a copy of the titer results, EHSD did not receive a copy of the titer until Friday, 5/11/07. At that time, (9 AM), the Office of Research Compliance was informed via email that this was a reportable incident. According to the Texas Department of State Health Services, a titer of greater than 1:256 is evidence of a prior infection, but, it DOES NOT confirm that the infection was recent. EHSD spoke with the researcher, Dr. James Samuel, on Friday via cell phone, and was assured that no symptoms of disease had manifested themselves in the individual with the elevated titer, or any other employee. Dr. Samuel was out of town until late Monday, May 14, but responded via email with the hiring date of date he arrived on job, possible past exposures (prior to employment), possible on the job exposures (BL3, BL2 access logs), and any other individuals potentially exposed who were not currently being monitored. According to Dr. Samuel, had been hired 8/18/2005, and had reported for work on 11/07/2005. He had possible exposures while working in a veterinary diagnostic lab in . He had been potentially exposed to the agent while at TAMU.

On Tuesday May 15 at 1:45 PM, I met with Dr. Samuel and Chen at their Laboratory in and obtained additional information on the potential exposures. Although had not entered the BL3 laboratory in s, he had assisted a Veterinarian on Dr. Samuel's staff with blood drawings of animals at the Building in room on four separate occasions. The individual had been working with antigens of Coxiella. Copies of the entry logs into the BL3 for . are attached.

It was determined that had not had a baseline test until the draw on 4/20/2007. It was also determined that Dr. Samuel's Laboratory Special Practices requires that baselines be collected prior to any exposures.

The following paragraph summarizes the findings.

was CJIS approved and had accessed the 972 Facility on four (4) occasions prior to the baseline. Laboratory Special Practices does call for baselines prior to exposure. The Facility Access was for Animal Room . . . , NOT the aerosol chamber housed in The individual participated in blood drawing from animals that had been exposed to Coxiella on three of the dates, assisting the DVM. The DVM, who also conducted aerosol studies with Coxiella in the Madison Chamber, has shown elevated titers in the past, but has not been tested this year. According to Dr. Samuel the reason for not having a recent test was due to some individuals being out of town. Dr. Samuel was urged to get the individuals tested as soon as practical ndicated that he had not been ill, and was not feeling ill at the time. He is scheduled for a follow-up with S&W on June 1, as confirmed by Scott & White. indicated that he had possible previous exposure from a veterinary diagnostic lab in when he was working with cow serum.

The conclusions drawn would suggest possible previous exposure, although lab exposure at TAMU, although remote, cannot be completely ruled out. does work with antigens of Coxiella, which theoretically could cause elevated titers. Although a baseline titer should have been conducted or a serum sample collected prior to access, no unusual incidents or deviations from established protocols were noted. Individual was wearing a PAPR and protective clothing, and followed proper decontamination procedures will continue to be monitored under the Occupational health Program as outlined above.

Summarizing the findings, the principal investigator failed to follow written protocols requiring baseline blood drawings prior to exposure. Two individuals in the Laboratory have not had 2007 titers drawn. Previous exposure is a possibility, but occupational exposure at TAMU cannot be ruled out.

Addendum, May 18, 2007

A question was raised concerning the access the individual had to the agent, or contaminated surfaces. As a result, I conducted a follow-up phone interview at 12:45 PM on Friday, May 18, 2007, with Kasi Russell-Londrigue, the Veterinarian who was present and escorted on all four visits. Kasi stated that never came into direct contact or had access to the agent. According to Kasi, did not draw the blood but only observed. At no time during access did he come into direct physical contact with the agent, or the blood drawn. Kasi took the blood and spun it down for serum, placing the serum in a locked refrigerator. In theory, the agent isn't in the serum being only in the cells. The serum was later heat treated in preparation for an ELISA test. This should have completely inactivated any Coxiella that could have been in the serum, although there should not have been any agent present did have access to the heat treated serum.

FACILITY ACCESS LOG **ROOM #** _____ **BUILDING #** **PI NAME** Samuel

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
8/18/06	Britt Lack	Britt Lack	CMP	8:55	BL					
8/19	Gradon Draper		cmp	1023 1100						
8/20	Gradon Draper		CMP	1020 1109						
8-21	Kasi Russell-Lodge		MMP	8:35 10:00	KR					
8/21	Gradon Draper		CMP	221 439						
11-6-06	John Delaney		CMP	9:40	JD					
11-6-06	Kasi Russell-Lodge		MMP	10:05 11:55	KR					
11			mmp	10:05 11:55		CC	R	Atm ID	KR	CC KR
11/6										
11/7	Gradon Draper		CMP	154 301						
11/7/06	Kasi Russell-Lodge		MMP	2:15 3:35	KR					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #_____** **BUILDING _____** **PI NAME** Samuel

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial)
				In / Out						By
11-14-06	EDWARD SHAW		ESA	1:45		✓	R	ID 08230644	KR	ES - KR
			MMPA	2:30						
11/15/06	Kasi Russell-Lobrano		MMP	8:55 / 10:40	KR					
11/			MMP	8:55 / 10:00			R	UIN	KR	KR
11/16/06	Gradon Draper		CMP	215 / 331						
11/16/06	Gradon Draper		CMP	250 / 350						
11/16/06	Sean Knox		CMP	8:40 / 11:55	SK					
11/17/06	Amy Henson		CMP	1:20 / 4:35	AH					
11/18/06	Amy Henson		CMP	8:14 / 9:19	AH					
11/19/06	Amy Henson		CMP	8:10 / 9:10	AH					
11/22/06			MMP	9:50 / 11:05			R	UIN	KR	KR
11/22/06	Kasi Russell-Lobrano		MMP	9:50 / 11:25	KR					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILITY ACCESS LOG **ROOM #** 140 **BUILDING #** 972 **PI NAME** Samuel

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
12/1/06	Sean Knox		CMP	10:21 / 1:00	SK					
12/3	Gordon Draper		CMP	1154 / 02	GD					
12/4	Gordon Draper		CMP	846 / 1223	GD					
12/5	Gordon Draper		CMP	854 / 1118	GD					
12/6	Amy Henson		CMP	9:43 / 12:10	AH					
12/6	Chen Chen		MMPA	10:00 / 10:40		CC	R	21600686	KR	KR
12/6	Kasi Russell		MMPA	10:00 / 10:40	KR					
12/6	Kasi Russell-Hoodjer		MMPA	11:11 / 11:30	KR					
12/7	John D. Delaney		CMP	8:54 / 11:07	JD					
12/7	John D Delaney		CMP	1:25	JD					
12/8	Amy Henson		CMP	2:40 / 5:14	AH					

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

From: "Mattox, Brent S" <bsmattox@tamu.edu>
To: "Raines, Angelia" <araines@vprmail.tamu.edu>
Date: 5/18/2007 1:12:42 PM
Subject: RE: Draft - RE: Investigative Report on Q Fever

Angelia:

I have additional information I did not include in the report. After reading your email, I decided to contact Kasi Russell-Lodrigue at around 12:45 today, who was present during the entries of Chen. According to Kasi, which was also my understanding, Chen did not draw the blood but only observed. At no time during access did he have access to the agent, or the blood drawn. Kasi took the blood and spun it down for serum, placing the serum in a locked refrigerator. In theory, the agent isn't in the serum being only in the cells. The serum was later heat treated in preparation for an ELISA test. This should have completely inactivated any Coxiella that could have been in the serum, although there should not have been any there anyway. Chen did have access to the heat treated serum.

Thus, in my opinion, he never had direct access to the agent. Why his titer is elevated remains the unanswered question. Please add this email to my report as an attachment. The training issue is still a good point. There still seems to be confusion over what "escorted" means and what that entails for the escort, and a discussion about pre-screening and serum banking probably needs to occur.

Hopefully, this email will help alleviate some of the concerns over access. Feel free to forward or distribute this email as you see fit.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 18, 2007 12:22 PM
To: Ewing, Richard
Cc: Vernon Tesh; Kretzschmar, Bert; Mattox, Brent S; Meyer, Chris; Salsman, John M; Kelly, Scott; Thomas Ficht; Tiffany Agnew; Fuller Bazer
Subject: Draft - RE: Investigative Report on Q Fever

Dr. Ewing,

I am trying to draft our report to CDC and need input regarding how the institution is going to handle this issue of non-compliance.

Per the response from Brent below, it appears that an employee who was not approved for access to a select agent was allowed to use it. I am very concerned and think that immediate action is needed in order to prevent future occurrence. We are planning training for all Select Agent personnel and it will be conducted by June 30th, but in the mean time I would like to suggest some type of immediate action be taken.

I have to submit the report to CDC today. With your input on the action

required, I will include it in the documentation. I will send a draft of the of the report to you as well as the PI, BSO, IBC and Departmental contacts for review as quickly as possible.

Thanks,
Angie

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/18/2007 11:39:33 AM >>>
Below are responses to your three questions concerning the high titer issue. Please note that the employee has not shown signs or symptoms of any illness, so this is an investigation of a high Q fever titer, not an investigation of Q fever.

1. The first visit to 972 was to draw blood from pre-exposed varmints (in other words, no potential exposure to the agent). The remaining three were to draw blood that would have potentially contained the AGENT, not antigen. These three trips would constitute documented risk of exposure due to the proximity of the agent (in rodent and blood). The first exposure is more remote, with the agent not being present in the same room as the employee. Further, I recommend that all work with select agents involve pre-exposure screening, including all visitors. I recommend (for example) that all individuals entering the BL3 suite at LARR be required to have titers drawn for Q fever and Brucella, in addition to TB testing. Obviously, this recommendation needs to go to the IBC.

2. The researcher's own protocols require pre-exposure monitoring and were apparently disregarded. However, we may want to look at the facility plan to require not just TB screening for access, but baseline serum titers for anyone entering the facility (BL3 rooms) regardless of planned exposure. That is what we are doing with the contractor, but his risk is obviously higher (cutting into contaminated ductwork linking all the rooms).

3. The SOP regarding pre-screening was not followed, according to the PI. I do not know if re-training is necessary, but clearly the PIs should be informed that pre-screening is a necessity for their employees, and that they must strictly adhere to their written SOPs.

Hope this helps,

Brent S. Mattox
Biological Safety Officer

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Friday, May 18, 2007 11:06 AM
To: Mattox, Brent S
Cc: Vernon Tesh; Kretzschmar, Bert; Meyer, Chris; Salsman, John M; Thomas Ficht; Tiffany Agnew; Fuller Bazer
Subject: Re: Investigative Report on Q Fever

Hi Brent,

Thanks for sending the report. I am preparing form-3 to send to CDC and want to make sure I have the correct information. I will send it to

you, Jim and Bert to review before I send it. However before completing it, I have a few questions:

1. During the 4 times the employee accessed the Lab, was he exposed to the antigen only?
He was not DSAT approved until 1/07 and the facility access logs were completed prior to that approval. I want to make sure we include the correct information in the report.

2. Do the plans (security, safety, incident or surveillance) need to be changed as a result of this incident? If so, what changes are needed.

3. In reviewing the report, it appears that the SOP that required screening prior to work in the lab was not followed. If this is the case, when will refresher training be conducted? Since your report will be presented to the IBC at the next meeting, we will need to be sure the follow up letter from the committee indicates what type of training documentation is required.

Thanks again for the report.

Angelia

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/17/2007 10:05:52 AM >>>
Angelia:

Please find attached another pdf of the investigative report on the Q fever titer. I inadvertently left off copies of the entry logs for 972.

Thanks,

Brent

Note to File:

Based on the investigation of the incident, the BSO reviewed requirement for baseline blood draws during annual training sessions conducted June 2007.

All SBAT personnel who will continue to have access to facilities attended the training.

Angelia Raines
7/18/07

From: "Mattox, Brent S" <bsmattox@tamu.edu>
To: "Raines, Angelia" <araines@vprmail.tamu.edu>, <jsamuel@medicine.tamhsc.edu>
Date: 5/11/2007 9:00:55 AM
Subject: Elevated Titer for Q Fever

Angelia/Dr. Samuel:

Scott and White informed me that a high titer (Phase II 1:1024) was recelved on a new addition (baseline titer) to the Occupational Health Surveillance Program yesterday afternoon (5/11/07). Due to issues with obtaining a copy of the titer results, our response was delayed until this morning. According to the Texas Department of State Health Services, a titer of greater than 1:256 is evidence of a prior infection, but, it DOES NOT confirm that the infection was recent. EHSD will be conducting an investigation concerning this issue, and will need the date of hire and the work history of the individual, including any possible exposures, since employment at Texas A&M Health Sciences Center. If any other individuals have been potentially exposed, please notify our office. A detailed occupational history of past possible exposures prior to employment is also requested from the employee.

According to recent statements from CDC, it is EHSD's opinion that this constitutes a reportable condition to CDC. It is also our understanding that this reporting is to be done by the Office of Research Compliance. We will provide a summary of our findings to the Office of Research upon completion of the investigation. The employee will continue to be monitored by the Occupational Health Program as directed by the occupational health physician at Scott & White.

If you have any further questions, please let me know. A copy of the titer result is attached.

CC: "Meyer, Chris" <c-m-meyer@tamu.edu>, "Salsman, John M" <jmsalsman@tamu.edu>

From: "Mattox, Brent S" <bsmattox@tamu.edu>
To: <jsamuel@medicine.tamhsc.edu>
Date: 5/11/2007 2:11:02 PM
Subject: High Titer Report

Dr. Samuel:

Please let me know if the employee was potentially exposed to any rDNA from Coxiella (this is for NIH purposes), and if any additional employees could have been exposed. If the employee has no known exposures since his arrival at A&M, let me know that. I believe you left a number when you attempted to contact my cell phone at 12:10, but the cell phone message was unintelligible in places, unfortunately one of which was the number.

I understand that you are out of the Office this afternoon, but I will be in touch with you upon your return Monday.

Thanks,

Brent

CC: "Salsman, John M" <jmsalsman@tamu.edu>, "Raines, Angelia" <araines@vprmail.tamu.edu>

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY M.D.
COMMISSIONER

1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us
TDD: 512-458-7708

Submitter copy to: ** DUPLICATE REPORT ** Date: 5/2/2007

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #:
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

DOB: 4/26/1981

Patient Address:

Date Rcvd: 4/23/2007
Spec Type: SERUM

Test Reas: DIAGNOSIS

Please fax your NPI to 512.458.7533 by May 23, 2007. Delay in sending the NPI risks reimbursement as well as the reimbursement of your health care partners. Federal Regulation (Health Insurance Portability and Accountability Act of 1996 (HIPAA)) outlines you must share your NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes.

Final Results

Specimen Numbers:
Date Collected: 4/20/2007

BRUCELLA AGGLUTINATION		<1:40

An agglutination titer of <1:40 is considered to be negative.
This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved or cleared by the US Food and Drug Administration (FDA).

Q FEVER IFA	**PHASE I	<1:64
	PHASE II	1:1024

A single Q fever IFA titer of greater than or equal to 1:256 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing evidence of recent infection is a fourfold rise in antibody titer between an acute serum

and [illegible] scent serum. Reactions to both phase I and phase II antibodies often [illegible] phase II titer. The phase II antibody is usually higher than the phase I titer. In chronic Q fever phase I titers rise in later specimens while phase II titers fall or remain constant.

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
1100 W. 49th Street • Austin, Texas 78756
1-888-963-7111 • http://www.dshs.state.tx.us
TDD: 512-458-7708
DAVID L. LAKEY M.D.
COMMISSIONER

(continued)

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University		2. Entity registration number (if applicable): APHIS# CDC# 200606050489		
3. Entity address (NOT a post office address): TAMU 1111	4. City: College Station		5. State:	6. Zip Code: 77843-1111
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: (979) 845-8585	9. FAX: (979) 862-3176	10. E-mail: rewing@vprmail.tamu.ed	
11. RO or facility director address (NOT a post office address): same as above	12. City:		13. State:	14. Zip Code:
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 04/17/2007	18. Type of immediate notification: ☐ E-mail ☐ Fax ☑ Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) SOPs were reviewed. Decontamination procedures were changed.				

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 04/03/2006	28. Date of last inventory: 12/12/2006	29. Name of principal investigator for laboratory with select agents and toxins First: James MI: Last: Samuel	
30. Location of incident (building and room #):	31. Location of incident (within room (e.g., freezer, incubator)): N/A	32. Biosafety level of laboratory where incident occurred: BSL3	
33. Name and telephone number of agencies or local authorities notified: Brazos County Health Department 979 361-4440	34. Symbols or markings on vials (if any): N/A	35. Agent was recovered (theft/loss): ☐ No ☐ Yes	

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☑ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): Bio-Safety Officer

37. Provide a detailed summary of events (attach additional sheets if necessary):

As a result of recent reporting problems, Texas A&M has been auditing all Select Agent files to ensure that any incident involving theft, loss or release has been properly report to the CDC.
On 4/17/07, we reviewed a file involving elevated titers, which at the time, were not considered to be a release because there was no indication of having clinical symptoms of illness associated with Q fever. Two of the employees also indicated that they had a history of elevated titers based on previous work they performed. None of the individuals with elevated titers presented with clinical signs of illness.
While we still seek your guidance in defining 'Occupational Exposure" until there is more clarify, all elevated titers will be reported to the CDC as a release. After receiving information regarding the elevated titers, Texas A&M's Occupational health and Safety Office as well as the Investigator, ensured that the lab was decontaminated as safety precaution and the SOPs were reviewed and updated to include new plans for decontamination

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION

38. APHIS authorization number from transfer form:	39. CDC authorization number from transfer form:
40. Name of carrier:	41. Airway bill number/bill of lading number/tracking number:

42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
52. Sender was contacted regarding incident: ☐ No ☐ Yes	53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS

54. Hazards posed by release: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

55. Exposures: ☐ No ☑ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)

Three Employees

56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)

See attached

57. Medical treatment was provided: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES							
LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED							
	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^8 pfu/ml)
1	Coxiella burnetii						1 x 10
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent:  Typed or printed name of Respondent: Angella Raines

Title: Alternate Responsible Official Date: 04/24/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

VPR
Office of the Vice President for Research
Texas A&M University

April 24, 2007

Office of Research Compliance

Academy for Advanced Telecommunication and Learning Technologies

Center for Information Assurance and Security

Comparative Medicine Program

Institute for Scientific Computation

Integrative Center for Homeland Security

Microscopy Imaging Center

National Center for Foreign Animal and Zoonotic Disease Defense

Office of Distance Education

Office of Graduate Studies

Office of Proposal Development

Office of Sponsored Projects

Professional Development Group

Technology Commercialization Center

Texas A&M University Research Park

Texas A&M University

[illegible]

Mr. James F. McGee
Centers for Disease Control & Prevention
Division of Select Agents & Toxins
1600 Clifton Rd, NE., Mailstop A46
Atlanta, GA 30333

Mr. McGee:

Attached is form 3 for an incident involving elevated titers in three individuals who were working with the antigen of the select agent Coxiella. This was reported to you by phone on 4/17/07.

As you know, as a result of recent reporting problems, Texas A&M has been auditing all Select Agent files to ensure that any incident involving theft, loss or release has been properly report to the CDC.

On 4/17/07, we reviewed a file involving elevated titers, which at the time, were not considered to be a release because there was no indication of clinical symptoms of illness associated with Q fever. Elevated titers are determined by comparison with a baseline titer collected from the employee at initial hiring or assignment to an area containing the agent. Two of the employee's initial baseline titers indicated that they had a history of elevated titers based on previous work they performed. None of the individuals with elevated titers presented with clinical signs of illness.

While we seek your guidance in defining 'Occupational Exposure" until there is additional guidance, all elevated titers will be reported to the CDC as a release.

After receiving information regarding the elevated titers, Texas A&M's Occupational health and Safety Office as well as the Investigator, ensured that the lab was decontaminated as a safety precaution and the SOPs were reviewed and updated to include new plans for decontamination.

Please feel free to contact our office at (979) 847-9362, if additional information is needed.

Sincerely,

Angelia Raines
ARO/Director, Office of Research Compliance
Texas A&M University (#C20060605-0489)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TO: Richard Ewing, Responsible Official
Texas A&M University
Mail Stop - 1186
College Station, TX 77840
Fax: (979) 862-3176

FR: Centers for Disease Control and Prevention, Division of Select Agents and Toxins

RE: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

DATE: January 30, 2007

We have received your report of APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) received from Texas A&M University on December 29, 2006 concerning your entity's investigation of the loss of *Coxiella burnetii*. Based upon the review of the report and additional information provided, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has no further questions at this time regarding this matter.

Paul Mehta, M.D.
Team Leader/Health Scientist
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, MS A-46
Atlanta, GA 30333
Telephone: (404) 718-2011; FAX: (404) 718-2096

Transmission Report

Date/Time	01-18-2007	05:57:36 p.m.	Transmit Header Text	
Local ID 1	979 862 3176		Local Name 1	VPR COMPLIANCE
Local ID 2			Local Name 2	

This document : Confirmed
(reduced sample and details below)
Document size : 8.5"x11"

TEXAS A&M UNIVERSITY

Vice President for Research - Office of Research Compliance
1186 TAMU
College Station, TX 77843-1186

Telephone: 979.458.1467 **Facsimile: 979.862.3176**

Date: 01/18/2007

To: Paul Mehta, Centers for Disease Control (CDC)

Facsimile: (404) 718-2096

From: Angelia Raines, ARO

Attached is the response to your letter, which was received on 1/10/07.

If you have questions, please feel free to reach me at 979 847-9362.

Best Regards,
Angelia Raines, ARO
(Registration C 20060605-0489)

SHOULD YOU EXPERIENCE ANY DIFFICULTIES IN RECEIVING THIS FACSIMILE, PLEASE CALL THE OFFICE AT (979) 458-1467.

Total Pages Scanned : 18 Total Pages Confirmed : 18

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001	045	404 718 2096	05:53:47 p.m. 01-18-2007	00:03:08	18/18	1	EC	HS	CP28800

Abbreviations:

HS: Host send	PL: Polled local	MP: Mailbox print	TU: Terminated by user	
HR: Host receive	PR: Polled remote	CP: Completed	TS: Terminated by system	G3: Group 3
WS: Waiting send	MS: Mailbox save	FA: Fail	RP: Report	EC: Error Correct

TEXAS A&M UNIVERSITY

Vice President for Research - Office of Research Compliance
1186 TAMU
College Station, TX 77843-1186

Telephone: 979.458.1467 Facsimile: 979.862.3176

Date: 01/18/2007

To: Paul Mehta, Centers for Disease Control (CDC)

Facsimile: (404) 718-2096

From: Angelia Raines, ARO

Attached is the response to your letter, which was received on 1/10/07.

If you have questions, please feel free to reach me at 979 847-9362.

Best Regards,
Angelia Raines, ARO
(Registration C 20060605-0489)

SHOULD YOU EXPERIENCE ANY DIFFICULTIES IN RECEIVING THIS FACSIMILE, PLEASE CALL THE OFFICE AT (979) 458-1467.

VPR
Office of the Vice President for Research
Texas A&M University

1/11/2007

Office of Research Compliance

Academy for Advanced Telecommunication and Learning Technologies

Center for Information Assurance and Security

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Institute for Scientific Computation

Integrative Center for Homeland Security

Microscopy Imaging Center

National Center for Foreign Animal and Zoonotic Disease Defense

Office of Distance Education

Office of Graduate Studies

Office of Proposal Development

Office of Sponsored Projects

Professional Development Group

Technology Commercialization Center

Texas A&M University Research Park

Texas A&M University

1186 TAMU

1500 Research Parkway

Suite B150

College Station, Texas

77843-1186

979.458.1467

FAX 979.862.3176

Paul Mehta, M.D.
Centers for Disease Control & Prevention
Division of Select Agents & Toxins
1600 Clifton Rd, NE., Mailstop A46
Atlanta, GA 30333

Re: 42 C.F.R. 73.19 (Notification of theft, loss, or release0

Dr. Mehta:

The following are responses to your letter, received on January 10, 2007, regarding form 3 (report of loss, theft, or release).

Question 1: What is the current status of the investigation? Has the disposition of the mouse been determined?

Response: The current status of the investigation is 'closed.' After inspecting the facility, interviewing all parties involved and reviewing all documents related to the incident, we have determined the following:

The missing mouse was most likely included in the autoclaved bedding material and disposed. It had been used to produce cultures and was scheduled to be sacrificed on the day of the incident. The day before, the cages had been changed. The animals were counted prior to the cage change and none were missing. The animals were later moved to clean cages. At the time that they were moved, a count was not preformed. The following day is when the next count was performed and at that time it was determined that the mouse was missing. The cages had already been autoclaved and the bedding had already been disposed.

Because door sweeps are in place and vermin traps are distributed throughout the suite, it is unlikely that any other scenario could have occurred.

Question 2: What are the protocols for removing dead animals from cages?

Response: Animals are placed in biohazard bags, autoclaved, and disposed of by incineration. If the animal can not be immediately removed from the lab, they are placed temporarily in a secured 20 degree C freezer.

Question 3: Please submit copies of all protocols for the decontaminating waste from animal studies.

Response: Please see attachment 'A'.

Question 4: Please submit copies of procedures for the handling of autoclaved animal carcasses?

Response: Please see attachment 'B'.

Question 5: What follow up training has been conducted to prevent future occurrences.

Response: All personnel have been instructed to always count the animals immediately before handling them in any way. They have been instructed on how to document the counts and have been retrained on the process for reporting any discrepancy. Finally, they have been instructed how to halt activity and secure the lab until an investigation is completed.

Question 6: Have there been any inventory discrepancies in the past?

Response: There have been no inventory discrepancies in the past.

Question 7: Please provide a list of people with access and the access logs where the animal was housed.

Response: Please see attachment 'C'.

I hope you will find this information helpful. Please feel free to contact our office at (979) 847-9362 if additional information is needed.

Sincerely,

Angelia Raines
ARO/Director, Office of Research Compliance
Registration #: **C20060605-0489**.

Attachment A
(Waste Decontamination)

APPROVED

STD OPERATING PROCEDURE: A-I.L.1
Revision 2/05 kjg

REMOVAL OF BIOHAZARDOUS WASTE

RESPONSIBILITY:

Full-time Animal Care Staff only - following health testing (if required), training and task assignment. **NOTE: Only staff with Department of Justice clearance for access to Select Biological Agents and Toxins may work with projects involving the use of select agents/toxins.**

PROTECTIVE APPAREL:

Clean coveralls
CMP approved footwear
Latex gloves - several pairs
Face mask - dust/mist type in the event of aerosol risk
Spray bottle with appropriate disinfectant solution
Back support belt (optional, but strongly recommended)
Spill kit for biohazardous waste
Cellular telephone for emergency communication

GENERAL INFORMATION:

1. The Ancillary Supervisor will coordinate transporting waste loads to the designated incinerator to ensure that the incinerator operator will be present when load is delivered. Biohazardous waste from Main and Ancillary will be transported in conjunction with the regular incinerator loads.
2. Only full-time animal care staff who have been specifically trained on biohazardous waste removal and protocols specific to the biohazard will handle these duties. Whenever possible, two employees will be assigned for each waste removal trip.
3. Any breaches in biohazardous waste handling or any accidents must be reported to the employee's supervisor immediately.
4. **All ABSL carcasses/waste must be autoclaved before being transported to the incinerator/biodigestor.**

TASKS:

Primary Option:

1. Autoclave all biohazard bags (animal carcasses/tissues are to be bagged separately from trash waste). Use stainless steel pans under bags containing carcasses in the autoclave.
2. Unload the autoclaved carcasses/waste after ensuring that the cycle was completed and proper temperatures were met.
3. All bagged carcasses are placed into a red biohazard waste barrel (with top) and the barrel is then placed into the animal carcass cooler until ready to incinerate or biodigest.
4. All trash waste is taken to the trash dumpster located near the back dock (after being autoclaved).

Emergency Option: (if autoclave is not functioning)

1. Prior to transporting biohazardous waste, put on clean coveralls and place a biohazard waste spill kit into the transport vehicle.
2. Verify with the Ancillary Supervisor which incinerator location will be used.

3. While still in the BSL-3 suite and properly suited, doubled bag all waste that is to be removed, seal bags with tape, and spray the outside of the bags with an appropriate disinfectant (meeting the minimum contact time required). The bags are then placed into leak proof red biohazard waste barrels (with lids secured) and placed into the biohazard airlock.

4. After ensuring that lids are properly secured, remove the barrels from the airlock and secure them in place in the back of a covered vehicle for transport.

5. When all biohazardous waste for that day's trip has been loaded, carefully drive to the designated incinerator location for waste disposal.

6. Put on 2 pairs of latex gloves and a dust/mist face mask.

7. Unload the biohazard waste barrels one at a time. Set one barrel near the incinerator, remove the lid from the barrel, and carefully remove one bag at a time and place it into the incinerator.

8. When the barrel is empty, replace the lid securely, and return the barrel to the transport vehicle. Repeat this process with each barrel until all are empty.

9. Dispose of gloves and face mask into the incinerator.

10. Return to Main dirty dock and, using the hose-end foam sprayer located there, thoroughly disinfect the biohazard waste bins, lids, and the back of the transport vehicle with the appropriate disinfectant solution for the minimum contact time required. Take the barrels to Dirty Cage for sanitation.

11. Thoroughly rinse the back of the transport vehicle with water after disinfecting it.

BIOHAZARDOUS WASTE SPILLS/LEAKS:

If a biohazardous waste spill or leak occurs, immediately report the spill to your direct supervisor (notify Environmental Heath & Safety if outside the ABSL-3 containment area), use the spill kit and handle as follows.

1. Be sure to have on all required area protective apparel (when in ABSL-3 area). If outside the ABSL-3 area, put on a dust/mist face mask and 2 pair of latex gloves. Be sure your gloves are intact. If not, replace them.

2. Apply the appropriate disinfectant to the spill. If the spill is solid matter, spray with disinfectant mist. If the spill is liquid matter, pour disinfectant first around the perimeter of the spill, then pour disinfectant on the spill to cover it. Place paper towels on the liquid spill/disinfectant to absorb it.

3. Carefully clean up the spill with paper towels, disposing of the material in an intact biohazard waste bag. When all solid and liquid material is cleaned up, spray the spill site with the appropriate disinfectant mist again, then dry the residue, disposing of the paper towels in the biohazard waste bag.

4. Remove your outermost pair of latex gloves and dispose of them in the same biohazard waste bag. Put on a clean pair of gloves, and then seal the waste bag with tape.

5. Double bag and seal both bags to avoid further spills. Autoclave and/or incinerate the bags.

SAFETY:

1. **INJURIES**: All injuries must be reported to the employee's direct supervisor as soon as possible. Some injuries require immediate reporting (before any other tasks are completed).

2. When handling biohazardous wastes, you **MUST** follow the safety procedures outlined above to ensure personal safety. Any breach in handling these wastes, such as tears in bags, must be reported to the supervisor immediately.

3. Full-time animal care staff that work in the Biohazard Area and/or handle biohazardous waste will be routinely tested for exposure to specific biohazardous agents as directed by the Occupational Health physician.

Approved: Deborah Shrig Date: 2/14/05

Attachment B
(Handling Animal Carcasses)

RESPONSIBILITY:

All full-time or part-time animal caretakers trained and assigned the task. **NOTE: Only staff with Department of Justice clearance for access to Select Biological Agents and Toxins may work with projects (animal carcasses) involving the use of select agents/toxins.**

PROTECTIVE APPAREL:

Clean lab coat
CMP approved footwear
Latex gloves - for all direct animal contact
Face mask - optional but strongly suggested

GENERAL INFORMATION:

1. Sanitation schedule of necropsy coolers/freezers:

Carts	1 x per week and as needed
Barrels	1 x per week and as needed
Racks/storage bins	1 x per week and as needed
Cooler	1 x per week and as needed

**Cooler is mopped with a 1% Lysol /water solution.*

2. All storage racks/bins and empty containers located inside of the carcass disposal cooler will be sent through Dirty Cage to be washed/sanitized.

3. Animal carcasses are designated as either "hold" or "non-hold."

4. A list is posted on the necropsy door indicating how carcasses should be treated, *i.e. hold or non-hold*, according to each investigator. **NOTE: if list is not posted or investigator's name is not found on the list, check with the area supervisor for instruction.**

5. Carcass disposal logs will be placed at the Main carcass disposal cooler and the Building carcass disposal cooler and are to be filled out for all animal carcasses that are placed into the coolers (both hold and Non-hold animals). Animals that are marked for food and placed into the food (carcass) cooler at Main **will not** have to be logged in on the carcass disposal log. **NOTE: animal carcasses marked for food will be given as a food source to other (larger) animals and therefore must not contain anything that could possibly be harmful to the animals that will ingest the carcasses (ie. metal staples, hazardous toxicology, etc.). All animals marked for food must be placed into transparent ziploc bags (label with room # and date) before being placed into the food cooler so that they can easily be checked for hazardous items such as metal staples.**

6 Animal carcasses that are picked up from the Building or Building on main campus will be brought back to the Main facility, weighed (separately by area), placed into the Main carcass disposal cooler and each area's account will be charged for the (weighed) amount of animal carcasses respective to their area.

7 Animal carcasses are discarded either in a ziploc bag or **DOUBLED** trash liners. At Main, all hold animal carcasses are to be bagged and marked (date, investigator's name, room #, and/or mortality card copy) and then stored in the investigator's labeled bin located in the necropsy cooler. All discarded non-hold animal carcasses are to be un-bagged and placed into the carcass disposal barrel located in the necropsy cooler. **NOTE: only animal carcases are to be placed into the carcass disposal barrel (do not place plastic bags, metal objects, paper towels, etc. into the disposal barrels as these items will cause harm to the biodigestor).**

8. Necropsy coolers are located:
   - the Main facility (room
   - the Support facility (building
   - the Building (dirty cage)
   - the P / building (hallway outside rm

9. Identification must be included with mortality carcasses indicating:
   - the date
   - the investigator
   - the room number
   - the accompanying mortality card if applicable

10. Ziploc bags or trash liners should not be over filled with animal carcasses (about 1/3 filled or less).

11. Glass is not allowed in any bags that will be transported to the incinerator. All glass should be placed in the glass bin located on the Main back dock or in an approved sharps containers if in biohazard (autoclave out of the biohazard area).

12. Area necropsy coolers are checked or emptied weekly as directed by respective area supervisors.

13. Any questions should be directed to the area supervisor.

HOLD ANIMALS:

Some carcasses are temporarily stored in the necropsy cooler (for 1 week) to enable the investigator to make collections or observations of the animal before discarding. Special areas are allocated and clearly labeled for these carcasses:

- At the Main facility, a polycarbonate cage is set up inside the necropsy cooler labeled with each investigator's name (if listed on the "Hold" list). Anything in this cage is not to be removed for incineration unless it is older than 1 week old or unless directed to do so by authorized personnel such as area supervisors, investigators, and veterinarians.
- CMP Support and the Ancillary facilities generally do not have a need to hold carcasses for investigators. Should the situation arise, the area supervisor will make special arrangements.

NON-HOLD ANIMALS:

Non-hold animals are placed in the coolers of each respective area.

-
- has a disposal barrel for Non-hold animals inside of the necropsy cooler.
- has a refrigerator/freezer. Do not place carcasses in the top (refrigerator) unless the bottom (freezer) is full or refrigeration is preferred.
- The Reynolds building has a freezer in the dirty cage area.
- The Psychology department has a freezer compartment set aside for necropsy storage in the hallway outside of rm This needs to be checked/emptied frequently due to its small capacity. Carcasses are taken by the Ancillary crew to the necropsy cooler for storage.

NOTE: All animal carcasses in need of disposal at Biology will be coordinated by the Ancillary Supervisor prior to pickup.

DISPOSAL:

1. Necropsy coolers are emptied as needed (usually weekly).
2. Upon request, the Ancillary crew will pick up carcasses from Ancillary areas not directly attended to by CMP personnel. Carcasses from these areas must be weighed (separately), recorded on the necropsy disposal log at and stored in the LARR Main necropsy cooler until they can be incinerated or biodigested.
3. Carcasses are collected from all coolers and transported to the incinerator/biodigestor at the Vet School. Personnel in charge of the incinerator/biodigestor are informed/made aware of loads in advance by the Ancillary Supervisor. The assigned caretakers will gather carcasses from all needed coolers. The CMP Support Supervisor coordinates Support's necropsy disposal.
4. Occasionally, the incinerator/biodigestor at the Vet School is out of service. Usually, it is back online before other arrangements have to be made. However, if the coolers appear to be reaching capacity, notify the CMP Program Manager to pursue other options. The CMP Main & Support supervisors will coordinate with the CMP Program Manager in using other options.

INCINERATOR/BIODIGESTOR:

1. CMP uses incinerators/biodigestors operated by other departments.
2. The most frequently used incinerator/biodigestor is located at the Vet School.
3. The Ancillary Supervisor will coordinate use with the individuals who oversees the Vet School incinerator/biodigestor.
4. The Ancillary Supervisor will coordinate disposal times **weekly** with the Vet school incinerator/biodigestor personnel.
5. Items taken to the incinerator/biodigestor must not include glass, paper, metal, plastic or other foreign objects.

REMOVAL OF BIOHAZARD CARCASSES: (See SOP A-I.L.1. Removal of Biohazard Waste)

Only full-time animal care staff who has been specifically trained on biohazardous waste removal and protocols specific to the biohazard will handle these duties. Whenever possible, two employees will be assigned for each waste removal trip. Any breaches in biohazardous waste handling or any accidents must be reported to the employee's supervisor immediately. **All ABSL carcasses/waste must be autoclaved before being transported to the incinerator/biodigestor.**

Primary Option:

1. Autoclave biohazard bags containing animal carcasses/tissues. Use stainless steel pans under carcass bags in the autoclave.
2. Unload the autoclaved carcasses after ensuring that the cycle was completed and proper temperatures were met.
3. All bagged carcasses are placed into a red biohazard waste barrel (with top) and the barrel is then placed into the animal carcass cooler until ready to incinerate or biodigest.

Emergency Option: (if autoclave is not functioning)

1. Prior to transporting biohazardous carcasses, put on clean coveralls and place a biohazard waste spill kit into the transport vehicle.
2. Verify with the Ancillary Supervisor which incinerator location will be used.
3. While still in the BSL-3 suite and properly suited, double bag all carcasses that are to be removed, seal bags with tape, and spray the outside of the bags with an appropriate disinfectant (meeting the minimum contact time required). The bags are then placed into leak proof red biohazard waste barrels (with lids secured) and placed into the biohazard airlock.
4. After ensuring that lids are properly secured, remove the barrels from the airlock and secure them in place in the back of a covered vehicle for transport.
5. When all biohazard carcass barrels for that day's trip have been loaded, carefully drive to the designated incinerator location for carcass disposal.
6. Put on 2 pairs of latex gloves and a dust/mist face mask.
7. Unload the biohazard carcass barrels one at a time. Set one barrel near the incinerator, remove the lid from the barrel, and carefully remove one bag at a time and place it into the incinerator.
8. When the barrel is empty, replace the lid securely, and return the barrel to the transport vehicle. Repeat this process with each barrel until all are empty
9. Dispose of gloves and face mask into the incinerator.

10. Return to Main dirty dock and, using the hose-end foam sprayer located there, thoroughly disinfect the biohazard waste bins, lids, and the back of the transport vehicle with the appropriate disinfectant solution for the minimum contact time required. Take the barrels to Dirty Cage for sanitation.

11. Thoroughly rinse the back of the transport vehicle with water after disinfecting it.

Approved: Melanie Thrug Date: 2/10/05

Attachment C
(Personnel Access)

Personnel who are have approved access to Lab (1/9/07)

James Samuel – PI
Masako Andoh
Heather Bridges
Suat Cirillo
Chen Chen
Laura Hendrix
Joshua Hill
Eunhee Lee
Katja Mertens
John Quarles
Kasi Russell
Kelly Soltysiak
Nathan Unsworth
Guo-Quan Zhang
Yan Zang

Kim Abatie
Elizabeth Browder
Ralph Callicott
John Delaney
Gordon Draper
Thomas Ficht
Stacey Gillenwater
Ken Gillenwater
Vincent Gresham
Randi Harbour
Amy Henson
Melanie Ihrig
Gabrielle Kapp
Sean Knox
Sean Knox
Laura Quinilven
Kevin Saunders
Deborah Sargeant
Christine Sivula
Jody Smith
Stephen Sterle

Tif
-Scot Hoster 5/15/07 should have been on this list or we should have amended it.

✓ Need to look for original info - 8/11/08

Scott Hoster was inadvertently left off the list. We attempted to correct. After reviewing our records it appears that he was

Attached is the access log, used where animals are housed. We have also provided a sample of a completed access log for this facility.

FACILITY ACCESS LOG

ROOM #_____ BUILDING #_____ PI NAME _____

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY							THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initital)	Received Hazard Training (Initial)
				In / Out	DOJ Authorized	Visitor Continue →		Form / Number		To / By

[1] Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
[2] Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

FACILI.. ..CESS LOG ROOM ... ...IN(___ PI NAME Samuel

ALL persons entering this facility MUST sign In and Out – Please write legibly

THIS SECTION TO BE COMPLETED BY ALL PERSONS ENTERING THIS FACILITY						THIS SECTION TO BE COMPLETED BY ALL VISITORS			
Date	Printed Name	Signed Name	Department/ Organization	Time	Status (Initial One)	[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initials)	Received Hazard Training (Initial)
[redacted]									
zhula	SS Holster	Stoltz	CMP	10:35 / 11:15	SH				
2/21	Yan zhang	YZ	MMP	11:20 / 12:00	YZ				
2/21	MASAKO ANDOH	Masako	MMPA	14:00 / 17:40	MA				
21/06	Katja Kostas	Kostas	MMP	5:00 / 5:30	KM				
22	Kelly Solbyscke	KySol	MMPA	9:00 / 9:15	KS				
2/22	D. Sargent	D. Sargent	CMP	10:53 / 11:35	DS				
06	Katja Kostas	Kostas	MMP	11:45 / 12:00	KM				
2	Scot Holster	Stoltz	CMP	2:20 / 3:05	SH				
2	Gabby Kapp	Maureen K	CMP	2:25 / 3:60	GK				
4	Yanzhang	YZ	MMP	10:00 / 11:00	YZ				
4	D. Sargent	D. Sargent	CMP	11:02 / 11:20	DS				

Purpose of Access: Maintenance (M) – Include Description of Work; Delivery (D); Research (R); Tour (T); Inspection (I)
Acceptable Forms of ID: Current Drivers License (DL) – Include Issuing State; Government ID Card (GID); Passport (P)

GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins.

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the RO or facility director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

2. The RO or facility director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   A. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
   B. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."

3. The RO or facility director faxes or mails the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usd
or CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5

Sent on 12/26/06

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University			2. Entity registration number (if applicable): APHIS# CDC# C20060605-0489	
3. Entity address (NOT a post office address): Mail Stop - 1186	4. City: College Station		5. State:	6. Zip Code: 77840
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: 979 8458585	9. FAX: (979) 862-3176		10. E-mail: rewing@vprmail.tamu.ed
11. RO or facility director address (NOT a post office address): same as above	12. City:		13. State:	14. Zip Code:
15. Type of incident: ☐ Theft ☑ Loss ☐ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 12/22/2006	18. Type of immediate notification: ☐ E-mail ☐ Fax ☑ Telephone	

19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) The review is still on-going.

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 12/21/2006	28. Date of last inventory: 12/20/2006	29. Name of principal investigator for laboratory with select agents and toxins First: James MI: Last: Samuel	
30. Location of incident (building and room #):	31. Location of incident (within room (e.g., freezer, incubator)): Cage # 86163		32. Biosafety level of laboratory where incident occurred: ABSL3
33. Name and telephone number of agencies or local authorities notified: TAMU UPD	34. Symbols or markings on vials (if any): N/A - Ear notch on animal		35. Agent was recovered (theft/loss): ☑ No ☐ Yes

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☑ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☑ Called police department (case #) 12-06-5068 ☑ Other (explain): contacted TAMU Environmental Health and Safety, ARO, and RO

37. Provide a detailed summary of events (attach additional sheets if necessary):

A mouse that was infected with Q-fever was discovered missing on 12/21/06. An animal census was perfromed on 12/20/06 and there was no discrepancy. On 12/21/06, several of the animals were being euthanized , when it was discovered that one was missing. We are currently investigating the lab to determine if the animal was euthanized in error or if other actions resulted in the discrepancy.

We will update CDC on the progress of our investigation.

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION				
38. APHIS authorization number from transfer form:			39. CDC authorization number from transfer form:	
40. Name of carrier:			41. Airway bill number/bill of lading number/tracking number:	
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):				
	SENDER INFORMATION		**RECIPIENT INFORMATION**	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	
50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes			51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)	
52. Sender was contacted regarding incident: ☐ No ☐ Yes			53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes	

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS
54. Hazards posed by release: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)
Low dose of coxiella burnetti in a prevacinated mouse should result in minimal hazards if any.
55. Exposures: ☐ No ☐ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)
56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)
Area was decontaminated based on standard (ABSL3) procedures as outlined in the BMBL
57. Medical treatment was provided: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED

	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^8 pfu/ml)
1							1 x 10
2							1 x 10
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: [redacted] Typed or printed name of Respondent: Angelia Raines

Title: ARO (Director - VPR Office of Research Coml Date: 12/22/2006

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

TEXAS A&M UNIVERSITY
Environmental Health & Safety Department

To: Angelia Raines
Office of the Vice President for Research

From: Nancy Eaker
Environmental Health & Safety

Date: January 11, 2007

Subject: Notes regarding Dr. Russell's mice

I spoke with Dr. Russell and looked through her lab notebook this morning. I've attached photocopies of the pages from December 13, 2006 through December 20, 2006. I've made additional notes on those pages in blue ink. I've also attached a copy of the BL3 Entry Log. From my discussion with Dr. Russell, the BL3 entry log, and notes taken on December 22, 2006 at the interview with CMP personnel, the following was determined:

- Dr. Russell weighed all of her mice on December 13, 2006. None were sacrificed at that time.
- CMP changed out the cages on December 13, 2006, after Dr. Russell had handled the mice.
- The number of animals in the room from 12/8/06 to 12/13/06 was 154, as per CMP.
- The number of animals in the room from 12/14/06 to 12/19/06 was 129, as per CMP.
- CMP changed out the cages on December 20, 2006 prior to Dr. Russell entering the BL3 suite. The number of animals in the room on 12/10/06 was 113, as per CMP.
- Dr. Russell sacrificed and weighed all of her mice on December 20, 2006. One mouse was missing.
- The number of animals in the room on 12/21/06 was 16, as per CMP.
- There were no animals left in the room on 12/22/06, as per CMP.

Please let me know if you have any questions.

cc: Brent Mattox, EHS

4472 TAMU • College Station, Texas 77843-4472 • (979) 845-2132 • FAX: (979) 845-1348

BL3 Entry Log

Reynolds Building BL3 Facility

(In order of entry as noted by Nancy Eaker on 01/10/07.)

Date	Name	Dept.	Comments
12/13/2006	Kasi Russell	MMPA	
	Yan Zhang	MMPA	
	Masako Anown	MMPA	
	Scot Holster	CMP	
	Masako Anown	MMPA	
		MMPA	
	Masako Anown	MMPA	
12/14/2006	Eunhee Lee	MMPA	
	G. Zhang	MMPA	
	Kasi Russell	MMPA	
	Eunhee Lee	MMPA	
	Yan Zhang	MMPA	
	Stacie Brown	CMP	
	Eunhee Lee	MMPA	
	Masako Anown	MMPA	
	Eunhee Lee	MMPA	
12/15/2006	Yan Zhang	MMPA	
	Stacie Brown	CMP	
	Stacie Brown	CMP	
	G. Zhang	MMPA	
	Joshua Hill	MMPA	
	Eunhee Lee	MMPA	
12/16/2006	Chris Knowlton	CMP	
12/17/2006	Gordon Draper	CMP	
12/18/2006	Yan Zhang	MMPA	
	Katia Mertenes	MMPA	
	John Delaney	CMP	
	G. Zhang	MMPA	
	D. Sargent	CMP	
12/19/2006	Masako Anown	MMPA	
	Kelly Soltysiak	MMPA	
	Masako Anown	MMPA	
	Kelly Soltysiak	MMPA	
12/20/2006	Katia Mertenes	MMPA	
	Stacie Brown	CMP	
	Kelly Soltysiak	MMPA	
	Kasi Russell	MMPA	
	Eunhee Lee	MMPA	
	Katia Mertenes	MMPA	
	Lizet Opmeer	MMPA	
	Kasi Russell	MMPA	
	Kasi Russell	MMPA	

11 Dec 06 Made fresh tcm.

12 Dec 06 H^3T added to 96 lymphoprolif. assay cultures. cells harvested in Mwangi lab. Filters left in the Mwangi lab to run later.

13 Dec 06 Mice weighed Groups of mice in question.

Group	Number	Body wt (g)
1	1	18.256
	2	20.761
no #s	3	18.985
	4	19.006
	5	19.224
2	1	18.129
	2	20.788
	3	20.640
	4	21.832
	5	19.212
3	1	21.311
	2	20.753
	3	18.897
	4	19.635
	5	20.648
	6	21.001
4	1	20.554
	2	21.362
	3	19.068
	4	19.994
	6	20.841
5	1	19.187
	2	20.703
	4	20.412
	5	20.396
	6	20.117
6	1	17.228
	2	22.590
	3	20.947
	4	20.922
	5	21.365
	6	20.139

Group	Number	Body wt (g)
7	1	20.376
	2	21.699
	3	20.363
	4	20.867
	5	21.755
	6	22.102
8	1	20.134
	2	21.895
	3	21.056
	4	21.766
	5	18.581
	6	19.539
9	1	20.847
	2	20.361
	3	18.975
	4	21.274
	5	19.123
	6	17.856
10	1	20.203
	3	20.160
	4	21.545
	5	18.021
	6	18.843
11	1	20.693
	2	20.412
	3	19.477
	4	20.995
	5	19.138
	6	21.340

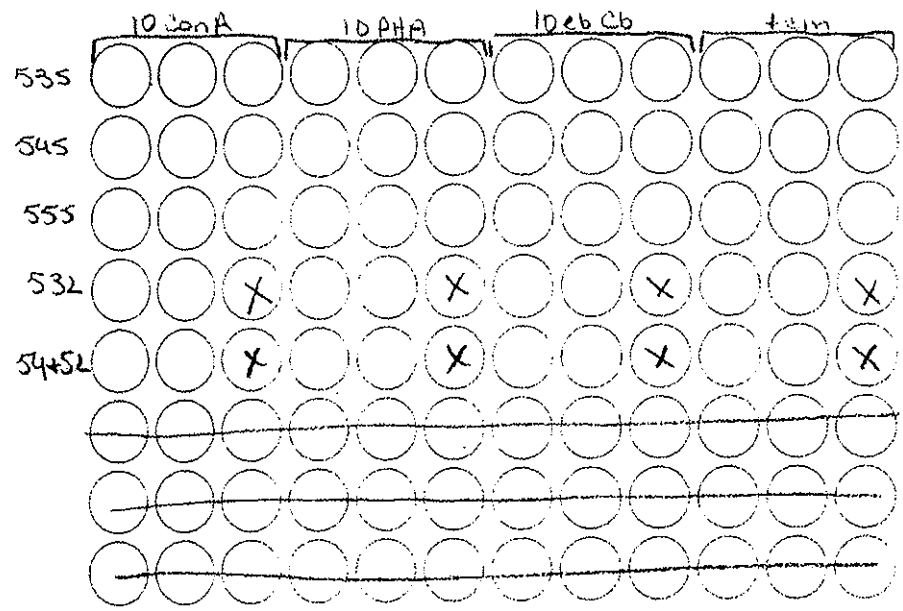
Group	Number	Body wt (g
12	1	19.74
	2	18.57
	3	19.21
	4	19.69
	5	19.83
	6	21.54
13	1	16.05
	2	21.22
	3	20.13
	4	20.52
	5	19.34
	6	18.92
14	1	19.1C
	3	18.24
	4	19.98
	5	20.88
	6	19.24
15	1	18.0C
	2	17.67
no #s	3	18.82
	4	19.16
	5	19.97
16	1	21.56
	2	18.9C
	3	18.37
	4	22.7C
	6	20.6
17	1	20.0
	2	19.4
	3	19.0
	4	22.5
	5	21.6
	6	21.8

19 Dec 06 cont. Sac'd + exsanguinated Gps 85253-55. Spleen + l.n. (axillary + inguinal) collected for lymphoprolif. assays.

Guinea pigs

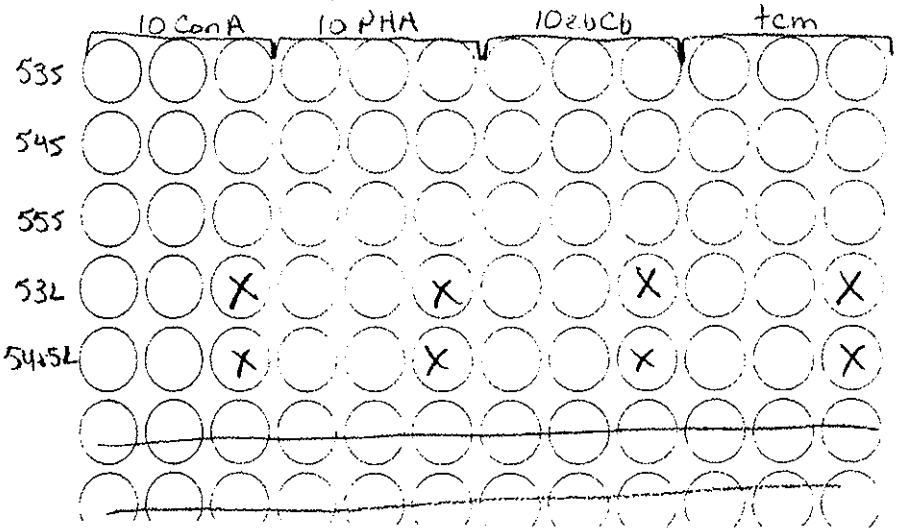
14 Dec 06 GP Spleens + l.n. homogenized + cultured for lymphoprolif. assays.

Guinea pigs



14 Dec 06

10ug/mL Indomethacin



→ Mice from CMP, not MSU mice at Reynolds

14 Dec 06 2 ICR mice sacrificed @ CMP + exsanguinated - blood to Josh.

cont. [2 gps in Rm, bled from lateral saphenous - blood to Josh.

→ Guinea pigs

18 Dec 06 H^3-T added to lymphoprolif cultures.

cells harvested in Mwangi lab + filters kept there for reading tomorrow.

Guinea pigs

19 Dec 06 Lymphoprolif assays from Gps 85235-37, 247-52, + 253-55 run on β cell counter in Mwangi lab.

Guinea pigs

Plate 1
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 1/Shelf: 1/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	901	923	899	588	761	783	205	134	205	310	359	330
B	221	154	236	178	254	201	199	230	264	250	300	318
C	387	356	371	326	313	262	216	244	189	189	248	437
D	278	231	285	321	317	384	203	130	206	165	212	266
E	252	159	242	211	228	164	189	207	155	182	216	331
F	236	190	165	310	208	232	168	170	118	216	174	229
G	23	17	41	27	18	35	4	23	31	10	29	45
H	10	12	4	0	4	8	12	6	10	2	6	22

End of plate 1

Plate 2
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 2/Shelf: 2/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	28932	26037	35674	16419	16745	16618	557	679	659	284	254	201
B	33643	59593	61478	38637	50701	35699	6161	7194	2347	1293	1031	1126
C	64580	66566	69574	22653	35185	23848	114	332	115	151	119	298
D	76232	71971	74306	46136	45304	44070	826	970	1132	302	258	294
E	47517	54782	52696	38212	34318	37162	1598	778	857	161	284	241
F	44670	68628	8963	24432	39647	47814	711	177	116	114	163	108
G	2099	1225	1527	1564	955	51	19	18	18	27	16	33
H	97	29	17	17	10	14	6	4	14	12	6	8

End of plate 2

Plate 3 Guinea Pigs
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 3/Shelf: 3/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	10574	11221	14512	4391	5202	4543	1180	1123	1033	828	625	528
B	4305	6442	6082	1358	1279	1239	458	368	375	363	369	334
C	7383	6182	7414	1955	1908	1942	508	511	488	306	344	421
D	58256	79084	1482	70361	63038	62934	138	134	161	189	246	68
E	65031	70590	57194	48687	39369	46306	10117	7441	10715	559	588	165
F	43620	53468	51084	13914	21510	15849	4522	11334	8437	482	500	374
G	1405	2806	99	3746	1066	2461	538	31	1669	27	298	96
H	21	41	27	19	18	14	4	19	12	10	12	2

End of plate 3

Plate 4
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 4/Shelf: 4/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	57962	50647	53503	29069	33879	26640	1621	1485	1382	558	590	629
B	47455	46316	1163	35184	47821	397	1399	1493	195	344	342	258
C	53325	56629	207	29932	47117	307	303	185	171	226	216	550
D	962	2199	405	2578	1869	340	185	159	169	193	272	671
E	587	362	388	498	368	495	218	212	271	186	310	859
F	442	322	475	207	290	302	226	288	563	390	331	304
G	33	85	21	31	31	55	37	66	202	104	63	86
H	14	14	10	14	10	41	16	12	35	10	12	8

End of plate 4

Plate 5
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 5/Shelf: 5/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	32568	16179	23141	6200	1511	5905	895	1302	1936	278	715	786
B	63208	53047	27828	37945	12086	28699	3148	4246	5394	324	556	260
C	80710	74889	27430	11114	7299	4772	9846	12150	4769	302	600	280
D	32159	50183	186	28355	37085	165	2510	2274	50	580	242	26
E	698	1512	264	3459	4039	327	592	462	269	596	88	22
F	167	213	132	794	520	58	337	265	102	427	65	10
G	41	52	16	50	78	8	45	29	6	59	29	6
H	14	19	16	10	16	16	12	31	8	2	39	8

End of plate 5

Plate 6
Cassette information:
Assay:-/Prot:-/Cass:-/Func:-/Cassette no: 6/Shelf: 6/8*12

CCPM1

	1	2	3	4	5	6	7	8	9	10	11	12
A	9753	41868	33033	3873	7801	16125	4905	3252	3891	747	635	79
B	32017	52046	44754	31388	45045	27858	10116	10272	6746	437	625	133
C	63699	51956	33883	10052	10877	6644	9061	11166	7795	534	518	367
D	40938	28659	262	22286	17836	232	2511	2491	145	391	334	129
E	552	576	99	922	934	230	382	345	141	329	373	253

Mice in question.

20 Dec 06 Sac'd Montana mice. Serum + spleens collected + saved for ELISA + RT PCR. Samples in BioLab -20°C.

Group 1 mouse #5 was not in the cage and was not in most recent change-out (Ken checked). Room was also checked.

Wts (spleen+BLO) on next pg. (pg 14)

Some mice in groups 3-12 + 16-17 had marked peritonitis at necropsy. (Animals w/ marked peritonitis are indicated w/ a "P" in front of their #s on the x/l spreadsheet.) The extent of peritonitis did not appear to be related to spleen size.

28 Dec 06 L929 cells recovered + restocked w/ fresh media.

3 Jan 07 Supplemented L929 cell media + split out flasks.

9 Jan 07 Rec'd RFP for ACLAM Foundation

Important dates: Letter of Intent Jan 30, 2007
Full Grant Proposal April 5, 2007

Grant idea - Evaluation of novel diagnostic methodologies (cp ELISA + PCR re vs. IFA, serology) to determine Q fever infection status in laboratory sheep.

CoPIs - Dr S + Masako?

Apply for the Elizabeth R. Griffin Research Foundation grant for zoonotic dzs.

<CD8 Ab arrived in Peters group in CA. Alliquotted + stored @ -80°C — See Peters exp. notebook.

Group	Number	Body wt (g)	Spleen wt (g)
1	1	20.048	1.440
	2	22.329	1.255
no #s	3	20.075	1.094
	4	19.979	1.078
	5		
2	1	18.906	0.543
	2	21.390	0.182
	3	21.633	0.601
	4	22.828	1.285
	5	20.602	0.901
3	1	22.712	1.177
	2	22.517	1.522
	P3	20.413	1.203
	4	21.029	1.196
	5	22.125	1.545
	6	21.949	1.360
4	1	21.425	0.738
	P2	22.986	1.272
	3	20.180	1.179
	P4	20.744	0.872
	P6	21.871	0.518
5	1	20.319	1.289
	P2	21.421	0.511
	4	21.754	0.932
	5	21.540	1.292
	P6	20.622	0.258
6	P1	17.653	0.444
	2	22.951	0.458
	3	21.759	0.572
	4	22.652	1.509
	5	23.090	1.304
	6	21.149	0.997
7	1	21.937	1.379
	2	22.450	1.078
	P3	21.719	1.422
	4	21.616	0.489
	5	22.504	1.193
	P6	23.544	1.176
8	P1	20.752	0.986
	P2	22.942	0.756
	3	22.487	1.302
	4	22.740	1.233
	5	19.105	0.837
	6	20.716	0.987
17	1	20.429	0.722
	P2	20.291	0.794
	3	19.947	1.139

Group	Number	Body wt (g)	Spleen wt (g)
9	P1	21.564	0.624
	2	21.304	1.098
	3	19.795	1.076
	4	22.235	0.732
	5	20.786	1.298
	6	18.228	1.054
10	P1	20.611	0.534
	3	21.370	1.136
	P4	22.734	1.049
	5	18.853	1.012
	6	19.481	0.507
11	P1	21.469	0.860
	P2	20.937	0.546
	P3	20.190	0.689
	4	21.903	0.931
	5	20.128	0.995
	P6	22.654	1.188
12	P1	21.179	1.215
	2	19.004	1.165
	3	19.817	0.499
	4	20.467	1.007
	5	21.331	1.439
	6	23.140	1.354
13	1	16.310	0.566
	2	21.883	0.422
	3	21.835	1.224
	4	20.944	0.318
	5	20.692	1.387
	6	19.880	1.309
14	1	19.941	1.275
	3	18.914	0.525
	4	21.179	0.961
	5	22.344	1.627
	6	20.251	0.405
15	1	19.540	1.214
	2	18.375	1.126
no #s	3	19.883	1.185
	4	20.486	1.123
	5	21.518	1.153
16	P1	22.798	0.791
	P2	19.471	0.649
	3	19.117	1.22
	P4	23.579	0.741
	6	21.723	1.094
17	P4	23.38	1.002
	5	23.786	1.479
	P6	22.377	1.542

Office of Research Compliance
Quality Assurance – IBC Adverse Event (AE) Audit

QA Date:7-21-07
QA Reviewer: Angelia Raines
Lab Number:Unknown
PI:Unknown

Records received from:

B. Mattox Date: **07-19-07**

AE Date:**04-08-2004** AE Type: **Exposure**

Biohazardous material or toxin involved: **Brucella**
AE Reported to: RO: **X** ARO:**X** CDC_____ NIH_____ IBC_____
Other (describe)**ULAC (now known as IACUC), the BSO/ARO, Dept. Head**

Description of AE.
A graduate student injected her hand with Brucella. The student saw an MD and was placed on antibiotics.

Outcome of AE Investigation: No documentation available.

Review Findings: The AE occurred in 2004 and the only records available for review were emails. There was no documentation to support an investigation, medical follow-up beyond initial treatment or reporting requirements. Although it appears that the incident could have involved a SBAT, this could not be verified. Most records older than 3 years old were not maintained.

The AE occurred before TAMU developed clear procedures for reporting, investigating and monitoring AEs. SOP 601, 602 and 603 are now in place and all employees have been trained.

Mattox, Brent S

From: Mattox, Brent S
Sent: Tuesday, April 13, 2004 8:26 AM
To: Buckley, Michael
Subject: RE: Re: Lab accident

I have to call CDC this morning about another import/export question (not any of our regular contacts), otherwise the reply looked OK. I suspect we answered too broadly in some cases, as CDC seemed to be keying off of singular observances, but they were issues that needed dealt with anyway. Wonder when CDC will respond? NOTE: We will be officially transferred out of Business Services on the 15th (Thursday). We will be reporting (as far as I can tell) to Charlie Clark. As far as I can tell, our functions will not change. I will let you know what CDC has to say.

Brent

-----Original Message-----
From: Buckley, Michael
Sent: Tuesday, April 13, 2004 6:40 AM
To: Mattox, Brent S
Subject: RE: Re: Lab accident

Brent,

Sounds good, how is everything else going? How did the CDC response look to you?

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research
College Station, Texas 77843-1112
979.847.9362

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 4/12/2004 1:20:01 PM >>>
We were informed. All accidents are investigated, but there is no requirement with the exception that needle sticks must be reported to TDH under the bloodborne pathogens rule.

Brent

-----Original Message-----
From: Buckley, Michael
Sent: Monday, April 12, 2004 9:00 AM
To: Mattox, Brent S
Cc: Meyer, Chris; Wei Zhao
Subject: Fwd: Re: Lab accident

Brent,

Not sure if you have been informed about this accidental exposure.

I have looked thru the CFRs and can't find anything which requires us report this incident - are you familiar with any requirements? Also, does EHS usually investigate this events and file an internal report on
them? I was just curious if we should cross reference the procedure this tech was using with what is described in the protocol as a QA

issues to see if there were procedure problems, or just an mistake. If
you need any information out of the file here just let me know and we'll
have it sent over to you.

What are your thoughts?

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research
College Station, Texas 77843-1112
979.847.9362

>>> Michael Buckley 4/12/2004 8:53:17 AM >>>
Betsy,

Thanks for passing this along. I will brief Wei at our meeting this afternoon - not sure what else would be required. I have looked over the federal regulations on SBATs and did not find any reporting requirements for accidental exposures.

Mike

Michael W. Buckley, Ph.D.
Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research
College Station, Texas 77843-1112
979.847.9362

>>> "Betsy Browder" <ejb@tamu.edu> 4/9/2004 4:59:02 PM >>>
Melanie and Mike,

EHS and HR are informed through the First Report of Injury but I wanted
to let you both know about this to avert surprises.
If there is a need for further documentation that either of you might be aware of please let John Quarles know.
Thanks,
bb

>>> John M. Quarles<QUARLES@medicine.tamu.edu> 4/9/2004 4:10:45 PM >>>
Thanks Betsy. We've already done that and the "sharps" report also.

>>> "Betsy Browder" <ejb@tamu.edu> 04/09/04 04:10PM >>>
Hi John,
Nothing specific regarding the animals but the "First Report of Injury"
form needs to get to the Campus Environmental Health and Safety Office.

Their fax number is 5-1348.
bb

>>> John M. Quarles 4/9/2004 10:01:07 AM >>>
Betsy-
One of our graduate students injected her hand with Brucella yesterday

Director, Research Compliance
Texas A&M University
MS 1112
Office of the Vice President for Research
College Station, Texas 77843-1112
979.847.9362

>>> "Betsy Browder" <ejb@tamu.edu> 4/9/2004 4:59:02 PM >>>
Melanie and Mike,

EHS and HR are informed through the First Report of Injury but I wanted
to let you both know about this to avert surprises.
If there is a need for further documentation that either of you might be aware of please let John Quarles know.
Thanks,
bb

>>> John M. Quarles<QUARLES@medicine.tamu.edu> 4/9/2004 4:10:45 PM >>>
Thanks Betsy. We've already done that and the "sharps" report also.

>>> "Betsy Browder" <ejb@tamu.edu> 04/09/04 04:10PM >>>
Hi John,
Nothing specific regarding the animals but the "First Report of Injury"
form needs to get to the Campus Environmental Health and Safety Office.

Their fax number is 5-1348.
bb

>>> John M. Quarles 4/9/2004 10:01:07 AM >>>
Betsy-
One of our gra late students injected her hand with Brucella yesterday afternoon. She saw a doc at S&W, is on antibiotics, and has a appointment with occupational health. Is there any reporting we need to
do to you or ULAC or any thing about animals?
Thanks,
John

USDA

REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2006

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. The report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

SECTION 1 – TO BE COMPLETED BY ALL ENTITIES

1. Entity name: Texas A&M University			2. Entity registration number (if applicable): APHIS# CDC# 200606050489	
3. Entity address (NOT a post office address): 1112 TAMU	4. City: College Station		5. State: TX	6. Zip Code: 77843-1112
7. Responsible Official (RO) or facility director First: Richard MI: Last: Ewing	8. Telephone: (979) 847-9362	9. FAX: (979) 862-3176		10. E-mail: arainee@vprmail.tamu.edu
11. RO or facility director address (NOT a post office address): 1112 TAMU	12. City: College Station		13. State: TX	14. Zip Code: 77843-1112
15. Type of incident: ☐ Theft ☐ Loss ☑ Release	16. Immediate notification provided to: ☐ APHIS ☑ CDC	17. Date of immediate notification: 04/10/2007	18. Type of immediate notification: ☑ E-mail ☐ Fax ☐ Telephone	
19. An internal review of laboratory procedures and policies has been initiated to prevent recurrences of loss of select agents and toxins at this entity: ☐ No ☑ Yes (If yes, please provide additional details in an attachment.) (See explanation in Section 2)				

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED (Please see page 4.)

27. Date and time of incident: 02/09/2006	28. Date of last inventory: 03/12/2007	29. Name of principal investigator for laboratory with select agents and toxins First: Thomas MI: A Last: Ficht	
30. Location of incident (building and room #):	31. Location of incident (within room (e.g., freezer, incubator)): Aerosol Chamber		32. Biosafety level of laboratory where incident occurred: BSL3
33. Name and telephone number of agencies or local authorities notified: Health Dept. (512) 458-7318	34. Symbols or markings on vials (if any):		35. Agent was recovered (theft/loss): ☐ No ☐ Yes

36. Provide a summary of actions taken:
☐ Called ambulance ☐ Called fire department ☐ Closed laboratory doors ☐ Closed building ☐ Consulted MSDS or chemical database
☐ Called police department (case #) ☑ Other (explain): See below

37. Provide a detailed summary of events (attach additional sheets if necessary):

Several months ago, one of our laboratory employees had an elevated titer (1:160) for Brucella. The lab report stated "...evidence of prior exposure", but "it does not confirm that the exposure was recent." While the exact cause is not known, the exposure could have occurred on 02/09/2006, and would have been the result of improper decontamination procedures. Specifically, the employee may have reached into an aerosol chamber after a run. The chamber was located within the BL3 lab. The laboratory's Bio-safety plan has since been updated and all lab personnel have been retrained. All other lab personnel have also been tested and found to be negative. The incident occurred during the time we were transitioning CDC compliance responsibilities within our organizational structure. This information should have been immediately reported to the CDC, but it was not. We now have a process in place to ensure notification of a loss, theft or release and we are auditing all records to ensure all incidents have been properly reported.

SECTION 3 – IF THE INCIDENT OCCURRED DURING TRANSFER PROVIDE THE FOLLOWING INFORMATION

38. APHIS authorization number from transfer form:	39. CDC authorization number from transfer form:
40. Name of carrier:	41. Airway bill number/bill of lading number/tracking number:
42. Package description (size, shape, description of packaging including number and type of inner packages; attach additional sheets if necessary):	

	SENDER INFORMATION		RECIPIENT INFORMATION	
43. Name of person:	a. First: MI: Last:		b. First: MI: Last:	
44. Name of entity:	a.		b.	
45. APHIS/CDC registration number:	a. APHIS:	b. CDC:	c. APHIS:	d. CDC:
46. PHS/USDA import permit number:	a. PHS:	b. USDA:	c. PHS:	d. USDA:
47. Date shipped:	a.		b.	
48. Telephone:	a.		b.	
49. FAX:	a.		b.	

50. Package with select agents and toxins received by requestor: ☐ No ☐ Yes	51. Package with select agents and toxins appears to have been opened: ☐ No ☐ Yes (If Yes, explain)
52. Sender was contacted regarding incident: ☐ No ☐ Yes	53. Carrier/courier was contacted regarding incident: ☐ No ☐ Yes

SECTION 4 – TO BE COMPLETED ONLY FOR RELEASE OF SELECT AGENTS AND TOXINS

54. Hazards posed by release: ☑ No ☐ Yes (If Yes, explain. Use an attachment if necessary.)

55. Exposures: ☐ No ☑ Yes (If Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)

1 employee showed evidence of prior exposure

56. Area was decontaminated: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)

The aerosol chamber is now flushed with a disinfectant rather than using manual cleaning methods. In addition, personnel are now using positive air displacement respirators instead of the N95 face mask.

57. Medical treatment was provided: ☐ No ☑ Yes (If Yes, explain. Use an attachment if necessary.)

The employee had previously been treated by a private physician and is currently being monitored.

SECTION 2 – TO BE COMPLETED BY ALL ENTITIES

LIST OF SELECT AGENTS AND TOXINS LOST, STOLEN OR RELEASED

	20. Select Agents and Toxins	21. Characterization of Agent	22. Number of Vials	23. Form (powder/liquid/ slant)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10^9 pfu/ml)
1	Brucella melitensis						
2							1x10^9 cfu/ml
3							1 x 10
4							1 x 10
5							1 x 10
6							1 x 10
7							1 x 10
8							1 x 10
9							1 x 10
10							1 x 10
11							1 x 10
12							1 x 10

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Respondent: _____ Typed or printed name of Respondent: Angella Raines

Title: ARO, Director of Research Compliance Date: 04/11/2007

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

Subject: FW: Workmen's Compensation
Date: Friday, April 21, 2006 1:27 PM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" bsmattox@tamu.edu, Angelia Raines ARaines@vprmail.tamu.edu, Tiffany Agnew tmagnew@tamu.edu
Cc: "L. Garry Adams" gadams@cvm.tamu.edu, "David N. McMurray" mcmurray@medicine.tamhsc.edu, njones@medicine.tamhsc.edu, More...
Conversation: Workmen's Compensation

Brent

I wanted to let you know that has been diagnosed with brucellosis. apparently contracted the disease during an experimental challenge at (CMP) on the ninth of February 2006. At that
time along with Dr. McMurray were training us in the use of the Madison chamber for aerosol inoculations.

has been home sick for several weeks being treated by personal physician and was only recently diagnosed. I heard about this last week (Mon or Tues) and instructed other personnel present at that challenge to have an an immediate blood draw for testing. The results should be available in another week or two.

We do not know the exact cause of exposure, although we assume
it may have occurred as a result of cleaning out the Madison chamber after an aerosol run. In the future we plan to flush the chamber with disinfectant rather than using manual cleaning methods. The chamber will be wiped out after running disinfectant through the chamber, but this will involve the use of a long-handled applicator or mop. In addition, we will not rely on the use of N95 face masks and will instead use positive air displacement respirators.

In the initial aerosol trials we relied on the experience of the TB researchers for the level of precaution typically employed in such experiments. It is suspected
that a conjunctival route of infection is responsible for infection, perhaps as a result of manually cleaning the Madison chamber. It is my fault for not recognizing the differences between Brucella and Mycobacteria in regard to routes of infection.

An isolation was made from a blood culture by physician and sent to TDH for confirmation. It would be helpful if EHSD could requested a sample of this isolate for culture confirmation here.

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

Subject: Re: <no subject>
Date: Monday, April 24, 2006 4:56 PM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: "Mattox, Brent S" bsmattox@tamu.edu
Cc:
Conversation: <no subject>

Oddly, they asked me to find out about Dr. Ding's number.

I will ask if we can get this info through I was considering asking to take part in our blood testing program which we were going to schedule in May. Unless you think we need it sooner.

On 4/24/06 4:03 PM, "Mattox, Brent S" <bsmattox@tamu.edu> wrote:

> By the way, I heard from Scott & White today: all titers were negative. I do
> need a copy of the Lab results on though. I can go the
> long route or would perfer getting a copy through possible. Did
> you have retested at S&W?
>
> As to the Ding subject, I don't understand why you had to contact Virginia
> Tech instead of our illustrious Office of Compliance. Isn't that their job?
>
> Brent
>
> -----Original Message-----
> From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
> Sent: Monday, April 24, 2006 1:51 PM
> To: Charlotte Waggoner
> Cc: Raines, Angelia; Tiffany Agnew; Mattox, Brent S
> Subject: Re: <no subject>
>
> Thanks. CDC's approval process doesn't seem to be getting any faster. I will
> pass this on to my compliance office.
>
> Taf
>
>
>
>
> On 4/24/06 1:09 PM, "Charlotte Waggoner" <ren@vt.edu> wrote:
>
>> Hi Dr. Ficht....
>>
>> Xicheng's DOJ ID number at Virginia Tech was Hope this helps...
>>

>> At 10:53 AM 4/24/2006, you wrote:
>>> Dear Ms. Waggoner
>>>
>>> We are aware of the need to renew Dr. Ding's CDC approval. We were
>>> asked by our compliance office to obtain his previous number to
>>> expedite this request.
>>>
>>> If you prefer I will ask that the compliance office contact you
>>> directly for this info.
>>>
>>>
>>> Charlotte M. Waggoner, RBP
>>> University Biosafety Officer/Responsible Official Environmental,
>>> Health and Safety Services (MS 0423) Virginia Tech
>>> 459 Tech Center Drive
>>> Blacksburg, Virginia 24061
>>> http://www.ehss.vt.edu/
>>>
>>> ren@vt.edu
>>> (540) 231-5864
>>> (540) 231-3944 FAX
>>>
>>>
>>>
>>>
>>> Sincerely,
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979-862-1088 fax

Subject: Re: <no subject>
Date: Tuesday, April 25, 2006 11:46 AM
From: Tom Ficht <tficht@cvm.tamu.edu>
To:
Conversation: <no subject>

I have not heard back from Brent and I think anything will work. But according to the select agent guidelines we are required to report any laboratory exposures to the CDC. So I guess he will need to have some record. I do not know how this impacts on your personal files??? Since this has been done through a personal physician you may be within your rights to deny any of these requests. Having said that I don't know either way how this would impact me or the university, but that should not be your concern.

I guess as PI I can't help but be involved, but it does seem like something that is best handled between you and Brent Mattox (as representative of EHSD).

I am glad to help (as a non-physician), and would like to suggest that you take part in our blood testing so that we can carefully watch your titer. Perhaps you could ask your personal doctor his thoughts?

Another thought is for you to go to Scott and White and get a blood draw immediately (desk E is Occupational Health) . I can meet you there if you like.

tom

On 4/25/06 11:30 AM,
wrote:

> Tom,
>
> All I have is a preliminary report on the blood cultures done at St. Joseph's as well as the earlier report from CPL on the first blood culture. Serology was never done on me. Is this what Brent needs to see? I can copy both sheets and campus mail them to you tomorrow as I don't have them here at work.
>
> >>> Tom Ficht <tficht@cvm.tamu.edu> 04/24/06 4:56 PM >>>
> Oddly, they asked me to find out about Dr. Ding's number.
>
> I will ask if we can get this info through I was considering

asking [redacted] to take part in our blood testing program which we were going to schedule in May. Unless you think we need it sooner.

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Subject: FW: Prophylaxis for Lab exposure to Brucella
Date: Tuesday, September 19, 2006 10:21 AM
From: Tom Ficht <tficht@cvm.tamu.edu>
To: ZakirShaikh@mhd.com
Conversation: Prophylaxis for Lab exposure to Brucella

Dear Dr. Shaikh

Here are some references containing new approaches that were used in conjunction with oral doxycyclin+rifampin to treat a recent exposure here.

Sincerely,

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

------ Forwarded Message
From:
Date: Tue, 19 Sep 2006 09:23:05 -0500
To: Tom Ficht <TFICHT@cvm.tamu.edu>
Subject: Re: FW: Prophylaxis for Lab exposure to Brucella

Hi Tom,

This is the reference and I both happened to find; ironically, it appeared in print on my first day of treatment. Anyway, he actually deviated from this protocol because I received the gentamicin IV for 7 days, not IM, as this regimen suggests. PLUS I also took a combination of oral rifampin AND doxycycline for a 45 day period. I can't imagine any organisms surviving that!

Take care,

p.s. we've added some dates to our BSL3 calendar for this Fall, but I think we can still easily accommodate your group's needs.

Clin Infect Dis. <javascript:AL_get(this, 'jour', 'Clin Infect Dis.');> 2006 Apr 15;42(8):1075-80. Epub 2006 Mar 13.
Efficacy of gentamicin plus doxycycline versus

streptomycin plus doxycycline in the treatment of brucellosis in humans.

- **Hasanjani Roushan MR** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Hasanjani+Roushan+MR%22%5BAuthor%5D> ,
- **Mohraz M** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Mohraz+M%22%5BAuthor%5D> ,
- **Hajiahmadi M** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Hajiahmadi+M%22%5BAuthor%5D> ,
- **Ramzani A** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Ramzani+A%22%5BAuthor%5D> ,
- **Valayati AA** <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Search&itool=pubmed_AbstractPlus&term=%22Valayati+AA%22%5BAuthor%5D> .

Department of Infectious Diseases, Yahyanejad Hospital, Babol Medical University, Babol, Iran. hagar2q@yahoo.ca

BACKGROUND: In the treatment of human brucellosis, antibiotic regimens containing an aminoglycoside are reportedly associated with fewer relapses. METHODS: This prospective, randomized study employed doxycycline (100 mg administered orally twice daily for 45 days) in combination with either streptomycin (1 g administered intramuscularly daily for 14 days; the DS regimen) or gentamicin (5 mg/kg per day administered intramuscularly for 7 days; the DG regimen). Efficacy of treatment was determined by rates of failure or relapse with a follow-up period of 1 year. RESULTS: Ninety-seven patients with a mean age (+/- standard deviation [SD]) of 33.74+/-15.47 years and 94 patients with the a mean age (+/-SD) of 36.2+/-14.14 years were treated with regimens DG and DS, respectively (P = .277). The clinical manifestations in both groups of patients were similar with the exception of sweating, which was more common in the DG group (P = .04). Three (3.2%) of the patients in the DS group and 3 (3.1%) of patients in the DG group experienced relapse (difference, 0.1%; 95% confidence interval [CI], -4% to 5%; P = 1.0). Overall, 7 (7.4%) of the patients in the DS group and 5 (5.2%) of the patients in the DG group experienced failure of therapy or relapse (difference, 2.2%; 95% CI, -4.5% to 8.9%; P = .563). The actuarial probability for relapse at 12 months after completion of therapy was 4.3% in the DS group and 2.1% in the DG group (difference, 2.2%; 95% CI, -2.8% to 7.2%). CONCLUSIONS: The combination of oral doxycycline for 45 days plus intramuscular gentamicin for 7 days is equally as effective as traditional therapy using doxycycline for 45 days plus streptomycin for 14 days.

PMID: 16575723 [PubMed - indexed for MEDLINE]

>>> Tom Ficht <tficht@cvm.tamu.edu> 09/19/06 8:45 AM >>>

Do you have the reference for the iv gentamycin treatment?

Tom

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

---- Forwarded Message
From: "Shaikh MD, Zakir A" <ZakirShaikh@mhd.com>
Date: Thu, 14 Sep 2006 17:37:55 -0500
To: <Paul.Southern@utsouthwestern.edu>, <Rita.gander@utsouthwestern.edu>, <tficht@cvm.tamu.edu>
Conversation: Prophylaxis for Lab exposure to Brucella
Subject: Prophylaxis for Lab exposure to Brucella

Hi All,
I would like to find out if there are any recent updates in recommendations for prophylaxis of Microbiology personnel with potential exposure to Brucella (as a result of bubbling while performing catalase test from misreading of gram stain as GPC). The exposed personnel has been counseled about lack of data about prophylaxis in this scenario, but has elected for antimicrobial prophylaxis.

I would certainly appreciate any input in this regard.
Zakir

Zakir Shaikh, MD, MPH, CPE, FIDSA

Hospital Epidemiologist

Medical Director, Infection Control

Methodist Health System

Dallas, TX

(214)947-2351

****

------ End of Forwarded Message

------ End of Forwarded Message

TEXAS Department of State Health Services

Texas Department of State Health Services

1100 WEST 49TH STREET
AUSTIN, TEXAS 78756-3194
(512) 458-7318

LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Date: 5/25/2006

Submitter copy to:

SCOTT AND WHITE CLINIC-02180184
1600 UNIVERSITY DRIVE
attn: Jack Crouch
COLLEGE STATION, TX 77840

Spec #:
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient _____ DOB:

Patient Address:

Date Rcvd: 5/18/2006 Test Reas: DIAGNOSIS
Spec Type: SERUM

NEW REQUIREMENT: Due to regulatory (CLIA) requirements, effective February 14, 2005, all specimen forms must include the date of collection or the specimen will be rejected.

Final Results

Specimen Numbers:
Date Collected: 5/16/2006

BRUCELLA AGGLUTINATION	**1:160

A single Brucella agglutination titer of greater than or equal to 1:160 is evidence of a prior infection, but, it does not confirm that the infection was recent. The most convincing serologic evidence of recent Brucella infection is a fourfold rise in antibody titer between an acute and a convalescent serum.

<< BRUCELLA AGGLUTINATION is Reportable to Health Dept >>

Susan U. Neill, Ph.D., M.B.A.
Director, Laboratory Services Section
CLIA License Number 45D0660644
www.dshs.state.tx.us/lab

OPERATING PROCEDURES FOR THE BIOSAFETY LABORATORY SUITE,

THOMAS A. FICHT, PROFESSOR AND L. GARRY ADAMS, PROFESSOR

VETERINARY PATHOBIOLOGY

February 22, 2007

Table of Contents

Acknowledgements

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

Personnel wearing appropriate personal protective clothing and equipment conduct all procedures involving the manipulation of infectious materials. Additionally, all procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices. The laboratory has special engineering and design features.

The following standard and special safety practices, equipment and facilities apply to the Biosafety Level 3 Laboratory Suite Disinfectants used include ethanol, 1% (w/v) Virkon-S and 10% (v/v) commercial bleach. Virkon-S is safe for use on human skin and is as effective as bleach at reducing *Brucella* viability. Ethanol is used for flame sterilization and may be used to clean surfaces, but is much less effective than either Virkon-S or bleach at inactivating *Brucella*.

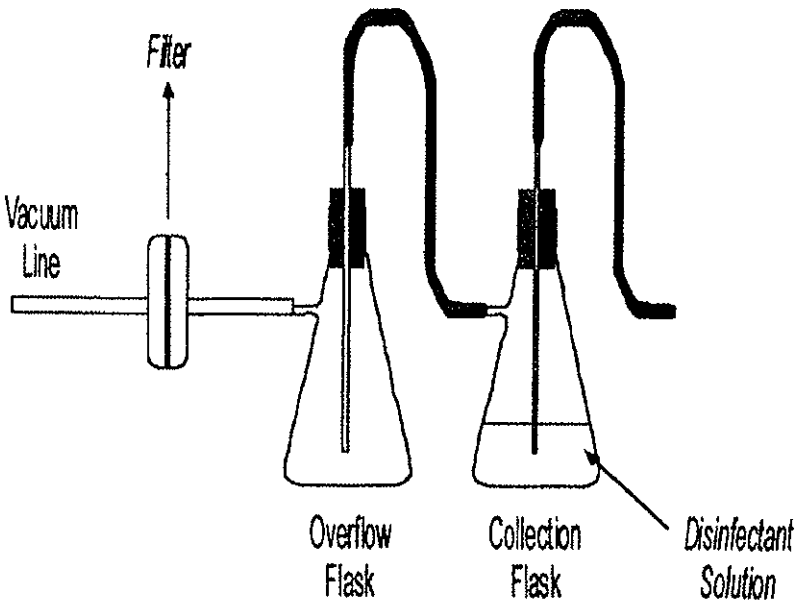

Fig. 1 Safety trap setup for use with in house vacuum line.

3.11 Spill procedures have been posted in

3.12 To use the vacuum lines for aspirating biological fluids, use two large flasks in series with a microbiological filter (0.2 – 0.45 μm).

3.13 The telephones in the BSL3 suite are for emergency use only, to provide additional safety for you. Remember that you are holding potentially contaminated latex gloves very close to your face, that these gloves are touching the receiver, which is very close to your face and mouth, and that someone else will be using the receiver after you.

13.1 Remove the outer pair of latex exam gloves before picking up the receiver.

13.2 Decontaminate the receiver immediately after every use.

13.3 Do not give the BSL3 phone number to friends. They can leave a message, and you can return their calls when you leave the BSL3 suite. If there is an emergency, laboratory or office staff can transfer the call or come into the BSL3 suite to give you the message.

4. AEROSOL CHALLENGES

4.1 Intrafacility transfer forms are completed and faxed to EHSD before transfer.

4.2 *Brucella* suspensions used for inoculations are prepared and loaded into

conical tubes in r the biological safety cabinets.

4.3 Inoculum containing viable organisms is transported from the facility in generalized "triple" packaging (primary receptacle, water tight secondary packaging, durable outer packaging) required for a biological agent of human disease.

3.1 This packaging requires the "Infectious Substance" label on the outside of the package. This packaging must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations.

3.2 Such samples are transported through the men's or women's locker rooms at the / under constant supervision from approved persons.

4.4 At the personnel will change from street clothes into appropriate wardrobe

4.1 In the outer locker room, street clothes are removed and scrubs put on.

4.2 In the inner changing room, two pairs of gloves, facemask, tyvek suits and masks (N95 rated 3M 8210 or Tecnol PFR95) are put on before entry into the main hallway.

4.5 At the , animals will be transported to in microisolyzer cages and removed in the biological safety cabinets and loaded into cages for challenges.

4.6 Madison Chamber preparation and use

6.1 Plug cord from control box into the wall socket. Check the light on the control box. Connect the source of compressed air (e.g., building; tank) through the small flow meter to the nebulizer. Make sure that the compressed air regulator reads at least 30 psig. When the main switch is on, the vacuum pump, fans, and timer should be operating.

6.2 Carefully unscrew the glass jar from the nebulizer and place about 10 ml of challenge suspension in the jar. Attach the jar to the nebulizer unit and adjust the vertical stainless steel tube so that the lower (intake) end is about half an inch below the level of fluid in the jar.

6.3 Load the animal basket into the chamber, being careful to center it so that it doesn't touch the fan blades. Close the door and turn on the main switch, activating the vacuum pump, fans, and timer. Reset the timer to zero.

6.4 Check the main (room) air flow meter (the larger meter on the right). The center of the float (ball) should run about "21".

6.5 Turn on the compressed air and simultaneously start the timer. The air flow rate through the compressed air flow meter should read about 5 psig. Check visually to be certain that the challenge inoculum is being nebulized.

6.6 After exactly 300 seconds (5 min), the compressed air supply to the nebulizer should be shut off and the nebulization process will stop. Flow through the small meter will drop to zero, and visual inspection of the nebulizer will show no

activity. The timer should continue to run.

6.7 After an additional 600 seconds (10 min) or 900 seconds (15 min) total on the timer, turn off the main switch, stopping the vacuum pump, fans, and timer.

6.8 Open the chamber door and remove the animal basket. Remove the glass nebulizer jar, discard the challenge suspension, wash the jar thoroughly, and reload a fresh 10 ml volume of nebulizer suspension. Return to Step 3 above.

6.9 At the end of the infection procedure, spray the inside of the chamber with disinfectant and wipe down very thoroughly. Leave clean nebulizer jar upside down on paper towels on the sideboard to drain and dry.

4.7 Nebulizer jars are filled with inoculum under the safety cabinet.

7.1 After use, culture will be decanted back into 50 ml conical tubes under the cabinet and saved and transported back to building

7.2 The nebulizer jar is filled with bleach to disinfect. The nebulizer "probe" is dipped in 10% bleach, followed by two dips in sterile water.

4.8 Mice are removed from the chamber and placed back into the microisolyzer cages under the biological safety cabinet. Sealed cages are transported back to the room housing the mice.

4.9 After animals are removed, tubes are disinfected under the safety cabinet (Clorox bleach wipes, 10% bleach on paper towels, 1% (w/v) virkon on paper towels) before being brought to the sink for washing.

4.10 The inside of the chamber is cleaned from front to back with 10% bleach or 1% (w/v) virkon to surface decontaminate the chamber.

4.11 The innoculum is returned to in approved containers

11.1 After thorough decontamination of container containing innoculum, containers are placed inside approved durable (leak-proof) transport container that is then closed, sealed, and disinfected as well.

4.12 Personnel remove tyvek suits and place in approved containers to be autoclaved by CMP personnel.

12.1 Full-face respirators are surface decontaminated with 70% ethanol.

12.2 Scrubs are removed in inner changing rooms and placed in containers to be autoclaved by CMP personnel. Facemasks and gloves are thrown away.

12.3 Hands are thoroughly washed before entering the outer changing room.

12.4 Street clothes and personal belongings are worn and collected before exiting BL-3 suite.

5. Routine Cleaning and Decontamination Procedures

5.1 Sharp objects

Brucella Exposure

According to the personal physician individual tested positive for Brucella and has been under treatment. Actual exposure occurred on 2/9/06, during the cleaning of an aerosolization chamber. Several individuals were present, but only cleaned the unit by climbing partially into the chamber to disinfect it. Follow-up titer 5/16/06 indicated 1:160, satisfactory. Dr. Fickt has corrected the cleaning procedure to prevent individuals from contacting internal surfaces until disinfected.

From: Angelia Raines
To: Ewing@vprmail.tamu.edu,f-bazer@tamu.edu
Date: 4/10/2007 9:20:57 PM
Subject: Select Agent Exposure

Several months ago, one of our laboratory employees had a slightly elevated titer, which indicated "evidence of prior exposure" to Brucella. The incident occurred during the time we were transitioning CDC compliance responsibilities from the Environmental Health and Safety Department to the Office of Research Compliance (ORC). It should have been immediately reported to the CDC but was not. All reporting responsibilities are now managed by the ORC and we have a process in place to insure immediate notification of a loss, theft or release/exposure. I have contacted CDC about the oversight and I am in the process of submitting the proper incident report to them.

All other lab personnel have since been tested and found to be negative.

In investigating the incident, we found that the exposure most likely occurred because of improper decontamination procedures. Specifically, the employee climbed into an aerosol chamber which was located in the BL3 lab. Following the incident, the laboratory's operating procedures were updated and all lab personnel were retrained.

Please let me know if you need further information regarding this incident.

Thank you,
Angie

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax
(770) 789-3456 Cell

CC: TAgnew@vprmail.tamu.edu

From: Angelia Raines
To: Mattox, Brent S
Date: 4/24/2006 3:07:57 PM
Subject: Fwd: FW: Workmen's Compensation

Brent,

Please let me know how you are going to proceed regarding the attached communication. Also, please let me know the outcome of your review of Dr. Samuels materials that I sent you.

Thanks much!

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

CC: ibc@tamu.edu; Salsman, John

From: Angelia Raines
To: Bazer, Fuller
Date: 4/21/2006 3:40:35 PM
Subject: Fwd: FW: Workmen's Compensation

FYI...

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

From: Angelia Raines
To: Ihrig, Melanie
Date: 4/24/2006 3:03:49 PM
Subject: Fwd: FW: Workmen's Compensation

Hi Melanie,

You probably already received the attached, but just in case...

Best,
Angie

Angelia Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

Mattox, Brent S

From: Mattox, Brent S
Sent: Monday, April 24, 2006 4:04 PM
To: 'Tom Ficht'
Subject: RE: <no subject>

By the way, I heard from Scott & White today: all titers were negative. I do need a copy of the Lab results on though. I can go the long route or would perfer getting a copy through if possible. Did you have her retested at S&W?

As to the Ding subject, I don't understand why you had to contact Virginia Tech instead of our illustrious Office of Compliance. Isn't that their job?

Brent

-----Original Message-----
From: Tom Ficht [mailto:tficht@cvm.tamu.edu]
Sent: Monday, April 24, 2006 1:51 PM
To: Charlotte Waggoner
Cc: Raines, Angelia; Tiffany Agnew; Mattox, Brent S
Subject: Re: <no subject>

Thanks. CDC's approval process doesn't seem to be getting any faster. I will pass this on to my compliance office.

Taf

On 4/24/06 1:09 PM, "Charlotte Waggoner" <ren@vt.edu> wrote:

> Hi Dr. Ficht....
>
> Xicheng's DOJ ID number at Virginia Tech was Hope this helps...
>
> At 10:53 AM 4/24/2006, you wrote:
>> Dear Ms. Waggoner
>>
>> We are aware of the need to renew Dr. Ding's CDC approval. We were
>> asked by our compliance office to obtain his previous number to
>> expedite this request.
>>
>> If you prefer I will ask that the compliance office contact you
>> directly for this info.
>>
>>
>> Charlotte M. Waggoner, RBP
>> University Biosafety Officer/Responsible Official Environmental,
>> Health and Safety Services (MS 0423) Virginia Tech
>> 459 Tech Center Drive
>> Blacksburg, Virginia 24061
>> http://www.ehss.vt.edu/
>>
>> ren@vt.edu
>> (540) 231-5864
>> (540) 231-3944 FAX
>>
>>
>>
>>
>> Sincerely,
>>

>> Thomas A. Ficht, Ph.D.
>> Professor
>> Veterinary Pathobiology
>> Texas A&M University
>> 4467 TAMU
>> College Station, TX 77843-4467
>> 979-845-4118 ph
>> 979-862-1088 fax
>
> Charlotte M. Waggoner, RBP
> University Biosafety Officer/Responsible Official Environmental,
> Health and Safety Services (MS 0423) Virginia Tech
> 459 Tech Center Drive
> Blacksburg, Virginia 24061
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>

Thomas A. Ficht, Ph.D.
Professor
Veterinary Pathobiology
Texas A&M University
4467 TAMU
College Station, TX 77843-4467
979-845-4118 ph
979-862-1088 fax

From: Shannon Davis
To: Bazer, Fuller; Browder, Betsy; bsmattox@tamu.edu; ddavis@cvm.tamu.edu; Ewing, Richard; Ficht, Thomas; gadams@cvm.tamu.edu; mihrig@tamu.edu; Samuel, James; Tesh, Vernon
Date: 4/13/2007 2:01:09 PM
Subject: **Notification of CDC Site Visit 4/16/07**

I just got a call from CDC in response to our report of *Brucella* exposure. They are planning on conducting a site visit beginning Monday morning. Further information is attached.

Angella Raines

Angella Raines
Director, VPR Office of Research Compliance
TAMU 1186
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
araines@vprmail.tamu.edu
(979) 847-9362 office
(979) 862-3176 fax

CC: Cornett, Dianne; Raines, Angella; Wilson, Van

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 13, 2007

Richard Ewing, Responsible Official
Texas A& M University (Registration #C20060605-0489)
1500 Research Parkway, Suite B150, TAMU 1186
College Station, TX 77843-1183
Fax: (979) 862-3176

Subject: 42 C.F.R. § 73.19 (Notification of theft, loss, or release)

Dear Dr. Ewing:

This is to acknowledge the receipt of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins) from Texas A& M University dated April 11, 2007 that reported an occupational exposure to *Brucella*. Based upon the review of the report, the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) has additional questions:

1. Please provide a copy of the medical surveillance plan and describe how the follow up was conducted as a result of the incident.
2. Please provide all occupational health records pertaining to the exposed individuals and any individuals that have presented with symptoms associated with a possible exposure to *Coxiella, Brucella,* or *Mycobacterium tuberculosis*.
3. Please provide documentation in regards to the risk assessment that was preformed for work with *Brucella*.
4. Please describe the decontamination procedures used for the aerosol chamber and any modifications incorporated to these procedures as a result of this incident.
5. Please provide all standard operating procedures (SOPs) and certification documents as it relates to the aerosol chamber.
6. Please provide a summary of events that occurred with this incident including the follow-up review that your entity conducted to assure that any other similar incidents do not occurred.
7. Since your entity failed to meet the reporting requirements of 42 C.F.R. § 73.19, please provide a plan of how Texas A& M University will achieve compliance with 42 C.F.R. 73. In addition, please explain if your entity failed to meet other required federal and state reporting requirements.
8. Please provide access logs for Room nd all rooms were work with *Brucella* is performed.
9. Please explain how your incident response plan, security plan, and biosafety plan have been modified as a result of this incident.

10. Please provide any personal protective equipment or entry requirements that may be needed prior to entry into your laboratories.
11. Please provide any documents regarding unexpected animal illness.
12. Please provide an assessment of the risks of continuing to utilize the aerosol chamber.
13. Please provide a detail description of the measures implemented to protect the employees from exposures while decontaminating the aerosol chamber including any enhanced personal protective equipment (PPE) utilized and the medical surveillance activities implemented. The long term follow-up of employees should be included in this response.

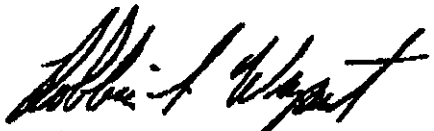
The DSAT will be conducting an inspection of your entity on April 16, 2007 to assess the measures implemented by Texas A& M University to protect the staff and public from exposure to pathogenic microorganism, the measures implemented to prevent further incidents and to evaluate your entity's compliance with the select agent regulations. Please make available all staff members involved in the incident described in your report dated April 11, 2007 to be interviewed by the inspection team.

On April 16, 2007, the following representatives from the CDC will be visiting Texas A& M University:

Diane Martin, Lead Inspector
Richard Henkel, Biosafety Officer
Melissa Resnick, EIS Officer

Please have the response and any supporting documentation available for the inspectors upon their arrival to your entity on April 16, 2007.

Please contact Lori Bane, Compliance Officer with the DSAT at 404-718-2006 or at the address listed below if you have questions.



Robbin Weyant, PhD, CAPT, USPHS
Director
Division of Select Agents and Toxins
Coordinating Office of Terrorism Preparedness and Emergency Response

CDC Emergency Contact Information

Police, Fire, Medical = 9- 911

Dr. L. Garry Adams
(Investigator)
Work (979) 845-5092

Dr. Thomas A. Ficht
(Investigator, IBC Co-Chair)

Dr. John M. Quarles
(Department Head)

Ms. Tiffany Agnew
(Program Coordinator, IBC)
Work (979) 458-3624
Mobile (706) 414-7133

Dr. Melanie Ihrig
(Director, Comparative Medicine Program)
Work (979) 845-7433

Ms. Angelia Raines
(Director, Research Compliance)
Work (979) 847-9362

Fuller Bazer
(Assoc. VP for Research)
Work (979) 693-2872

Lt. Bert Kretzschmar
(University Police, Crime Prevention Unit)
Work (979) 845-8900

UPD (979) 324-0773

Dr. James Samuel
(Investigator)
Work (979) 862-1684

Dr. Elizabeth Brandon
(Assoc. Director, Comparative Medicine Program Work (979) 845-7438

Mr. Brent Mattox
(Alternative Responsible Official)
Work (979) 845-2132

Dr. Frank Stein
(Assoc. Director, Comparative Medicine Program)
Work (979) 845-6488

Mr. Donald Davis
(Investigator)
Work (979) 845-3174

Ms. Ellen Mitchell
()
Work (979) 847-8642

Dr. Vernon Tesh
(Investigator)
Work (979) 862-4113

Dr. Richard Ewing
(Vice President for Research, Responsible Official)
Work (979) 845-8585

Dr. D Partin
USDA
Mobile (979) 679-2312

Dr. Van Wilson
(IBC Co-Chair)
Work (979) 845-5207

University police.....845-2345
College station police.....764-3600
College station fire.....764-3700
TAMU environmental health and safety.....845-2132
TAMU area maintenance.....845-5542
TAMU maintenance (24 hours).....845-4311
Radiological emergencies 862-1111

Callcott, Diane

From: Raines, Angelia
Sent: Thursday, April 12, 2007 2:06 PM
To: James McGee
Cc: Tiffany Agnew
Subject: Form 3

Attachments: Form 3-Ficht (faxed).pdf; Angelia Raines.vcf


Form 3-Ficht (faxed).pdf (253 ...


Angelia Raines.vcf (513 B)

Hi Jim,

Thanks for following up with me regarding the Brucella exposure. I also briefly spoke with Paul Mehta. Attached is an electronic copy of the report that was faxed to you. Per my conversation with Dr. Mehta, I will be prepared to send additional information about changes in our safety plan after we get the official response from your office.

To recap our conversation about the exposure:

- It most likely occurred in February 2006.
- The employee was tested, and treated.
- Other lab personnel were tested and found to be negative for exposure.
- The Lab Director reviewed his Biosafety Plan to determine if changes were needed.
- The Biosafety Plan was modified as a result of the incident.
- Lab personnel were updated and retrained on the changes.
- Form 3 was not submitted at the time of the event, as required; however a process is now in place to ensure immediate notification. We have also submitted the required report.

Thanks for sharing with me that many institutions have been unclear as to whether they needed to report some exposures based on the information contained in the Form-3 instructions. While I fully understand the regulatory requirements, clarity in these instructions could indeed assist the reporting process.

Thanks again for your insight and assistance!

Angelia Raines

Angelia Raines
Director, VPR Office of Research Compliance TAMU 1186 1500 Research Parkway Suite 150 B (Centeq Building) College Station, Texas 77843-1186 araines@vprmail.tamu.edu
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GUIDANCE DOCUMENT FOR REPORT OF THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 3)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity is required by regulation (7 CFR 331.19, 9 CFR 121.19, and 42 CFR 73.19) to notify APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov) immediately upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent and toxin. In addition, clinical or diagnostic laboratories and other entities that possess, use or transfer a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing must immediately report upon discovery of a theft, loss, or release of select agent or toxin. After the initial reporting, this form (APHIS/CDC Form 3) must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins.

For theft or loss of select agents or toxins, the entity must notify the appropriate local, state, or federal law enforcement agencies. For release of select agents or toxins, the entity should notify the appropriate local, state, and federal health agencies.

PURPOSE

This form is to be used by the RO or facility director to report the theft, loss, or release of select agents or toxins. A copy of the completed form and attachments must be maintained by the entity for three years.

INSTRUCTIONS

1. Immediately notify APHIS or CDC via telephone, fax, or e-mail and appropriate local, state, or federal law enforcement agencies (theft or loss) or appropriate local, state, and federal health agencies (release).

2. The RO or facility director must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration.
   A. For reporting of a theft or loss, complete sections 1 and 2. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified. For reporting a theft or loss that occurred during transfer, complete sections 1, 2, and 3 and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."
   B. For reporting a release, complete sections 1, 2, and 4. For reporting a release that occurred during transfer, complete all sections and include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins."

3. The RO or facility director faxes or mails the form to APHIS or CDC **within 7 calendar days** of the theft, loss, or release.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

TEXAS A&M UNIVERSITY

INSTITUTIONAL BIO-SAFETY PROGRAM (IBSP)

INSTITUTIONAL POLICIES And STANDARD OPERATING PROCEDURES

Office of Research Compliance
Centeq Building
Ste. B 150
1500 Research Parkway
College Station, Texas 77843-1186

Revised: 7/25/07

TABLE OF CONTENTS

Introduction

When the scientific community began exploring the new and very misunderstood realm of recombinant DNA, the public became apprehensive about its impact on human health and the environment. As a result of this concern, scientists came together at a landmark 3 (three) day event known as the *Asilomar Conference.* During this conference, a system of institutional and federal oversight was developed, which was to be guided by the National Institutes of Health (NIH).

While the *NIH Guidelines* is a "living" document that details Biosafety practices for institutions and investigators to follow, Institutional BioSafety Committees (IBCs) were formed over 25 years ago as local oversight for research involving recombinant DNA. In addition, many institutions have given their IBCs oversight of other research involving other Biohazardous materials, such as carcinogens and Biohazardous agents. In an attempt to implement these guidelines, IBCs are required to establish written policies and standard operating procedures (SOPs) to which all research activities should conform.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The Act) requires entities to register with the U. S. Departments of Health and Human Services (HHS) or Agriculture (USDA) if they possess, use, or transfer select biological agents or toxins that could pose a severe threat to public health and safety or to animal or plant health or animal or plant products. In addition, the act requires:

- Maintenance of a comprehensive national database of select agents and toxins.
- Monitoring and enforcement of laboratory compliance with safe handling procedures.
- Increased security measures including controlled access to select agents and toxins and the screening of entities and personnel.
- Criminal and civil penalties for the inappropriate use of threat agents including specific viruses, bacteria, fungi, and toxins.

In support of this Act, CDC has primary responsibility for regulating the possession, use, and transfer of 39 biological agents and toxins that have the potential to pose a severe threat to public health and safety. The CDC Select Agent Program oversees these activities and registers all laboratories and other entities in the United States that possess, use, or transfer a select agent or toxin.

Under the authorities granted in the Act, the Select Agent Program performs specific functions to ensure the safe and secure handling and transfer of select agents and toxins. These functions include:

- Promulgation of an interim final rule on December 13, 2002 (42 CFR Part 73) implementing the Act.
- Evaluation and approval of requests to possess, use, and transfer select agents and toxins.
- Registration of laboratories that possess select agents and toxins.
- Approval of transfer of select agents and toxins among registered laboratories.
- Inspection of laboratories to ensure appropriate safety and security measures are being followed.
- Maintenance of a national database of registered laboratories.

There are currently 318 entities registered with the Select Agent Program. The Select Agent Program has conducted over 380 inspections since February 7, 2003, when the regulations became effective. All registered entities have been inspected at least once. Regulated entities include: academic institutions; biomedical centers; commercial manufacturing (e.g., the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories (including clinical and diagnostic laboratories); and research facilities.

In accordance with the Act, implementing regulations detailing the requirements for possession, use, and transfer for select agents and toxins were published by HHS (42 CFR part 73) and by USDA (9 CFR part 121 and 7 CFR part 331) .
Registration of an entity requires that an "Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins" (APHIS/CDC Form 1) should be completed and submitted to either HHS Centers for Disease Control and Prevention (CDC) or to USDA Animal Plant Health Inspection Service (APHIS). Registration also requires that the U.S. Department of Justice (DOJ) complete a security risk assessment (SRA) for the facility, its owners, and the designated responsible official. Before registration is granted, the facility must also meet Biosafety requirements that are commensurate with the risk that the select agent or toxin poses and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.
An entity that needs to register in order to possess, use, or transfer a select agent or toxin must submit its registration information to either APHIS or CDC, but is not required to submit the application to both APHIS and CDC.

In accordance with the final rule (42 C.F.R. Part 73) and (9 C.F.R. Part 121 & 7 C.F.R. Part 331), the IBC has the authority to review, approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. The Texas A&M University's Institutional Biosafety Program (IBSP) policies and procedures provide guidance and responsibility, just as well as these policies.

The Texas A&M Select Agent Program SOPs apply to all the oversight of the IBC and the methods of reporting. These SOPs are reviewed periodically to ensure that they are up-to-date, that new legislation or regulations are reflected in the policies and that daily activities are being performed as described in the SOPs.

The policies and procedures set forth in this standard operating procedure are applicable to all faculty, staff, employees and students at the Texas A&M University at College Station (TAMU), Texas Agricultural Experiment Station (TAES), Texas Engineering Experiment Station (TEES), Texas Transportation Institute (TTI), and the Texas A&M University System Health Science Center (TAMUSHSC), who propose to use any Biohazardous materials (which includes recombinant DNA, carcinogens, and Biohazardous agents) that may be harmful to human health and the environment in research, development and related activities.

At Texas A&M University, the definition of research varies across philosophical paradigms (as revealed by comparing federal regulations and the broad range of literature on research philosophies, purposes, and methodologies). While the IBCs govern research involving humans and the IACUCs governs research involving animals, IBCs are the "bridge" committees that review the science, safety, and the ethics of experimentation from the bench, through animal models, to the clinic.

In accordance with the Department of Health and Human Services (DHHS) through *The National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, in particular Sections III-A, III-D, and III-E, the IBC has the authority to review, approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. The guiding principles for such research are based upon the most recent version of these guidelines dated April 2002. The jurisdiction of the University IBC is defined by its binding commitment with the NIH and by Texas A&M University's institutional policies. In addition, Texas A&M University also has a Memorandum of Understanding with the Texas Engineering Extension Service, Texas Engineering Experiment Station, Texas Agricultural Extension Service, Texas Transportation Institute, and the Texas A&M University System Health Science Center to include oversight of these System components at the local level.

The Texas A&M University Institutional BioSafety Program (IBSP) SOPs apply to all the day-to-day operations of the IBC. These SOPs are reviewed periodically to ensure that they are up-to-date, that new legislation or regulations are reflected in the policies and that daily activities are being performed as described in the SOPs. NIH site inspections of an IBC may include an assessment of these SOPs.

These policies are based on current regulations, ethical principles, and guidelines for the protection of human health and the environment as research is conducted with recombinant DNA, and/or other biohazardous agents. These procedures detail how these policies are carried out, but are not an end unto them; instead, they are the framework upon which research activities in these facilities are conducted.

The volunteer members of the IBC are also expected to act as gatekeepers to ensure that the research community conducts research with the knowledge of the laboratory and personnel safety, while protecting the integrity of research involving recombinant DNA and other biohazardous agents.

STATEMENT OF AUTHORITY AND PURPOSE

Ethical Principles

Institutional BioSafety Committees (IBCs) are guided by the ethical principles applied to all research involving the use of recombinant DNA, as set forth in the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*. As the largest funder of biomedical research, the NIH has a fiduciary responsibility to ensure that these funds have proper oversight.

The Texas A&M University Biosafety program, including the IBC review, will be guided by the ethical principles governing all research involving Biohazardous materials as subjects that are set forth in the NIH Guidelines. Researchers must agree to abide by these principles and by the recommendations of the IBC.

Authority/Charter

INSTITUTIONAL AUTHORITY

An Institution's IBC is established and empowered under the auspices of that Institution's executive authorities, and, if federal funding is used to support recombinant DNA and/or other biological materials research in whole or in part, the Institution must file a registration with the National Institutes of Health Office of Biotechnology Activities (OBA). This Institution requires that all research projects involving recombinant DNA and/or other biological materials must be registered with, reviewed, and approved by the IBC prior to initiation of any research related activities.

The Texas A&M University IBC is established to review and approve all research projects involving recombinant DNA and/or other biological materials, regardless of the source of funding and location of the study. If the research is exempt according to NIH Guidelines (Section III-F-1-6), registration of the laboratory must still take place through an *Application for IBC Permit.* Regardless of sponsorship, research projects involving the use of recombinant DNA and/or biological materials are subject to the following policy:

> The safe conduct of experiments involving recombinant DNA depends on the individual conducting such activities. The *NIH Guidelines* cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment. The *NIH Guidelines* are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and the Principal Investigator in determining safeguards that should be implemented. The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, *it is the responsibility of the institution and those associated with it to adhere to the intent of the NIH Guidelines as well as to their specifics.* Each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that all recombinant DNA research conducted at or sponsored by that institution is conducted in compliance with the *NIH Guidelines.* General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary. (Section IV-A, *NIH Guidelines*)

As a condition for NIH funding of recombinant DNA research, institutions shall ensure that such research conducted at or sponsored by the institution, regardless of the source of funding, shall comply with the *NIH Guidelines.* Section I-D-1 of the NIH Guidelines states the following: "All NIH-funded projects involving recombinant DNA techniques must comply with the *NIH Guidelines.* Non-compliance may result in: (i) suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution."

In addition, Section I-D-2 states: "All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques must comply with the *NIH Guidelines.* Noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution."

The IBC has the authority to ensure that research is designed and conducted in such a manner that protects the health of laboratory personnel and the environment. Specifically:

1. The IBC must review, and has the authority to approve, require modification, or disapprove, all research activities that fall within its jurisdiction;
2. The IBC has the authority to conduct an annual review as it deems necessary to protect the health and environment of all research involving recombinant DNA and/or other biohazardous agents, including requiring a progress report from the Investigators and auditing the individual parts of the laboratory permit;
3. The IBC may terminate the approval of a laboratory permit;
4. The IBC will determine the biological safety level for each laboratory permit;
5. The IBC reserves the right to determine if a study is exempt from full committee review, based upon the *NIH Guidelines* (Section III-F).

The IBC has a relationship with other institutional research review committees. The IBC functions independently, but also in coordination with other committees. Research that is under review of other committees, may be awaiting IBC approval. Once the IBC has approved the laboratory permit, the approval will be articulated to the other review committees.

CHARTER

The Institutional Biosafety Committee (IBC) is responsible for reviewing and approving all activities related to the biological materials, recombinant DNA, and Center for Disease Control (CDC) select agents used in a Texas A&M facility or at an affiliate located on the College Station campus with an executed Memorandum of Understanding (MOU) for IBC services.

The IBC reviews research activities involving these agents in order to ensure that the activities are conducted in a manner that is safe for Texas A&M University personnel, the public and the environment. The IBC follows the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules on the use of recombinant DNA and human gene transfer and the "Biosafety in Microbiological and Biomedical Laboratories (BMBL)", as well as institutional policies and procedures.

The IBC is responsible for:

- developing and implementing policies related to the safe use of biological materials, recombinant DNA, and CDC select agents;
- reviewing all research protocols involving biological materials, recombinant DNA, CDC select agents;
- approving or disapproving such projects based on their hazard potential and proposed containment procedures;
- establishing, approving and monitoring proper laboratory conditions and procedures required for such projects;
- ensuring that the qualifications and training of individuals involved in research are adequate to ensure the use of appropriate laboratory safety techniques;
- approving proper disposal and decontamination procedures;
- Approving plans related to emergencies (e.g., accidental spills or contamination) or related to safety, security or incident;

- ensuring that any violations of the NIH Guidelines and/or incidents involving select agents are investigated and reported directly to the Responsible Official (RO) and NIH-OBA. The RO is responsible for reporting incidents to other agencies (e.g., CDC Division of Select Agent and Toxins)

The IBC meets monthly at a convened meeting. The public may participate in any portion of the meeting involving the review and discussion of research or activities involving rDNA. Minutes of IBC meetings may be shared with the public; however, information pertaining to non-rDNA research, which may be reviewed by an IBC sub-committee, will not be made available. Fifty one percent of the voting membership is necessary to establish a quorum to conduct business. The members are recruited from faculty based on their expertise in working with biological materials, recombinant DNA, and CDC select agents and from the College Station community.

The IBC consist of at least five voting members with each member appointed by the RO. The membership shall include someone with expertise in recombinant DNA technology, an animal expert, a plant expert, **at least two community representatives** and the Institutional Biological Safety Officer. *Ad hoc* consultants (e.g., a security expert for the review of select agent research) and a sub-committee will be used as needed.

Members shall serve for a term of three years, which may be renewed by the RO. The Chair shall be designated by the RO and the Committee shall report administratively to the RO.

The Office of Research Compliance - Institutional Biosafety Program staff shall serve as the administrative liaison between the committee and the research community.

The Director for the Office of Research Compliance shall serve as the contact for the NIH Office of Biological Activities and will ensure that NIH receives an annual report and all other notifications as required by guidelines.

Persons subject to this policy

All research and other activities involving recombinant DNA and other Biohazardous materials that are conducted by or under the direction of any full-time or part-time employee, trainee, or agent of Texas A&M University or designated affiliate shall be subject to review and approval by the IBC, regardless of the funding source if any, and regardless of the site at which the research is performed. This research and other activities include but are not limited to:

(1) Research conducted in connection with the employee, trainee, or agent's institutional responsibilities.
(2) Research sponsored by a School or Center in University.
(3) Research using any property or facility of Texas A&M University.
(4) Research involving the use of Texas A&M University's non-public information to identify or contact human research subjects or prospective subjects.

The obligation of part-time Texas A&M employees, trainees, and agents to obtain IBC approval of all activities involving recombinant DNA and other Biohazardous materials applies to such activities as are conducted under the auspices of their Texas A&M appointment or affiliation. Further, all research and other activities involving recombinant DNA and other Biohazardous materials that are conducted or under the direction of an individual who is not a Texas A&M University employee,

trainee or agent but whose research will use any property or facility of the University and/or whose research is sponsored by the Schools and Centers in the University shall be subject to review and approval by the IBC. In all cases described in this paragraph, the investigator(s) shall comply with all federal, state and University regulations governing such research.

Students are not permitted to serve as primary investigators for studies involving the use of recombinant DNA and other Biohazardous materials. Principal Investigators are defined as the receipt of the funding. Co-Investigators may be identified, but are only recognized as personnel authorized in the laboratory.

SCOPE and PURPOSE

To assure, both in advance and by periodic review, that appropriate steps are taken to protect human health and the environment where recombinant DNA or other Biohazardous materials are utilized in research. In addition, the IBC develops and publishes policies and guidelines on the use of recombinant DNA and other Biohazardous materials in research.

The IBC is charged with the responsibility of functioning under the direction of the Institutional Official and his or her designees for all protocols involving research with recombinant DNA and other Biohazardous materials at Texas A&M University and its affiliated institutions, except as noted, or at sites and institutions outside Texas A&M when conducted by or under the direction of Texas A&M University employees, trainees, or agents.

IBC REVIEW OF RESEARCH POLICY

All research involving the use of recombinant DNA and/or other biohazardous materials and all other activities, which even in part involve such research, regardless of sponsorship, must be reviewed and approved by the Texas A&M University IBC. No research involving recombinant DNA and/or other biohazardous materials (including Select Agents) may be initiated until the IBC has reviewed and approved the research protocol and all supporting documents. Upon approval, researchers will receive an approval letter and a completed laboratory permit. Specific determinations of the biological safety level of each approved laboratory are made by the IBC.

Research involving Select Agents will be reviewed by an Ad hoc sub-committee of the IBC. IBC will not grant approval for any project involving select agents until all issues raised by the sub-committee are addressed.

The IBC's purpose and responsibility is to protect the human health and environment within laboratory settings. The IBC reviews and oversees such research to ensure that it meets well established ethical principles and that it complies with *NIH Guidelines* and federal regulations 42 CFR Part 72, 73, 1003, as it pertains to the Select Agent Program.

To approve research protocols, the IBC shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (this is an essential condition for approval) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and, when appropriate, by using

procedures already being performed on the subjects for diagnostic or treatment purposes. This process consists of the completion of a Risk Assessment, and consultation with the Institutional BioSafety Officer (BSO).
2. The research protocol makes adequate provision for keeping the IBC informed of any modifications in the laboratory, such as new material, personnel, procedure, etc. to ensure laboratory safety.

The determination of a risk assessment may be found in Section II of the *NIH Guidelines*, along with the application of sound professional judgment as it relates to the agents/organisms to be used in the research activities in question.

1. The IBC will carefully weigh the relative risks and benefits of the research procedures to be applied to the subject.

2. Research activities designed to yield fruitful results for the benefit of individual subjects or society, in general, may incur risks to the subjects provided such risks are outweighed by the benefit to be derived from activities.

Failure to Submit a Project for IBC Review

The implications of engaging in activities that qualify as research that is subject to IBC review without obtaining such review are significant. Results from such studies may not be published unless IBC approval had been obtained prior to collecting the data. To do so is in violation of Institutional policy. It is also against Institutional policy to use those data to satisfy thesis or dissertation requirements. If an Investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the Investigator should submit a protocol to the IBC for review as soon as possible. If the IBC does not approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be published.

GENERAL ADMINISTRATION

100

SOP Number:	**IBSP 100-101**	Revision Number:	**00**	Effective Date:	
Title:	**Policies and Procedures Maintenance**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval Signature)				Date:	

1. POLICY

Following guidance of National Institutes of Health (NIH) Guidelines, and institutional policies, the IBSP will ensure that the human health and environment is protected in research involving recombinant DNA, and other Biohazardous materials.

Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of the aforementioned research for the adequate documentation of such oversight.

Standard operating policies and procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of rDNA and/or Biohazardous material research.

Specific Policies

1.1 Review, Revision, Approval of Policies & Procedures

1.1.1 Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of Texas A&M University may require a new SOP or a revision to a previously issued SOP.

1.1.2 Policies will be reviewed by the appropriate IBC Administrator on annual intervals.

1.1.3 Approval of new or revised SOPs is required prior to issuance.

1.1.4 Documentation of review and approval is required by signature of the responsible and authorized individuals.

1.2 SOP Dissemination and Training

1.2.1 When new or revised SOPs are approved, they will be disseminated to appropriate individuals and departments.

1.2.2 Training will be provided to all members of the IBC and the IBSP Compliance Staff on any new or revised policy and/or procedure.

Evidence of training must be documented and filed with the Program Coordinator.

1.2.3 Each new IBC member or IBSP staff employee must review all applicable SOPs prior to undertaking any responsibilities at the IBC. Evidence of training must be documented and filed with the Director of the Office of Research Compliance (or Program Coordinator). Investigators are responsible for reviewing all biosafety SOPs and ensuring that their staff are aware of biosafety compliance procedures.

1.3 Forms

Forms are used to: 1) ensure that policies are integrated into the daily operations of research and review throughout the Texas A&M University system, and 2) enable IBSP Compliance Staff to manage review, tracking, and notification functions consistently.

1.3.1 Only the most current version of all forms will be accepted and reviewed by IBC members and IBSP staff employees. These forms will be found at the IBSP webpage: http://researchcompliance.tamu.edu/ibc/ibcrevapp.

1.3.2 Non compliance with this policy may result in the delay of research initiation.

2. SCOPE

These policies and procedures apply to all IBSP Compliance Staff.

3. RESPONSIBILITY

The Director of the Office of Research Compliance (or designee) is responsible for establishing and periodically reviewing and modifying (as appropriate) IBC standard operating policies and procedures.

The IBC is responsible for review and approval of new and modified policies and/or SOPs. The Committee as a whole, separate from the IBC professional staff must act as reviewers. The IBC must establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the *NIH Guidelines*. As part of its general responsibilities for implementing the *NIH Guidelines*, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the *NIH Guidelines*. Such procedures may include: (i) statements formulated by the institution for the general implementation of the *NIH Guidelines*, and (ii) any additional precautionary steps the institution deems appropriate.

The Institutional Official/Responsible Official (Texas A&M Executive Vice President for Research) is responsible for granting final approval (as appropriate) to new and revised IBC policies. Changes that impact the university rules related to recombinant DNA and/or research involving other Biohazardous material will be communicated by the biosafety program staff to the Director of the Office of Research Compliance for a possible a submission of rule changes to the University Rules Committee.

4. APPLICATION REGULATIONS AND GUIDELINES

Section IV-B-1-a (*NIH Guidelines*)
TAMU 15.99.01M1,15.99.01,01.01.01.M2, 15.01.01.M3,15.01,15.01.01

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

7. PROCESS OVERVIEW

The Texas A&M University IBSP employees will maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBC Program Coordinator	Monitor appropriate sources and contacts for policy updates, note policies that may need revisions and indicate priority.	Updated NIH Guidelines; any updated CFRs
IBC Program Coordinator	Within agenda for the annual retreat, Committee will review any changes in guidelines and regulations to determine if changes to SOPs are necessary.	IBC Committee
Director of the Office of Research Compliance (or Program Coordinator) *IBC Compliance Staff*	Discuss changes and determine if additional procedures are required or if forms need revisions.	
IBC Program Coordinator	Revise policies and/or procedures. Revise forms if needed. Track changes.	
IBC Program Coordinator	Update policy and archive hard copies of previous policy.	
IBC Program Coordinator	Notify appropriate contact within the ORC to make changes to the web-electronic system and to archive previous version.	

	Replace & destroy paper copies of obsolete sections if any.	
IBC Program Coordinator	Notify research community & distribute new SOPs & forms as needed.	Notification of SOP Change email- Distribution "A"

SOP Number:	**IBSP 100-102**	Revision Number:	**00**	Effective Date:	
Title:	**Training and Education**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval Signature)				Date:	

1. POLICY

Training of the biosafety research personnel, IBSP Compliance Staff and IBC members is critical if the IBC is to fulfill its mandate to ensure the safety of human health and environment in research involving recombinant DNA and/or other Biohazardous materials in a consistent manner throughout the Texas A&M University research community. Training is also mandated by select agent regulations.

IBC members, IBSP staff, biosafety research personnel and others charged with responsibility for reviewing, approving, and overseeing research involving rDNA and other Biohazardous materials should receive detailed training in the regulations, guidelines, and policies applicable to this type of research.

The IBSP compliance office will provide training opportunities for IBC members, Compliance staff and investigators at Texas A&M University, at least annually.

The Patriot Act Task Force (PATF) was established on the campus of Texas A&M University to specifically address the Select Agent Program. The task force is comprised of individuals from diverse levels of experience and expertise, ranging from the scientific to the legal arena. All Select Biological Agents and Toxins (SBATs) PIs are members and actively participate in the education of the research community. In addition, members of the IBC are encouraged to have membership in the PATF. While active review of protocols involving SBATs are completed by the IBC (sub-committee), the PATF assists in the evaluation of the Safety, Security, and incident response guidelines and procedures for facilities that house SBATs.

Specific Policies

1.1 Training

1.1.1. Management level staff and members of the IBC who are overseeing research on recombinant DNA, as defined in Section I-B of the *NIH*

Guidelines, that is managed, funded, or taking place in an entity under the jurisdiction of Texas A&M University, will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.

1.1.2. The Program Coordinator establishes the educational and training requirements for the research community (based on input from the IO/RO and PATF), IBC members and staff who review research involving recombinant DNA and/or Biohazardous materials at this institution and who perform related administrative duties.

1.1.3. Members of the IBC will participate in initial and continuing training in areas germane to their responsibilities.

1.1.4. Chairpersons will receive additional training in areas germane to their additional responsibilities or as needed.

1.1.5. IBSP Compliance Staff will receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOP).

1.1.6. IBC members and IBSP staff will be encouraged to attend workshops and other educational opportunities focused on IBC functions. Texas A&M University will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

1.1.7. In the PATF meetings, continuous training is provided to SBAT PIs, specifically in the regulatory measures required for the various facilities and agents.

1.1.8. On an annual basis, mandatory Program training for all SBAT personnel will conducted, Annual training will include at least safety and security training, incident response training and training in order to maintain compliance with the Texas A&M select agent program (submission requirements, PPE, blood borne pathogen) information to any individual working in or visiting areas where Select Agents and Toxins are handled or stored. (42 CFR § 73.15) PI/LDs are required to conduct training each time their plans (security, incident or safety) are changed. All training must be documented.

1.1.9. Proof of training will be provided to the IBC annually for research involving select agents in order to continue research.

1.1.10. As pursuant to Section IV-B-1-h of the *NIH Guidelines*, the Texas A&M University IBC will ensure that the Principal Investigator and their personnel have sufficient training. By the completion of Attachment D in the *Application for IBC Permit*, and through grant proposal submissions, the IBC gathers this information.

1.1.9.1 Failure of a Principal Investigator to complete an Attachment D for their personnel will delay the approval of a submission.

1.2 Documentation

Training and continuing education shall be documented and added to the records of the IBC as described in these policies and procedures or a separate training record will be maintained.

SBAT training - Documentation of all SBAT training will include at a minimum:

- Date of training
- Names of Person (s) trained
- Description of the training
- Method used to verify understanding

1.3 Training Resources

The IBSP compliance office provides educational resources and training opportunities for those involved in research with rDNA and other Biohazardous material.

1.3.1 **Brown Bag** - Informational sessions provided to the research community to discuss the IBC processes, special topics related to research with Biohazardous material, offered once or twice a semester. They are very general, informal and scheduled during the lunch hour.

1.3.2 **Conferences and seminars** – Regional/national conferences such as Public Responsibility in Medicine and Research (PRIM&R) and American Biological Safety Association (ABSA) may be attended as needed.

1.3.3 **IBC Retreats**

In an attempt to provide continuous training for IBC members, the IBC will have annual retreats. IBC members, as well as other experts, will provide information to enhance the proficiency of the Committee.

1.4 Community Outreach

The IBC, in its attempt to enhance understanding of research involving rDNA, strives to provide the following activities to the research community and surrounding community:

- Presentations to various organizations
- Pamphlets on being research volunteers are available upon request
- IBC informational sessions to the public

The IBC will evaluate its outreach activities annually and make changes when appropriate.

2. SCOPE

These policies and procedures apply to all IBC members and staff.

3. RESPONSIBILITY

The Program Coordinator is responsible for establishing, conducting and/or supervising all relevant training programs for IBC members and staff.

IBC Chairperson (or designee) is responsible for guiding the development of IBC member training programs, in collaboration with the Director of the Office of Research Compliance (or Program Coordinator).

4. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR § 73.15

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

Training Checklist and Documentation – IBC Members

7. PROCESS OVERVIEW

IBC members will be given the opportunity to attend educational conferences and seminars in an effort to maintain the highest quality of knowledge and ability to properly review areas of laboratory safety and research involving recombinant DNA and other biohazardous materials.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Director of the Office of Research Compliance (or Program Coordinator)	Establish training and educational requirements and content for IBC members and staff. Set annual training budget.	
Director of the Office of Research Compliance (or Program Coordinator)	Based on budget constraints, determine training & education opportunities. Schedule speakers, acquire outside publications, and schedule attendance at PRIM&R, ABSA, and/or other seminars, as budget permits.	
Program Coordinator	Notify members of IBC of available training opportunities and deadlines for registration. Send reminders as needed.	
Program Coordinator	Maintain documentation of all training and education completed.	
Principal Investigator	Submission of personnel training documentation	Attachment D, grant proposals, other documents

Training Certification

Trainer(s): _____

_____

The following employee(s) received training regarding _____(e.g., safety, security, lab procedures, incident response and reporting)

Name	Please sign to indicate that you understood the training and have no questions	Date

The following information represents the topics covered:

_____
_____
_____
_____
_____
_____
_____

Include enough details to indicate the information covered and the method used to assess understanding.

SOP Number:	**IBSP 100-103**	Revision Number:	**00**	Effective Date:	
Title:	**Management of IBSP Personnel**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval Signature)				Date:	

1. POLICY

The IBSP Compliance Staff provides consistency, expertise, and administrative support to the IBC, and serve as a daily link between the IBC and the research community. Thus, the IBSP Compliance Staff is the most vital component in the effective operation of Texas A&M University's BioSafety Program. Therefore, the highest level of professionalism and integrity on the part of IBSP Compliance Staff is expected.

Specific Policies

1.1 Job Descriptions and Performance Evaluations

Members of the IBSP Compliance Staff should have a description of the responsibilities expected of their positions. The performance of IBSP Compliance Staff will be reviewed according to current Texas A&M University policy.

1.2 Staff Positions

Staffing levels and function allocation will be determined according to Texas A&M University policy, management assessment of support requirements and budget constraints.

1.3 Hiring and Terminating IBSP Compliance Staff

The human resource policies of Texas A&M University determine the policies for recruiting and hiring staff.

1.4 Delegation of Authority or Responsibility

Delegation of specific functions, authorities, or responsibilities by the Chairperson to a staff member must be documented in writing.

1.5 Documentation

The policies of Texas A&M University's Department of Human Resources determine the means of identifying, documenting and retaining formal staff interactions (such as performance reviews, termination procedures).

2. SCOPE

These policies and procedures apply to all IBSP Compliance Staff.

3. RESPONSIBILITY

Institutional Official is responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of the Director of the Office of Research Compliance (or Program Coordinator) and for guiding the Director of the Office of Research Compliance (or Program Coordinator) in establishing personnel requirements for other IBSP Compliance Staff.

Director of the Office of Research Compliance (or designee) is responsible for establishing personnel requirements and for hiring and evaluating the ongoing performance of IBSP Compliance Staff.

IBC Chairperson (or designee) is responsible for providing input on the ongoing performance of the Director of the Office of Research Compliance to the Institutional Official.

4. APPLICABLE REGULATIONS AND GUIDELINES

TAMU 33.99.03.M!, 33.99.03, 33.99.01.M1, 3.99.01, 33.99.01.M1.02

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

Director of the Office of Research Compliance Functions
Director of the Office of Research Compliance (or Program Coordinator) Functions
HR - Performance Evaluation Form

7. PROCESS OVERVIEW

IBSP management will maintain policies and procedures to promote the long-term commitment of employees and ensure the efficient and effective administration and enforcement of IBC decisions.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBSP Program Coordinator	With the input of the Director of the Office of Research Compliance, establish the requirements for IBSP Compliance Staff. Complete personnel recruitment and hiring as per HR policy.	
IBSP Program Coordinator	Compose job descriptions. Ensure that IBC Compliance Staff are adequately oriented and trained.	Functions of all IBSP staff – Job descriptions
ORC Director	Evaluate the performance of the IBSP Program Coordinator	Applicable Human Resources (HR) Guidelines Performance Evaluations
Institutional Official	Evaluate the performance of the Director of the Office of Research Compliance	Use appropriate HR forms
Director of the Office of Research Compliance (or IBC Program Coordinator	Evaluate the performance of the IBSP Compliance Staff Members.	Use appropriate HR forms

SOP Number:	**IBSP 100-104**	Revision Number:	**00**	Effective Date:	
Title:	**Signatory Authority**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval Signature)				Date:	

1. POLICY

The IBC Chairs, or designee are authorized to sign any and all documents in connection with the review and approval of research projects involving recombinant DNA and other Biohazardous materials, which have been reviewed and approved pursuant to Texas A&M University policies and procedures. In all cases individuals must sign their own name and no other and indicate their title under their signature.

Specific Policies

1.1 Authorization for Signatory Authority
Authorization to sign documents not described in this policy may be made in writing to the Director of the Office of Research Compliance (or Program Coordinator).

1.2 Results of Reviews, Actions and Decisions
The results of reviews and actions taken by the IBC, either by the full IBC or by expedited review, that grant or may appear to grant Investigators with initial or continuing approval of research, training or educational projects involving recombinant DNA or other Biohazardous materials, may be signed by the Chair or designee. Electronic correspondence does not require signature but a copy of the electronic notification will be maintained in the IBC study file folder.

1.3 Routine Internal Correspondence
The IBSP Coordinator may sign any action, letters, memos or emails between the IBC, and members of the faculty or staff of the Texas A&M University that provides information concerning the review of research protocols by the IBC or staff. IBC staff may also sign other IBC letters based on electronic notification of the application disposition by the Chair or designee.

1.4 Correspondence with External Agencies

Any letters, memos or emails sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the Institutional Official, IBC Chair or Director of the Office of Research Compliance (or IBC Program Coordinator) or the IO/RO.

1.5 Decisions Made by Chairperson

Any letters, memos or email sent representing the decision or opinions of the Chairperson of the IBC or his/her respective designees, may be sent electronically by designated IBSP Compliance Staff.

2. SCOPE

These policies and procedures apply to all IBSP Compliance Staff.

3. RESPONSIBILITY

IO/RO is responsible for establishing the overall procedure for delegating signatory authority.

Director of the Office of Research Compliance (or designee) is responsible for implementing and controlling signatory authority delegations.

IBC Chairperson, members and staff are responsible for adhering to institutional signatory authority policies.

4. APPLICABLE REGULATIONS AND GUIDELINES

TAMU 15.01.01.M5 (3.4)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

N/A

7. PROCESS OVERVIEW

The IBC Chair or Institutional Official may delegate approval authority to an IBC (member) designee.

The IBC member responsible for presiding over IBC meetings shall have authorization to approve protocols.

Correspondence may be sent electronically without signatures as long as the IBC Chair or designee approves the information.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Institutional Official, IBC Chair or Program Coordinator	Establish signature authority delegation based on nature of documents being signed. Sign all documents related to the review and approval of research projects and correspondence with external agencies. Staff members are not authorized to sign any correspondence with external agencies. In the absence of the Director of the Office of Research Compliance (or Program Coordinator), Institutional Official must sign such documents.	
IBSP Compliance Staff	Send electronically routine internal correspondence or actions taken by an IBC Chairperson if authorized to do so by the Chairperson.	

STRUCTURE OF

INSTITUTIONAL BIOSAFETY COMMITTEE

200

SOP Number:	**IBSP 200-201**	Revision Number:	**00**	Effective Date:	
Title:	**Composition of the IBC**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. POLICY

The IBC will be sufficiently qualified through the experience and expertise of its members and the diversity of the members' backgrounds, including diverse racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in research involving recombinant DNA and other Biohazardous materials.

The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant DNA research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, *Biological Safety Officer*). When the institution participates in or sponsors recombinant DNA research involving human research participants, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary); (ii) all aspects of Appendix M have been appropriately addressed by the Principal

Investigator; (iii) no research participant shall be enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and (iv) final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*). Institutional Biosafety Committee approval must be obtained from the institution at which recombinant DNA material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products)..

The IBC may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IBC. However, such ad hoc members may not vote with the IBC.

Alternate members may be used if they are formally appointed as alternate members. The alternate member's qualifications shall be comparable to those of the primary member to be replaced. When an alternate member replaces the primary member, the alternate member shall have received and reviewed the same material that the primary member would have received. The IBC roster shall identify the primary member(s) for whom each alternate member may substitute. In addition, the IBC minutes shall document when an alternate member replaces a primary member.

The Chairperson of the IBC will be appointed by the Vice President for Research with the concurrence of other Deans and Center Directors and the Health Sciences Center, for a term of three years. The Chairperson must hold either a Ph.D. or M.D. degree. Vice-chairpersons may be appointed by the Vice President for Research to assist the Chairperson with his/her duties.

The IBC may form ad hoc subcommittees when reviewing materials that are not regulated by the NIH guidelines. Select Agent research may be reviewed by a sub-committee, however if the project also involves rDNA, at a minimum, those activities will be review by the IBC.

IBC MEMBER LIST WITH DEGREES AND APPOINTMENTS

A record of the names, degrees, qualifications, terms, affiliation, and voting status of the members of the IBC will be maintained in the IBSP administrative office. *Ex officio* members will also be included in this record. The record represents the roster of members and will serve monthly as the list by which attendance is determined. However, for purposes of determining quorum, only voting members will be counted.

The institution shall file an annual report with NIH/OBA which includes: (i) a roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable); and (ii) biographical sketches of all Institutional Biosafety Committee members (including community members).

The IBC shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

Specific Policies

1.1 Membership Selection Criteria

The members of the IBC shall be sufficiently qualified through experience and expertise, for reviewing research protocols in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IBC shall include persons knowledgeable in these areas: rDNA, animal research, plant research, and human/human materials.

1.2 Composition of the Committee

A. Voting Members: In order to ensure the competence necessary to review and approve recombinant DNA activities, it is recommended that the Institutional Biosafety Committee possess varied backgrounds in an attempt to promote complete and adequate reviews of the types of research activities commonly reviewed by the IBC. Voting members may include:

1. Nonaffiliated members: The nonaffiliated members, who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which Texas A&M University will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IBC, and their services should be fully utilized by the IBC.

2. Scientific members: Most IBCs include Ph.D.-level physical or biological scientists. Such members satisfy the requirement for at least one scientist. When an IBC encounters studies involving science beyond the expertise of the members, the IBC may use a consultant to assist in the review. These members should: (i) include persons with expertise in recombinant DNA technology, biological safety, and physical containment; (ii) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

3. Alternates: Individuals fulfilling the role as an alternate must have experience that is comparable to that of the member they are replacing for those proceedings. Alternates are encouraged to actively engage in the discussion, and provide expert knowledge. In

the absence of the individual for which they are replacing, the vote of the alternate is recorded. However, if the individual for whom they are an alternate is present in the meeting, the vote of the alternate is not counted.

4. Chairperson: The individual IBC Chairperson should be a highly respected individual, from within Texas A&M University, fully capable of managing the IBC and the matters brought before it with fairness and impartiality. Although it is imperative for the Chair to be present at each convened meeting, proceedings may take place in their absence if quorum is achieved. The vote of the Chair holds the same weight as the members, but may break the tie in a split vote. The Chair will meet regularly with the Program Coordinator for guidance, and the formulation of the agendas for convened meetings.

5. Vice Chairperson: This individual must also be a highly respected individual, from within Texas A&M University, fully capable of managing the IBC in the absence of the Chairperson. The Vice Chairperson will also assist in the final approval of protocol review and request additional information from the Investigator, if so needed. The Vice Chairperson will meet regularly with the Program Coordinator, with or in the stead of the Chairperson, for guidance and the formulation of the agendas for convened meetings.

6. Ad hoc-Subcommittees: These committees will convene as needed and membership will be based on the expertise required (e.g., Security Expert and BSO may serve on select agent sub-committee.

B. Non-Voting Member: Due to the span over which the IBC reviews, there may be individuals that represent vital areas on the campus. These members may actively engage in the discussion of the research protocol and provide expert insight to the Committee, but their vote shall not be counted in the final voted decision. The presence of these individuals at convened meetings will be counted toward the formulation of the quorum.

2. SCOPE

These policies and procedures apply to the membership of the IBC.

3. RESPONSIBILITY

Institutional Official is responsible for ensuring the IBC has adequate resources to identify and recruit qualified potential members.

Director of the Office of Research Compliance (or Program Coordinator) is responsible for recruiting and training new IBC members.

IBC Chairperson (or designee) is responsible for recruiting and evaluating new IBC members.

4. APPLICABLE REGULATIONS AND GUIDELINES

Section IV-B-2-a-(2) (*NIH Guidelines*)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

IBC Membership Roster

7. PROCESS OVERVIEW

The Texas A&M IBC is comprised of experienced individual that are capable of reviewing the research needs of the University. Each member has a strong commitment to upholding the basic ethical principles regarding all research involving recombinant DNA and other Biohazardous materials. The composition of the committees will be based on NIH Guidelines and institutional needs.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBC Chairperson, IBC Vice Chairperson, IBSP Coordinator	Ensure the overall diversity of the IBC membership through non-discriminatory selection methods. Following established criteria, select new members, and replace members who resign or otherwise leave IBC service. Create agendas for all convened meetings.	Meeting agenda template
Director of the Office of Research Compliance (or Program Coordinator	Maintain a membership roster of all regular and alternate members, and ensure the annual report is submitted to the Office of Biotechnology Activities (OBA).	IBC Membership Roster
Program Coordinator	Maintain a file on all members, to include their curriculum vita, letters of nomination and other evidence of professional ability.	
Program Coordinator	Maintain a roster of available consultants who are eligible and qualified to attend meetings as invited consultants.	

SOP Number:	**IBSP 200-202**	Revision Number:	**00**	Effective Date:	
Title:	**Roles and Responsibilities**				
AUTHORIZATION					
Supervisor: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance *and* ARO	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Richard E. Ewing	Title:		Vice President for Research *and* Responsible Official	
Management: (Approval - Signature)				Date:	
Supervisor: (Printed Name)	Fuller W. Bazer	Title:		Associate Vice President for Research *and* ARO	
Management: (Approval - Signature)				Date:	

1. Policy

The roles and responsibilities for the following Texas A&M University personnel are listed below. These roles and responsibilities have been clearly delineated, documented and communicated to all select agent personnel:

- Responsible Official (RO)
- Alternate Responsible Official (ARO)
- Biological Safety Officer (BSO)
- Principal Investigators/Laboratory Director (PI/LD)
- Institutional Biosafety Committee (IBC)
- Office of Research Compliance (ORC)
- Comparative Medicine Program (CMP)
- University Police Department (UPD) Security Expert
- Manager of Occupational Health and Safety

Responsible Official (RO) –

This individual designated by Texas A&M and approved by the CDC has the authority and control to ensure compliance with regulations surrounding the CDC Select Agent Program and National Institutes of Health (NIH) guidelines for use of recombinant DNA (rDNA).

- The RO must be approved by the Health and Human Services (HHS) Secretary or Administrator following a security risk assessment by the Attorney General and approval by the CDC Division of Select Agents and Toxins Program (DSAT);

- The RO will be familiar with the requirements of 42 CFR Parts 72 and 73 - *Possession, Use, and Transfer or Select Agents and Toxins*;
- The RO has authority and responsibility to act on behalf of Texas A&M;
- The RO will ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used to determine compliance with the requirements of 42 CFR Parts 72 and 73. The results of each inspection will be documented and a written report will be submitted by the BSO to the RO and the IBC. All deficiencies identified during an inspection will be identified in the written report, as will a schedule for corrective actions.
- The RO will ensure the process for communicating all incidents to key contacts and regulatory agencies are carried out properly. When an incident occurs, the BSO or the UPD, in concert with the PI/LD, will immediately contact the ORC Director/ARO. The director will contact the RO, CDC and other agencies as needed, as well as other key Texas A&M contacts (e.g., President, Executive Vice President and Provost, research contacts, etc.) and will send all documentation of the event to the same parties.
- The RO will communicate the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification, if Texas A&M participates in this type of activity.
- The RO will communicate the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing using APHIS/CDC Form 4 within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.

Alternate Responsible Official (ARO)

An ARO is assigned to act for the RO in his/her absence. These individuals have the authority and control to ensure compliance with the regulations and to carry out all duties assigned to the RO when acting as the RO.

Biological Safety Officer (BSO)

As required by NIH, Texas A&M has appointed a BSO because the Texas A&M has faculty members who engage in research or activities that involve viable organisms containing rDNA molecules at a Biosafety Level containment 3. However, the BSO also ensures laboratory safety for all Risk Group 2 and 3 (RG2) (RG3) agents, particularly select agents. The BSO has a working knowledge of the laboratory practices and procedures within each select agent facility.

BSO duties include, but are not limited to:

- consultation and support to the research community regarding safe and secure practices for RG 2 and 3 laboratories (e.g., select agent);
- on-going independent monitoring of safety and security practices for each laboratory;

- serving as a voting member of the IBC and as an RO or ARO as needed by the institution;
- membership on the IBC to conduct periodic inspections (at least annually) in collaboration with the Environmental Health and Safety Department (EHSD) to certify that laboratory standards are followed and meet biosafety level requirements. The inspection report will be submitted to the IBC;
- monthly written reports to the IBC or institution regarding the select agent program;
- leader of investigation of any incident involving the release of a select agent, including preparation of an investigation report based on findings for review and consideration by the IBC regarding corrective action(s);
- submitting written reports of investigation to the ORC for preparation of reports to CDC or other regulatory agencies and reviewing drafts to ensure accuracy and completeness (e.g., CDC form 3, NIH report of incident, etc.);
- conducting safety assessments and producing safety assessment reports for all RG3 laboratories. Conducting assessments before a PI/LD submits an application for approval to use biological agents, certain laboratory procedures, use a specific laboratory, or, if required, in response to an incident.
- review, as a member of the IBC, and provide feedback on information provided by the PI/LD in the safety, security and/or incident response plans;
- communicating to IBC and the Executive Vice President and Provost any significant problems, violations of the *NIH Guidelines* or any significant research-related accidents or illnesses, and determining if proper reports have been filed by the PI/LD;
- developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA research;
- working with PI/LDs in collaboration with UPD to ensure laboratory security;
- providing technical advice to PI/LD and IBC on research safety procedures;
- communicating directly to other key Texas A&M offcials as needed; and
- being thoroughly familiar with requirements of 42 Code of Federal Regulations (CFR) Parts 72 and 73- *Possession, Use, and Transfer or Select Agents and Toxin; Final Rule,* as well as the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, NIH Guidelines for use of rDNA and other regulations related to safety and security of laboratories using biological agents.

Principal Investigator/Lab Director (PI/LD)

The individual designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

PI/LDs are responsible for:

- ensuring that the IBC reviews and approves all activities within laboratories that involve the use of rDNA and other agents including select agents prior to initiation of research;

- informing the IBC of any modifications within the laboratory, including but not limited to changes in procedures, security, incident or safety plans, personnel, and research objectives;
- ensuring that reporting requirements are fulfilled and being accountable for any reporting lapses;
- communicating any adverse events and/or issues of non-compliance to the IBC; and;
- ensuring that all personnel entering his/her laboratory have received training and that no individual will have access to a select agent without proof of IBC and DSAT approval.

Institutional Biosafety Committee (IBC)

The IBC is responsible for reviewing and approving all activities related to Biohazardous materials, rDNA, and CDC select agents used in a Texas A&M facility or at an affiliate location with an executed Memorandum of Understanding (MOU) for IBC services.

The IBC reviews research activities involving these agents to ensure that they are conducted in a manner that is safe for personnel, the public, and the environment. The IBC follows NIH Guidelines for Research Involving Recombinant DNA Molecules and the use of rDNA and human gene transfer and the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL), as well as institutional policies and procedures.

The IBC is responsible for:

- developing and implementing policies related to the safe use of biological materials, rDNA, and CDC select agents;
- reviewing research protocols involving biohazardous materials, rDNA, CDC select agents;
- approving or disapproving projects based on their hazard potential and proposed containment procedures;
- establishing, approving, and monitoring laboratory conditions and procedures required for such projects;
- ensuring qualifications and training of individuals involved in research to ensure the use of appropriate laboratory safety techniques;
- approving proper disposal and decontamination procedures;
- approving plans related to emergencies (e.g., accidental spills or contamination), safety, security and an incident; and
- ensuring that any violations of the NIH and/or incidents involving select agents are investigated and communicated to the RO who then communicates incidents to the respective agency as specified in the NIH Guidelines for Research Involving Recombinant DNA Molecules and the "Biosafety in Microbiological and Biomedical Laboratories."

Institutional Biosafety Program staff in the ORC serves as the administrative liaison between the committee and the research community.

The ORC Director is the contact for the NIH Office of Biological Activities who ensures that NIH receives an annual report and other notifications as required by guidelines. The BSO shall serve as ARO or RO as required by the institution.

The Program Coordinator submits inspection reports to the RO and, when animals are used, to the (Institutional Animal Care and Use Committee (IACUC). The IBC also communicates findings to the RO as well as corrective actions required.

Office of Research Compliance (ORC)

The ORC, a unit of the Division of Research and Graduate Studies at Texas A&M University, is responsible for providing training and support to faculty, students, and staff in regulatory requirements for scientific research. The ORC functions as an administrative arm for the RO and the IBC in matters related to research compliance. Within the ORC, staff members are assigned to support the IBC to ensure that activities related to rDNA, and other biological agents and toxins, including select agents, are properly documented, tracked, and monitored. Responsibilities of the ORC include, but are not limited to:

- processing of incoming applications, annual reviews, and modifications on behalf of the IBC;
- processing CDC amendments and other correspondence on behalf of the RO/ARO;
- processing and submitting incident reports to the RO or ARO for submission to CDC or other regulatory agencies;
- providing and documenting select agent training at least annually;
- maintaining all IBC files and records;
- maintaining all CDC files and records;
- supporting the BSO/IBC to ensure that all laboratories are inspected annually;
- ensuring that CDC approval of applications or amendments are obtained prior to IBC notifying a PI/LD of approval of an application;
- ensuring coordination of reviews and inspections so that information is available for all compliance committees, e.g., IACUC review of IBC documents and IBC review of IACUC documents; and
- ensuring that IBC approval has been granted prior to approval by another research compliance committee is documented.

Comparative Medicine Program (CMP)

The CMP, a unit of the Division of Research and Graduate Studies, provides animal care, husbandry and appropriate veterinary care on behalf of Texas A&M.

University Police Department (UPD) Security Expert

The UPD Security Expert is responsible for ensuring that PI/LDs provide appropriate security concerns following conduct of an assessment of his/her laboratory.

The security expert will:

- conduct security risk/vulnerability assessments and provide a security assessment report to the PI/LD for development of a security plan;
- serve as a consultant to the IBC for review of security plans presented for IBC for approval;
- be responsible for finger printing personnel and submitting their Security Risk Assessment documents to the Federal Bureau of Investigation (FBI) for DSAT approval; and
- collaborate with the BSO and IBC by leading investigations of incidents involving loss or theft of a select agent.

Manager of Occupational Health and Safety

- EHSD manages the Occupational Health Program.
- EHSD will communicate with principal investigators, supervisors, employees, subject matter experts, relevant oversight committees, and/or the designated medical provider to identify potentially hazardous occupational health conditions and develop plans to limit the opportunity for injury, illness, or exposure related to the identified occupational risks.
- EHSD will cover costs associated with the prevention and treatment of occupational injury/illness for participants who have chosen to fully enroll in the program. EHSD will review occupational injuries and/or exposures and use information gained to amend or revise any plans and practices that were found to be deficient, inadequate, or the causative pretense to the incident.
- The PI/LD or supervisor will communicate with EHSD to identify and discuss occupational risks in their lab/department/agency, and will inform employee(s) of the risks associated with their employment.
- The PI/LD or supervisor is responsible for informing the employee(s) of the Occupational Health Program and the procedures for enrollment. The PI/LD or supervisor shall immediately notify EHSD of any suspected or confirmed occupational injury, illness, or exposure.
- The employee will communicate with their PI/LD or supervisor to identify and discuss occupational risks associated with their employment. The employee is required to complete the "Texas A&M University Occupational Health Program Enrollment Form" and submit it to EHSD. The employee may elect to fully participate in the program or decline the medical portion. The employee shall immediately notify their PI/LD or supervisor of any suspected or confirmed occupational injury, illness, or exposure.
- The designated medical provider (MP) will communicate with EHSD, PI/LDs, supervisors, and employees to identify potentially hazardous occupational health conditions and develop plans to limit the opportunity for injury, illness, or exposure related to the identified occupational risks. The MP will provide health assessments, pre-placement evaluations, immunoprophylaxis, medical surveillance, and other medical treatment to program participants as needed. The MP will inform EHSD of

any suspected or confirmed injury, illness, or exposure involving participants of the Occupational Health Program.

a. involving loss or theft of a select agent.

SOP Number:	IBSP 200-203	Revision Number:	00	Effective Date:	
Title:	**Management and Oversight of the IBC Membership**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Richard Ewing	Title:		Vice President for Research	
Management: (Approval - Signature)				Date:	

1. POLICY

The management of the membership of the IBC and oversight of member appointments, IBC related activities, communications, and other administrative details are the responsibility of the IO/RO with input and support by the Director of the Office of Research Compliance (or Program Coordinator).

Aside from the review of research activities that can be reviewed pursuant to an expedited process, the IBC will also review proposed research at convened meetings at which a quorum is present. The IBC will meet *monthly*, or at some other frequency determined by the IBC Chairperson and Program Coordinator. The Program Coordinator or designated staff member will coordinate meeting rooms, any invitations to guests for the IBC meetings, and other aspects necessary for the meeting. Scheduling of meeting rooms is done well in advance. The Committee generally meets every fourth (4^{th}) Wednesday of each month. IBC meetings are generally held in Room 130 H Centeq Building 1500 Research Drive, and the room will be scheduled for use at the designated meeting date and time. The Program Coordinator or designated IBSP staff member will ensure that all members are informed well in advance.

Specific Policies

1.1 Quorum

A quorum is defined as attendance of a majority (greater than 50%) of voting members. (Examples: a majority is 9 members of a 17 member committee or 10 members of an 18 member committee.)

1.1.1. A quorum consists of regular and/or alternate voting members and includes: at least one member.

1.1.2 An alternate member may attend in the absence of the regular member for whom she/he is the designated alternate. Presence of such a designated alternate voting member counts towards meeting the quorum requirements stated above provided the alternate has had sufficient time to review the meeting materials.

Documentation of the alternate member voting will be maintained in the meeting minutes.

1.1.3 The quorum must be present for each vote taken. If the quorum is not maintained when a member has abstained, then that vote must be deferred until the next meeting at which a quorum remains effective during the time the member abstained.

1.1.4 Requisite training must be completed, and a member's name must appear on the official roster of members prior to the first meeting in which they are to be counted as a voting member. The roster will be reviewed by the Director of the Office of Research Compliance (or designee) prior to each convened meeting to ensure accuracy.

1.2 Primary Reviewers

Prior to the meeting, the Program Coordinator will designate Committee members as primary or secondary reviewers for each research protocol. (The duties of a primary and secondary reviewer are described in SOP 203.)

1.2.1 Absent Primary Reviewer

Each new protocol should be reviewed in advance by the primary reviewer assigned, who will present the protocol in the convened IBC meeting. The primary reviewer's comments are to be recorded in the "Comment" section of IGPS, which may be seen by all Committee members. In the event that a primary reviewer cannot attend the IBC meeting, the reviewer should record their comments in IGPS and notify the Program Coordinator, who will ensure the secondary reviewer has ample time to review the protocol and the comments of the primary reviewer. The secondary reviewer will then be responsible for presenting the protocol at the convened meeting. In the event that the secondary reviewer cannot attend the meeting, the IBC Chair will then use comments from both the primary and secondary reviewers to present the protocol at the convened meeting. The comments of the primary reviewer will be used transcribed into the meeting minutes. After presentation, discussion and a vote on protocol disposition, the Program Coordinator will ensure all comments are recorded in IGPS.

Documentation, such as Pending Approval Memos, to the Investigator, will be derived from the comments captured in the meeting.

1.3 Meeting Materials Sent Prior to IBC Meetings

All IBC members will be sent study documentation and previous meeting minutes sufficiently in advance of the meeting to allow time for adequate review. These include:

1.3.1 Agendas:

A meeting agenda (which details new business items) will be prepared by the Program Coordinator or staff designee and distributed to IBC members prior to each meeting.

The IBC Chair(s) will meet with the IBSP Coordinator prior to the meeting to ensure all information to be discussed at a convened meeting is captured.

If a member has a conflict of interest with any study, they should inform the Chair(s) prior to the meeting. The IBC minutes should specifically reflect such abstentions as they occur during meetings.

1.3.2 Reviewer materials:

- A completed *Application for IBC Permit* submission form
- Any supplemental documents submitted by the Investigator
- Grant Application: The Program Coordinator will review the grant application, if any, to ensure that the research described in the IBC protocol is consistent with the grant application. The grant application does not need to be reviewed by every IBC member; however, a copy of the grant application or protocol should be retained in the protocol folder and made available to any IBC member who may wish to review it. The IBC may require the investigator(s) to: (i) summarize, and cross-reference specific information contained in the grant application; (ii) identify any IBC-approved protocols that describe the proposed research; and (iii) either certify that the application or protocol is consistent with any corresponding IBC protocol(s) or submit protocol amendments to reconcile any discrepancies.

1.4 Minutes

The Federal regulations for the protection of human subjects [45 CFR 46.115(a)(2)] require that "Minutes of IRB meetings... shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." The Texas A&M IBC has chosen to follow these requirements in respects to convened meeting minutes. These requirements are minimal, and more detail may be included in the minutes as necessary.

1.4.1 Recording: The IBSP Program Coordinator or designee will take minutes of each meeting using the IBC Agenda. Minutes will be written in sufficient detail to show the following:

- Meeting attendance; the minutes will show the certification of a quorum, including status of each attendee (regular member, consultant, etc.). The minutes will record the attendance at the meetings; actions taken by the IBC; protocol number and title for each protocol reviewed; the name of the principal investigator; the primary and secondary reviewers; and the results of the IBC vote;

- Actions taken by the IBC on each agenda item requiring full IBC action, including, the basis for requiring changes in or disapproving the research;
- Summary of the discussion of controverted issues and resolution;
- The minutes will also reflect the approval of exempt and expedited protocols.
- Requests for significant protocol modifications, issues of non-compliance and other issues of significance must be brought to the attention of the entire IBC at a convened meeting. When this is the case, the issues will be noted in the minutes.
- Voting results, including number for, against and members who abstained from the vote and the reason for the abstention.

1.4.2 Approval:

Draft minutes will be reviewed by the Coordinator and the Chair(s) before dispersed to the entire Committee. After this initial review, the minutes will be sent to the entire Committee for review at least five days prior to the next convened meeting for approval/changes at that meeting.

- Corrections to the minutes requested by the IBC will be made by the IBSP Program Coordinator or designee, and the minutes will be printed in final form and made available to members at the following meeting. The Program Coordinator will maintain copies of the minutes in meeting folders, as well as the agenda and pertinent materials discussed at the meeting.

1.5 Telephone Use

1.5.1 Convened meeting using speaker phone:

Should a member not be able to be physically present during a convened meeting, but is available by telephone, the meeting can be convened using a speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by such speakerphone may vote, provided they have had an opportunity to review all the material the other members have reviewed.

1.5.2 Meetings Conducted Via Telephone Conference Calls:

On occasion, meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference

call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Members not present at the convened meeting, nor participating in the conference call, may vote on an issue discussed during a convened meeting (no voting by proxy).

1.5.3 Meetings Conducted via Tele-Conference (TTVN)

In an effort to involve as many members as possible, meetings may be convened via teleconferencing. There must be a quorum present for official business to take place. All participating members will be recorded in the minutes.

Additional Policies

2. Term

Members, including the Chair, will serve on the IBC for a three (3) year term. Reappointment for additional terms may occur, by mutual agreement of the IBC Chairperson and Institutional Official. The IBC is appointed as the Institutional Committee to serve Texas A&M University as a whole, rather than a particular department. Therefore, members must not allow their own interest or that of their department to supersede their duty to protect the research involving recombinant DNA and other biohazardous materials.

2.1 Appointments

The Institutional Official, in consultation with the IBC Chair or Director of Research Compliance, has the authority to appoint members to the IBC. Members will be solicited from the Texas A&M University and local communities.

2.2 Resignations and Removals

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. The membership roster must be revised with any resignation or removal of members, and sent in to the OBA (Office of Biotechnology Activities). Upon receipt of the resignation letter, the IBSP Coordinator will document the term of the member in a gratitude letter to the member.

2.3 Compensation

Participation by Texas A&M University faculty or staff is considered a component of their job responsibilities as established by their supervisors. Members who are not affiliated with Texas A&M University shall receive reimbursement for parking and other miscellaneous expenses upon request.

2.4 Liability Insurance

Regular and alternate members have liability insurance coverage as part of their IBC membership in their capacity as agents of Texas A&M University.

3. Specific Duties – Regular Members

3.1 Nonaffiliated member(s): Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

3.2 Non-scientific members: Nonscientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IBC if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.

3.3 Scientific members: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IBC if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of subjects.

3.4 Chairperson: In addition to the above responsibilities (germane to the member's capacity), the Chairperson presides over the convened IBC meetings. The Chairperson ensures all correspondence to the research community is distributed in a timely manner. They are the approving authority for research that does not go to a full committee meeting. They are empowered to request additional information from researchers to ensure and document research proposals that possess questionable safety risk, pending IBC review. The Chairperson is also empowered, pending IBC review, to suspend the conduct of a study if he/she determines that an Investigator is not following the IBC's requirements.

3.4.1 The Chairperson may appoint a Vice Chairperson to assist or act on behalf of the Chairperson in IBC matters and at IBC meetings, either as a general procedure, or on a case-by-case basis. The Chairperson also may delegate any of his/her responsibilities as appropriate to the Vice Chairperson. Documentation of the duties of the Vice Chairperson will be in writing and maintained by the IBC Program Coordinator. The Vice Chairperson is responsible for securing appropriate consulting expertise as needed for selected reviews.

3.4.2 The task of ensuring that the IBC a respected part of the institutional community will fall primarily on the shoulders of these individuals. The IBC must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

3.5 Primary and Secondary Reviewers:
In addition to their duties described in SOP 203, section 1.1.4, each regular member will be expected to act as a Reviewer for studies before convened meetings, and as a Presenter at convened meetings. When a protocol comes into the IBSP office, Primary and Secondary Reviewers will be assigned. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol

within the IGPS system and at the convened meeting. They also recommend specific actions to the IBC, as he or she leads the IBC discussion of the study. The Primary Reviewers may be required to review additional material requested by the IBC for the purpose of study approval, such as the submitted grant proposal(s). The Secondary Reviewer contributes to the discussion, providing information at both the convened meeting and in the IGPS system for review of all committee members.

3.6 Alternate Members

The use of formally appointed alternate IBC members will be documented in the written policies and procedure manual of the IBC and will describe the appointment and function of each alternate member. The IBC membership roster will identify the primary member(s) for whom each alternate member may substitute. To ensure maintaining an appropriate quorum, the alternate's qualifications should be comparable to the primary member to be replaced. The IBC minutes should document when an alternate member replaces a member. When alternates substitute for a primary member, the alternate member should have received and reviewed the same material that the primary member received or would have received.

- Alternates are appointed by the Institutional Official (IO). Alternates will be listed on the IBC membership roster submitted to the OBA. The IO for Texas A&M University is the Vice President for Research (VPR).

- There is a specific one-to-one designation of IBC members and alternates. This is necessary to ensure that a committee is properly constituted, even when alternates are serving. The alternate should have expertise or experience as the regular member.

- The IBC minutes should document when the alternate member serves in place of the regular member.

- Alternate members are encouraged to attend IBC meetings and participate in IBC activities (i.e. protocol review and commenting) at a convened meeting and/or within the IGPS system, even when the regular member is present.

- An alternate contributes to the quorum and functions as an IBC member if the regular member for whom they serve as alternate is unavailable.

- Alternates should receive IBC training or orientation similar or identical to what is provided regular IBC members. The alternate will be given the same materials as the regular member since they may have to contribute in the stead of the regular member at any time.

- Alternate members are expected to "vote their conscience" as opposed to representing the position of the regular member for whom they serve.

3.7 New IBC Member Orientation

All members appointed to the IBC should attend an orientation briefing to receive TAMU specific policies and procedures manuals and other documents. The following documents will be given to the new members as part of an orientation packet:

Schedule of meetings
IBC Membership Roster
NIH Guidelines
IBC Submission Forms
IGPS Usage Document
Copy of Policy and Procedures Manual
Research Compliance Website Information and additional links
Research Compliance Contact Information

The Program Coordinator, assisted by the Chair if possible, will conduct the orientation briefing, explain the processes and procedures used by the IBC, and answer any questions from any new member.

4. SCOPE

These policies and procedures apply to all IBC Members.

5. RESPONSIBILITY

The IBSP Coordinator is responsible for clearly articulating all duties of potential and current IBC members.

The IBSP Coordinator is responsible for day-to-day management of the activities of the IBC members. The IBSP Coordinator will ensure the proper maintain all records pertaining to IBC membership in the ORC. IBC Chairperson (or designee) is responsible for management of the activities of the IBC members relevant to meeting conduct and review of research.

IBC Members are responsible for fulfilling their duties as specified.

6. APPLICABLE REGULATIONS AND GUIDELINES

TAMU 15.01.01.M3, 15.01(3)
Section IV-B-2-a- NIH Guidelines

7 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

8 ATTACHMENTS

New IBC Member Orientation Packet:

9. PROCESS OVERVIEW

The Director (or IBSP Coordinator) or IBC Chair will ensure that IBC members are aware of their responsibilities. The IBSP Coordinator shall ensure the membership has the expertise and commitment to meet its regulatory and institutional mandates.

10. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Institutional Official	In consultation with the Chairperson and other appropriate parties, identify members of Texas A&M University's faculty and staff and members of the local community to serve on the IBC(s).	
IBSP Coordinator	With the input of the Director of Research Compliance and the IBC Chair, document the expectations for members of the IBC.	Member Responsibilities – SOP 203
	Meet with prospective new members to discuss the responsibilities and time commitment of IBC membership with the interested parties.	New Member Orientation
IBC Chairperson /IBSP Coordinator	If the individual states he/she is indeed interested in becoming a member, the dates of all IBC meetings are given to the individual for consideration.	
	Request the Curriculum Vitae (CV) for review. If appropriate, forward the CV to the Institutional Official with a cover letter requesting appointment of the individual to a particular IBC.	
IBSP Coordinator	If the Institutional Official concurs with the recommendation of the IBC Director (or IBC Program Coordinator), an Appointment Agreement Letter is sent out to the interested party, with copies to their direct supervisor.	IBC Appointment Letter
IBSP Coordinator	Add the new member to the appropriate IBC Committee Roster and provide the new member a list of the current members on the IBC, listing their areas of expertise and telephone numbers. Send new member information to Director of the Office of Research Compliance to update the NIH Office of Biotechnology Activities (OBA). The new member is also given the New Member Information Packet.	New Member Information Packet Checklist
IBSP Coordinator	Notify the new member of the next meeting, sending a packet of agenda materials to review. Inform the member that he or she will not be assigned specific protocols to comment on until their second full meeting.	

Director of Research Compliance and IBSP Coordinator	Periodically review members' duties. Update SOP 203 as needed.	SOP 203
IBSP Coordinator	Ensure that members are carrying out their expected functions and that there is adequate staff support to ensure that members are able to function as documented.	
IBSP Coordinator	As needed, make recommendations to the Chairperson and Director regarding changes to descriptions, staffing, meeting scheduling, and other factors that affect members' ability to perform their roles.	
IBC Chair, Director of the Office of Research Compliance (or Program Coordinator)	Discuss the responsibilities and time commitment of IBC membership with the interested parties. If the individual states he/she is indeed interested in becoming a member, the dates of all IBC meetings are given to the individual for consideration. Request the Curriculum Vitae (CV) for review. If appropriate, forward the CV to the Institutional Official with a cover letter requesting appointment of the individual to a particular IBC.	New Member Information Packet Checklist
IBC Member	Read information in the New Member packet. Sign and return agreements, and review designated educational materials. Attend the next meeting of the IBC as an observer, in order to meet colleagues and observe the review process. Arrive at the first meeting about 1 hour early to meet with the Chairperson and attend a brief orientation/training program. New members are to be sensitive to conflicts of interest and confidentiality issues dealing with their service on the IBC.	
IBC Chairperson or Program Coordinator	Meet with the new member and review the role and responsibilities of being an IBC member, as well as the expectations of the position.	IBC Appointment Letter; Acknowledgement of Acceptance of IBC Appointment

Program Coordinator	Document that the new member has completed required training. If the new member has not completed required training within 90 days, remind the member to do so. If the member does not complete required training within the next 30 days, notify the Chairman and Director of the Office of Research Compliance.	Member Documentation Checklist

SOP Number:	**IBSP 200-204**	Revision Number:	**00**	Effective Date:	**4/20/06**
Title:	**IBC Review and Approval**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. Policy

In accordance with the NIH Guidelines (Section IV-B-2-b), the IBC is responsible for reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*. This review shall include: (i) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research; (iii) ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator; (iv) ensuring that no research participant is enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*), Institutional Biosafety Committee approval (from the clinical trial site) has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained; (v) for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations; (vi) ensuring that final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and (vii) ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

Specific Procedures:

1.1 The Texas A&M University IBC will review all complete applications and subsequent forms regarding any research conducted using Biohazardous or biohazardous materials. Research involving select agents may be referred by the IBC Chair or designee to an ad hoc subcommittee

1.2 New Submissions

1.2.1 All new *Applications for IBC Permits* submissions are reviewed by either the "Full Committee" process, "Expedited Review" process (Primary Reviewer, Chair, and BSO), or "Exempt Review" process.

1.2.1.1 All submissions involving select agents will be reviewed at a convened meeting.

1.2.1.2 While all select agent research must be approved by the IBC, it must also be approved by the CDC.

1.2.1.3 Submission of select agent research to the IBC should prompt the Investigator to consult with the BSO. Investigators must complete and submit the APHIS/CDC Form 1- Application for Laboratory Registration of Select Agents and Toxins.

1.2.1.4 Amending the select agent registration can be a lengthy process; therefore, Investigators are encouraged to meet with the BSO, the IBSP Coordinator, and complete the appropriate paperwork for approval to avoid delay in research.

1.2.1.5 Investigators must submit all the appropriate plans at the time of submission. Plans include: Security, Biosafety, and Incident Response Plan. (Templates of these required templates may be obtained from the ORC.)

1.2.1.6 In addition, Investigators undergo and submit documentation of training.

1.2.2 All *Applications for IBC Permits* are approved for three (3) years.

1.2.3 A specific IBC number is assigned to each new protocol by referring to the protocol database and using the next available number. This is a sequentially assigned number with a four digit prefix representing the year of initial submission, (e.g., 1999-56, 2005-112). All protocol information is entered into the protocol tracking database to track its original date of receipt, title, name of investigator, level of risk, review information, reporting and sponsor information, amendments, adverse events, correspondence, and approval status.

1.2.4 For each protocol received, electronic or written correspondence is sent to the Principal Investigator, providing the IBC number assigned.

1.2.5 The original submission documents are kept for use by the IBSP Staff. The documents will be reviewed at convened IBC meetings, and the review will be recorded in the meeting minutes. Ultimately, the original documents will start the official protocol file, which is maintained in the IBSP office.

A file labeled with the IBC number and the name of the principal investigator will be created for each submitted protocol, which will contain the protocol application and other study-related documents.

1.2.6 The Principal Investigator is notified by email that the protocol has been assigned to an agenda. He/she is provided the date of the IBC meeting and invited to the meeting to represent their protocol, if necessary.

1.2.7 When the IBSP staff receives a complete application submission, they will upload the information into the ESM Access Database and the IGPS system.

1.2.8 All Committee members will be notified, via email, that information has been uploaded into the IGPS system for their review and comments.

1.2.8.1 Committee members are asked to make comments by a certain date.

1.2.8.2 Members are asked to adhere to this date for purposes of review during the convened meeting.

1.2.8.3 Committee members will be assigned as a Primary Reviewer (PR) and a Secondary Reviewer (SR) at this stage, based upon their individual expertise.

1.2.8.3.1 Both the PR & SR are asked to review the protocol and be prepared to present the information in detail at the next convened meeting.

1.2.9 The Committee will conduct an initial review of all submitted protocols through the IGPS electronic system.

1.2.10 All protocols will be entered into IGPS.

1.2.10.1 If the protocol involves the use of rDNA, the members will review the information, make comments, and become familiar with the information prior to a convened meeting.

1.2.10.2 All protocols involving the use of rDNA must be approved at a convened meeting by the Full Committee.

1.2.10.2.1 If the Full Committee must review the protocol, it is prepared for the next convened meeting, and placed on the agenda.

1.2.10.2.2 A PR and SR are assigned.

1.2.10.2.3 Comments and disposition recommendations will be gathered at the meeting and recorded.

1.2.10.3 Protocols that involve the use of pathogens and/or toxins may be reviewed and approved through the IGPS system, which is considered the "Expedited Review" process.

1.2.10.3.1 If an "Expedited Review" or an "Exempt Review" is completed, it is not mandatory that the protocol is prepared for the next meeting. However, any action completed in between convened meetings will be presented to Committee members during the meeting and recorded in the minutes.

1.2.10.3.2 A PR and SR are assigned.

1.2.10.3.3 Comments must also be attained from both the Chair and BSO.

1.2.10.4 Reviewers are asked to explicitly state in their comments if they approve the protocol and at what biological safety level (BSL) they recommend containment of the material used in the research.

1.2.11 All permits that require Full Committee review must be submitted by the 2nd Wednesday of each month. For adequate review time, this date will be enforced.

1.2.12 A convened meeting will take place on the 4th Wednesday of each month.

1.2.12.1 Each Committee member will be reminded of the meetings two (2) weeks before the meeting is scheduled to take place, via an email reminder note.

1.2.12.2 All Committee members are asked to respond immediately to the email regarding attendance in an attempt to ensure quorum is met.

1.2.12.2.1 There must be confirmation from six (6) members in order to have a meeting. (*This number is determined by current membership.*)

1.2.12.2.2 Without quorum, no voting can take place during a convened meeting.

1.2.12.2.3 The inability to vote will inhibit protocols to be approved until the next convened meeting in which quorum is achieved.

1.2.12.2.4 Notification of the correct number of attendance at the meeting is also important for the ISBP staff to prepare for all those who are attending the meeting.

1.2.12.2.4.1 If members are unable to be physically present at the convened meeting, a teleconference may be arranged.

1.2.12.2.4.2 The IBSP staff needs to know at least two (2) weeks prior to the meeting to prepare for this proceeding.

1.3 Amendments

1.3.1 All changes to an approved laboratory permit including supporting materials (e.g., updated security plan for select agent research) must be submitted to the IBC for review and approval.

1.3.2 All Amendments involving select agents must go to a convened meeting for review and approval.

1.3.3 All Amendments will be assigned a Primary Reviewer (PR), Secondary Reviewer (SR), and or the Chair and BSO for initial review. The designated reviewers will provide the final determination if the Amendment needs to follow the Full Committee Review process, the Expedited Review process or the Exempt Review process.

1.3.4 All Amendments will be reviewed through the IGPS system.

1.3.4.1 The designated reviewers are asked to make comments in the IGPS system for the official files.

1.3.5 Amendments may be approved by the Chair, but will obtain recommendations by the designated reviewers.

1.3.6 Amendments that require Full Committee review (i.e. those involving Select Agents) will be placed on the meeting agenda and go to a convened meeting.

1.3.7 The IBSP staff will make the initial determination if the Amendment needs to be reviewed and approved through the Administrative Review process.

1.3.7.1 Amendments that involve a notification of a change in personnel, or change in funding source or agency may be administratively reviewed and approved by the IBSP staff.

1.3.7.2 Any Amendment that involves a change in funding that changes the procedures will not be administratively approved, but instead will be assigned a PR and SR.

1.4 Annual Reviews

1.4.1 All Annual Reviews are conducted every year and meant to monitor the research through proper documentation.

1.4.2 Approval documentation of Annual Reviews is necessary in order to continue research.

1.4.3 The IBSP staff will contact the Investigator 30-60 days prior to the original approval month.

1.4.4 Investigator will be asked to complete the Annual Review and submitted for review and approval.

1.4.4.1 Once approved, memorandums documenting this will be sent to the Investigator.

1.4.5 Annual Reviews that indicate no changes or modifications in the laboratory may be administratively reviewed and approved by the IBSP staff.

1.4.6 If the submitted Annual Review form indicates there are any modifications to the approved laboratory permit, the PI will be asked to submit an Amendment to document those modifications properly.

1.4.7 If an Amendment is submitted as a result of the Annual Review, the Annual Review may not be approved until the Amendment has been approved.

1.5 Final Approval

Final approval will not be issued until proof of recent laboratory inspections are received from the Texas A&M Environmental Health and Safety Department (EHSD). If the research involves a select agent, final approval will not be approved until all the select agent regulatory requirements have been satisfied (e.g., DSAT approval of registration amendment)

1.5.1 At the time in which notification of submissions are sent to Committee members, the IBSP staff will also provide EHSD with this information.

1.5.2 EHSD staff will provide documentation of laboratory inspection.

1.5.3 Facilities that are Biosafety Level 2 containment or above will receive laboratory certification.

1.5.4 Documentation of laboratory inspection/certification will be placed in protocol file.

1.5.5 The Investigator will be notified of final approval.

SOP Number:	**IBSP 200-205**	Revision Number:	**00**	Effective Date:	
Title:	**Facility Inspections**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	John M. Salsman	Title:		Director, Environmental Health Safety Department (EHSD)	
Management: (Approval Signature)				Date:	
Management: (Printed Name)	Vernon L. Tesh	Title:		Chairperson, Institutional Biosafety Committee	
Management: (Approval Signature)				Date:	

1. Policy

The IBC and the Environmental Health and Safety Department (EHSD) will work together to ensure safety is paramount in laboratories on the campus of Texas A&M University. Through the various submissions (New Applications for IBC Permit, Amendments, and Annual Reviews), both parties will share information that directly pertains to laboratories under the jurisdiction of Texas A&M.

Specific Procedures:

1.1 All requests for facility inspections will be initiated in the ORC. Once the Investigator completes a New Application for IBC Permit, Amendment form, or Annual Review, the IBSP Staff will notify EHSD. Laboratory facilities that are BSL2 and below are inspected annually by the Environmental Health & Safety (EHSD) staff.

- 1.1.1 Submissions will be initially reviewed by the IBSP staff, and sent to reviewers, if necessary.
- 1.1.2 Reports of these inspections will be provided by the EHSD staff for each individual PI.
- 1.1.3 Annual Review reports are generated by the IBSP staff and sent to the EHSD staff for documentation of recent laboratory and autoclave inspections.

1.2 Pursuant to 42 CFR § 73.9, all select agent facilities will undergo a joint annual inspection by representatives from both the IBC and EHSD.

1.2.1 During these annual inspections, the IBC Chair, the BSO, the IBSP Coordinator, and other IBC members will complete a site specific inspection form of said laboratories.

1.2.2 The Inspection team must consist of at least one voting member of the IBC and the BSO.

1.2.3 The Inspection team will use the joint IBC/EHSD checklist to complete the inspection.

1.2.4 The inspection of select agent facilities will consist of an inspection of documents (Security, Biosafety, and Incident Response Plans; Facility Access Logs, Agent Access Logs, agent verification, etc.) and the facility.

1.2.5 Official Inspection Reports will be generated upon completion of the inspection. Reports will be generated regardless if there were any inspection findings.

1.2.6 The official Inspection Report will be created based upon information the inspection team document in the checklist.

1.2.7 The official Inspection Report will be sent to the Principal Investigator and or Laboratory Director with dates of correction. "Major" and "minor" findings will be defined by the inspection team; "major" findings will have a rapid timetable for correction.

1.2.8 Inspection Reports will also be sent to the Institutional Official/Responsible Official (RO).

1.2.9 Documentation of these site inspections will be kept in the individual file folders of these laboratories.

2. SCOPE

These policies and procedures apply to all laboratories associated with and on the campus of Texas A&M University.

3. RESPONSIBILITY

The Investigator is responsible for notifying the IBC of any submissions that may require an inspection of the facility be completed. The IBSP Coordinator will ensure that this submission is communicated to both the IBC and EHSD.

IBC Members are responsible for reviewing the information in a timely fashion as to not impede research. EHSD is also responsible for responding in a timely fashion as to not to impede research. EHSD is expected to provide all relevant paperwork regarding laboratory inspections.

4. APPLICABLE REGULATIONS AND GUIDELINES

NIH Guidelines
42 CRF § 73.9

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

Inspection Checklist

7. PROCESS OVERVIEW

The Director (or IBC Program Coordinator) or IBC Chair will ensure that all parties involved are aware of their responsibilities and paperwork needed for review and approval of submissions.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Principal Investigator	Submit documentation to the IBC for review. Regardless of submission type, submissions must go to the IBC before an inspection will be completed.	IBC forms (New/Renewal Submission, Amendment, Annual Review)
IBSP Staff	Ensure submission is distributed to the IBC for review.	
IBSP Staff	Notifies EHSD of submission that may prompt an inspection of facilities. (Staff will send submission electronically to EHSD staff.)	
IBSP Staff	Ensure that reviewers provide comments in timely manner, and gather required documentation from EHSD. Upload documents into IGPS and place hard copy into files, if necessary.	
IBC Members & EHSD Staff	Complete joint annual inspections for SBAT facilities	IBC/EHSD Inspection Checklist
IBSP Staff	Notify the Investigator of any and all information that may be needed. Provide approval letter.	Approved Memo (template)

REVIEW OF RESEARCH

300

SOP Number:	**IBSP 300-301**	Revision Number:	**00**	Effective Date:	**4/20/06**
Title:	**Criteria for IBC Approval (Full Committee Review)**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval - Signature)				Date:	

1. POLICY

All research protocols that intend to involve recombinant DNA that do not fall within the six exempt categories of the NIH Guidelines, must be reviewed in a convened IBC meeting before study related procedures can be initiated. The criteria are based on the NIH Guideline and other stipulations that are unique to Texas A&M University's system.

Specific Policies

1.1 Minimal Criteria for Approval of Research

In order for a research project to be approved, the IBC must find that:

A. Risks in laboratories and to the environment are minimized:

By using procedures that are consistent with sound research design, which do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures articulated in the BMBL (Biosafety in Biomedical and Microbiological Laboratories).

B. Risks are well articulated, along with Investigator's knowledge of the materials proposed to work with, and the anticipated results.

In evaluating risks and benefits, the IBC will consider those risks that may result from the research (as distinguished in the BMBL). The IBC should consider possible long-range effects of the research in terms of the safety of laboratory personnel and the environment.

C. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of both laboratory personnel and the environment.

D. Studies are reviewed at periods appropriate to the degree of risk; the higher the Biosafety/Risk levels, the increased about of monitoring should reflect. At least annual monitoring is necessary.

1.2 Other Criteria

The IBC may require verification of information submitted by an Investigator. The IBC will determine the need to verify any information at a convened meeting. The purpose of the verification will be to provide necessary safety precautions when deemed appropriate by the IBC.

1.3 Reliance on Other Committees for Review and Approval of Research Conducted at Texas A&M University

The Texas A&M University IBC does not rely on other review committees to approve research involving recombinant DNA. The IBC may rely on an ad hoc subcommittee to review select agent research or other projects or other biohazardous materials. Other committees, such as the Institutional Animal Care and Use Committee (IACUC) must receive IBC approval (when needed) before granting final approval for projects involving rDNA or other biohazardous materials. The IBSP Coordinator will be responsible for ensuring arrangements to share documentation between the committees.

1.3.1 When applications come into the IBSP Compliance Office, an initial review is conducted. This initial review may reveal the use of live animals (Attachment A) or the use of human and/or human material (Attachment B).

1.3.2 If an Attachment is found in the initial review, the IBSP Staff member will complete a Verification Sheet (i.e. IBC/IACUC Verification Sheet).

13.3 Once the verification sheet is complete, the IBSP Staff member will share this information to the IBSP Coordinator for final verification that the information is complete. The verification sheet is then sent to the other Compliance staff for completion.

1.3.4 The verification form will be complete by the other Compliance program and returned to the IBSP. A copy of the completed verification sheet will remain in the protocol folder, and serve as documentation of the information being shared for compliance maintenance.

2. SCOPE

These policies and procedures apply to all IBSP Staff members and to research submitted to the IBC for review and approval.

3. RESPONSIBILITY

The IBSP Coordinator is responsible for ensuring that IBC reviewers have all the tools and resources they need to complete their research reviews.

The IBC Chair(s) (or designee) is responsible for providing IBC members adequate submission review training and ongoing guidance. The IBSP Coordinator and/or the IBC Chair(s) are responsible for selecting primary and secondary reviewers with the relevant expertise to perform reviews.

IBC Reviewers are responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IBC.

4. APPLICABLE REGULATIONS AND GUIDELINES

NIH Guidelines

TAMU 15.01.01.M2, 15.01.01, 15.01

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

IBC Submission Form

7. PROCESS OVERVIEW

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBSP Staff	Provide primary and secondary reviewers with appropriate protocol review materials.	IGPS
IBSP Coordinator	Select reviewers with appropriate expertise for the research to be reviewed.	
IBC Member (Reviewer)	Review research protocol and summarize findings on appropriate protocol review.	IGPS
IBC Member (Reviewer)	Ascertain whether any special considerations exist that may influence the review of a protocol.	
IBC Member (Reviewer)	Ascertain whether the evidence exists that third party verification of submitted information is needed.	
IBC Member (Reviewer)	Prepare summary of findings and recommendations for presentation at the next convened IBC meeting.	
IBSP Staff	Articulate Committee findings to Investigator.	Memo Template

SOP Number:	**IBSP 300-302**	Revision Number:	**00**	Effective Date:	
Title:	**Research Submission Requirements**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval - Signature)				Date:	

1. POLICY

IBC members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore this material must provide IBC members with enough information about a study to assess if it adequately meets the criteria for IBC approval.

A submitted *Application for IBC Permit* will be scheduled for IBC review when IBSP staff has determined that the information and materials submitted present an adequate description of the proposed research. If the application proposes the use of Recombinant DNA, and the work is outside of the six categories of exemption per *NIH Guidelines*, it will be placed on the agenda for review. If the application consists of other Biohazardous materials, it may be eligible for an expedited review, and will not be placed on the agenda. However, final determinations of expedited reviews will be made by the primary and secondary reviewers.

In order to effectively and accurately assess proposed research, the Institutional BioSafety Program (IBSP) and the Institutional BioSafety Committee (IBC) require detailed information concerning proposed research activities. To ensure all relevant information is gathered in a consistent manner, requests for review must be submitted with currently authorized forms and all necessary supporting documentation.

Research involving select agents must include a safety plan, security plan and an incident response plan. Personnel conducting research involving select agents must complete a security risk assessment and be approved by CDC DSAT.

Research may <u>not</u> be initiated until the IBC and any other committees (i.e., whose approval may be required) have given final written approval. The Principal Investigator will be responsible for notifying, in writing, all committees and other pertinent institutional officials of the respective committee approvals for the research protocol, prior to initiation of the protocol.

Specific Submission Requirements

1.1 New Submissions

A. Completed "Application for IBC Permit"

a. Most current version must be used and is located at http://researchcompliance.tamu.edu/ibc.

i. Part I (required) - includes Investigator Identification, Risk Assessment and Investigator Assurance.

ii. Attachment D (required) – Personnel Information

iii. Parts II – IV and Attachments A – C are required, as applicable, according to specific materials used in the protocol.

B. Copy of Funding Documents

a. Grant Proposal (if applicable)

b. Contract (if applicable)

C. The following are additional requirements for applications seeking approval for the use of Select Biological Agents and Toxins (SBAT).

a. Safety Pre-Review Assessment Report

i. This is generated by the BioSafety Officer after a preliminary inspection of the lab housing and manipulating the SBAT.

b. Incidence Response Plan

c. Security Plan

d. Safety Plan

e. Completion of CDC Form 1 – sections 4 and 5

i. This will be completed and submitted with the guidance of the IBSP Coordinator. Please call the ORC for more information and assistance.

ii. FBI961 form must be included for all personnel who will require a security risk assessment and CDC DSAT approval

1.2 Amendments

A. Completed "Amendment Application"

a. Most current version must be used and is located at http://researchcompliance.tamu.edu/ibc.

b. All proposed changes must be fully documented and detailed in the amendment form.

B. Copy of Funding Documents

a. This is required if a change or modification to funding requires a change to approved procedures.

i. Grant Proposal (if applicable)

ii. Contract (if applicable)

C. The following are additional requirements for amendments seeking approval for the use of Select Biological Agents and Toxins (SBAT).

If procedures have changed, the following need to be reviewed and edited to accommodate the new protocol and a copy of the revised plan submitted with the amendment form for review:

a. Safety Pre-Review Assessment Report

i. This is generated by the BioSafety Officer after a preliminary inspection of the lab housing and manipulating the SBAT.

b. Part II – A (Security, Safety and Incident Response Plan Review Form)

i. Copy of Incidence Response Plan

ii. Copy of Security Plan

iii. Copy of Safety Plan

c. Completion of CDC Form 1

i. This will be completed and submitted with the guidance of the IBSP Coordinator. Please call the ORC for more information and assistance.

1.3 Annual Review

Each permit is reviewed and renewed annually for up to three years.

A. Completed "Annual Review Form"

a. Most current version must be used and is located at http://researchcompliance.tamu.edu/ibc.

B. The following are additional requirements for amendments seeking approval for the use of Select Biological Agents and Toxins (SBAT).

a. PI Plan Review Form

b. Proof of recent inventory review (as specified in the CDC registration not less than annually)

1.4 Triennial Review (3 year new submission)

Upon the completion of the third year, a new application is required. See Section 1.1 above for the requirements for submission of a new application.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

The IBSP Coordinator is responsible for maintaining current research submission requirements for interested Investigators and for preliminary triage of all submissions.

The IBSP Coordinator or designated staff is responsible for preparing member review materials and reviewing submission elements.

The IBSP designated staff is responsible for submission receipt, tracking and acknowledgements.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115
21 CFR 56.108 (a) (4)
TAMU 15.01.01.M5, 15.01.01

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

IBC Submission Checklist
IBC Submission Application
Acknowledgement of Protocol Receipt
Pending Email Notice

7. PROCESS OVERVIEW

Investigators are responsible for submitting complete application and supporting information for IBC assessment.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool

Compliance Program Coordinator or designee	Receive initial submission Assign IBC number Send acknowledgement email to Investigator Enter protocol information into database Review submission for review type and completeness of submission Assign reviewer(s) and prepare file	*IBC Submission Checklist* *Acknowledgement/ Pending Email Notice*

SOP Number:	**IBSP 300-303**	Revision Number:	**00**	Effective Date:	
Title:	**Safety Risk Assessment**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Brent Mattox	Title:		Biosafety Officer	
Management: (Approval - Signature)				Date:	

1. Policy

Risk assessment is the process used to identify the hazardous characteristics of a known biohazardous agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a laboratory-associated infection (LAIs) and the probable consequences of such an infection. The information identified by the risk assessment will provide a guide for the selection of appropriate Biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs.

At Texas A&M University the completion of a risk assessment is a collaborative process involving the Principal Investigator/Laboratory Director (PI), the Biological Safety Officer (BSO), and the Institutional Biosafety Committee (IBC).

Specific Procedures:

1.1 The generation and submission of a risk assessment for research involving rDNA, biohazardous agents and/or biological toxins involves the submission of an *Application for IBC Permit* (ref.). That IBC application contains various forms and information that are important, however the focus of this procedure is the risk assessment.

1.2 The PI shall be the primary author of the risk assessment. It should be understood that the development of the risk assessment will, however, involve a number of laboratory personnel. In addition, as the risk assessment is being formulated, it will oftentimes be necessary that the PI communicate with the BSO for technical ssistance/advice with regard to appropriate safety practices and equipment.

1.3 The four steps as generally described below are the process that TAMU has established for the development of a risk assessment. The detailed information associated with these steps will be provided by the PI on the appropriate Parts and Attachments of the application for IBC Permit. Included as an attachment to this

procedure is Section II of the BMBL, Biological Risk Assessment. This document provides detailed guidance concerning information to be included in the risk assessment.

1.3.1 Identify the agent hazards and perform an initial assessment of risk
1.1.2 Identify laboratory procedure hazards
1.1.3 Make a determination of the appropriate Biosafety level and select additional precautions indicated by the risk assessment
1.1.4 Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment
1.1.5 Final approval of the risk assessment will be signed by the IBC Chair and the BSO.

1.3.1 Once the risk assessment has been generated by the PI, the PI shall sign an assurance that he/she will use lab practices that meet the determined risk assessment requirements. The assessment then shall be submitted to the Office of Research Compliance (ORC).

1.3.2 The ORC will ensure that the risk assessment is circulated for review by the BSO and the IBC.

1.3.3 During the review process, the BSO and/or IBC may generate comments or questions that must be addressed by the PI. In some cases it may be necessary to return the risk assessment to the PI for further clarification or revision.

1.3.4 Upon completion of the review process, the IBC shall vote to approve or disapprove the risk assessment. If approved, the BSO and Chairperson of the IBC shall sign the risk assessment.

1.3.5 The IBC file shall contain the original signed risk assessment and a copy shall be forwarded to the PI.

2. SCOPE

These policies and procedures apply to all research involving recombinant DNA, biohazardous agents and/or biological toxins.

3. RESPONSIBILITY

The PI is responsible for authoring and submitting the risk assessment. The BSO is responsible for providing technical assistance as requested by the PI. The BSO and IBC are responsible for reviewing, commenting and approving the risk assessment, if deemed acceptable. Ultimate approval of the risk assessment is the responsibility of the IBC.

4. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR 73

Biosafety in Microbiological and Biomedical Laboratory (BMBL). 5th ed., Washington, U.S. Department of Health and Human Services, 2007. Laboratory Biosafety manual. 3rd ed., Geneva, World Health Organization, 2004.

NIH Guidelines for research involving recombinant DNA molecules. Bethesda, The National Institutes of Health (US), Office of Biotechnology Activities, 2002.

5. ATTACHMENTS

Section II of the BMBL, Biological Risk Assessment

6. REFERENCES

Application for IBC Permit

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool

SOP Number:	IBSP 300-304	Revision Number:	00	Effective Date:	
Title:	**Research Exempt from IBC Review**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. POLICY

Research protocols involving the use of recombinant DNA (rDNA) only are exempt from full review by the IBC (Section III-F of *NIH Guidelines*). However, although NIH Guidelines state these exempt projects do not require review by the IBC, Investigators on the campus of Texas A&M must register all research protocols that involve the use of any Biohazardous/biohazardous agent or organism.

Research activities in which involve only the use of rDNA may be considered exempt. The criterion for these exemptions may be found in Section III-F-1 through Section III-F-6 of the *NIH Guidelines*. While the Investigator initial indicates which category their work may fall, final determination of exemption shall be made by the IBC, based on regulatory and institutional criterion. Documentation of this determination will be sent to the Investigator.

1.1 Exempt Research Activities

Research activities in which the only involvement of recombinant DNA (rDNA) may be reviewed are based upon one or more of the following categories, found in Section III-F of the *NIH Guidelines*, are exempt from IBC review:

1.1.1. **Section III-F-1.** Those that are not in organisms or viruses.

1.1.2. **Section III-F-2.** Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

1.1.3. **Section III-F-3.** Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

1.1.4. **Section III-F-4.** Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

1.1.5. **Section III-F-5.** Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment.

1.1.6. **Section III-F-6.** Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.

1.2 Risk concerns of research that is exempt from regulation

1.2.1 Investigators whose research is determined to meet the criterion for exemption must complete the risk assessment found in the Application for IBC Permit. Reviewers may require additional information to be submitted to ensure the risk is indeed minimal to laboratory personnel and the environment.

1.2.2 Investigators may be asked to submit a copy of the Standard Operating Procedures (SOPs) that should be posted in the laboratory.

2. SCOPE

These policies and procedures apply to Investigator claims for exemption from IBC review.

3. RESPONSIBILITY

The IBSP Staff is responsible for evaluating submissions that claim exemption from IBC review. The submissions are then assigned a primary and secondary reviewer that will make the final determination if the criteria for exemption have been met.

Once the review has been completed, the IBSP Coordinator is responsible for ensuring the information is articulated to the Investigator. The approved exempted protocols are listed on the agenda and reported at the next convened IBC committee meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

Section III-F-1 through Section III-F-6 (*NIH Guidelines*)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

N/A

7. PROCESS OVERVIEW

Provide review of protocols submitted for exemption status.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Office of Research Compliance	Maintain and make available submission information regarding research that is exempt from IBC review.	SOP 303
IBSP Staff	Completes initial review of protocols submitted for exempted status and route to designated reviewer for review.	IBC Submission Application
Designated Reviewer	Review study for exemption	Exemption Checklist (*NIH Guidelines*)
Designated Review/IBC Chair(s)	Provide guidance to IBSP Staff the disposition of the exemption claim.	
IBSP Staff	Document all determinations of exemption from IBC review including a brief description of the basis for exemption.	Application for IBC Permit Approval Letter

SOP Number:	**IBSP 300-305**	Revision Number:	**00**	Effective Date:	
Title:	**Research Expedited for IBC Review**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. POLICY

An expedited review procedure consists of a review of research involving Biohazardous/biohazardous material by the IBC Chair(s) and/or by a primary or secondary reviewer.

The categories of research that may be reviewed by the IBC through an expedited review procedure include research activities that (1) do not involve the use of rDNA and presents minimal risk to laboratory personnel and the environment, and (2) Amendments that do not involve the use of select agents.

1.1 The IBSP Coordinator will assign a primary and secondary reviewer upon receipt of the submission

1.2 The reviewers and the IBC Chair(s) or designee will be informed that the protocol is an expedited review. If the reviewers or the Chair(s) deem it necessary, the protocol may be considered an item that needs to go to a convened meeting. In that regard, the IBSP staff will inform the Investigator of the change in review status.

1.3 If the study qualifies for expedited review, the IBC Chair and BSO will ensure the document indicates the determination of risk.

1.4 Because the submission will not be reviewed at a convened meeting, an after action report documenting the approval of submissions approved by expedited review will be provided to the Committee members. The minutes will reflect this report.

1.5 Additional Items That May be Reviewed by Expedited Review

1.5.1 Pending approval subject to minor revisions, clarification:

Revisions to Applications for IBC Permits and other documentation or clarifications submitted as a result of full IBC review, and as a condition to final approval, may be reviewed by the IBC Chair or his/her designee. Final approval will be issued without returning to a convened meeting, providing

the revisions, documentation or clarifications do not indicate or result in a change to the study or change the risk/benefit ratio.

1.5.2 Continuing review:

The IBC Chair or designee may use the expedited review procedure to review renewal requests for previously approved research during the period for which approval is authorized.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC(s) that qualifies for expedited review.

3. RESPONSIBILITY

The IBSP Staff is responsible for identifying submissions that qualify for expedited review, then ensuring they are assigned to the proper reviewer.

The IBC Chair(s) or designed reviewer is responsible for conducting an expedited review.

The approved expedited protocols are listed on the agenda and reported at the next convened IBC committee meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

N/A

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

7. PROCESS OVERVIEW

The IBSP Staff will review the submissions and determine whether they can be expedited. Once that determination is made, the protocol will be routed to the IBC Chair(s) or his/her designated reviewer. The reviewer will make the final determination of whether the protocol qualifies for expedited review. Once approved, the Investigator will be notified.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool

IBSP Staff	Make initial determination regarding qualification for expedited review.	Application for IBC Permit
IBSP Staff	Forward complete application packet for expedited review, assemble reviewer's material and distribute to the chair or designee.	
IBC Member	Perform primary review; using all the appropriate worksheets. Document result of review	Expedited Review Checklist/Critique Sheet/ Expedited Approval Letter
IBC Compliance Staff	Upon completion of the review, update the database so that the protocol appears on the agenda for the next convened IBC meeting.	

SOP Number:	**IBSP 300-306**	Revision Number:	**00**	Effective Date:	**5-30-2007**
Title:	**Criteria for Triennial Review (3 year re-submission)**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. POLICY

Any research activity involving the use of Biohazardous and/or biohazardous material that has received initial review and approval by the IBC is subject to continuing review and approval. While IBC permits are approved for a three (3) years period, approved permits require two Annual Review submissions. The first and second Annual Reviews must be submitted 30-60 days prior to the anniversary of the permit approval date. At the conclusion of the third year, the Investigator is asked to submit a Triennial Review. All Triennial Reviews must be submitted 60 days prior to the anniversary. Triennial Reviews consist of:

- An IBC Annual Review form
- A new Application for IBC Permit submission
- All supporting documents.
- For select agents, the registration will be reviewed and completely reconciled at this time.

Specific Procedures

1.1 The IBC considers a completed Annual Review form to be notification of continuing review of protocols for purposes of renewal of the IBC approval period, at intervals appropriate to the degree of risk, which is determined at the initial review, but not less than once per year. "Not less than once per year" means that the research must be reviewed on or before the one-year anniversary of the previous IBC review date, even though the research activity may not have begun until some time after the IBC gave its approval.

Investigators or qualified designees are required to submit a periodic report prior to the expiration of the study or as specified by the IBC, but at least annually. The report should normally be filed about 45 days before the study approval period ends.

1.2 Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IBC approval. Extensions beyond the expiration date will not be granted. If Continuing Review Report forms are not received as scheduled, the Investigator must suspend the study and study enrollment until reports are reviewed and approved.

1.3.3 Continuing IBC review is required as long as individually identifiable follow-up data are collected on subjects enrolled in protocols. This remains the case even after a protocol has been closed at all sites and protocol-related procedures has been completed for all subjects. These renewal requests may qualify for expedited review.

1.3.4 Expired Protocols

If an Investigator wishes to continuing operations within a laboratory after the permit has expired, they are required to complete a new Application for IBC Permit, including all parts of the application that are applicable to the materials to be utilized in the laboratory. If the new application is not received within 10 business days from the date of expiration, the IBSP staff will notify the Investigator that the protocol has been terminated. The Investigator will be advised that all research must be halted immediately, if not already done so. ***The IBC will grant a 30-60 day provisional approval for Investigators requesting a new submission. However, this provisional approval will not be granted unless the Investigator has provided notification of continuing research through a completed Annual Review Form.*** While it is a courtesy of the IBC to send out renewal notices, it is ultimately the responsibility of the Investigator to renew protocols in a timely manner in accordance with the Federal Institutional guidelines. Failure to adhere to these guidelines will be considered an act of non-compliance and the IBC may have the research and/or funding suspended.

1.3.5 Grant Proposals

It is necessary for all grant proposals to be reviewed at the time an application is submitted in order to verify that there have been no changes. If there are any changes in funding, the IBC needs to be informed through the Amendment process. The entire grant proposal is not needed for review; the aim/scope of the study and the personnel information is needed for IBC review.

1.3 Investigator Notification

After the full board meeting, the disposition of the protocol is relayed to the Principal Investigator by an email correspondence. Any stipulations will also be relayed in the notification letter.

1.4 Filing/Record Retention

All related continuation documentation, including new IBC Forms, memoranda, and any other correspondence associated with continuing review will be filed in the protocol file. All continuing review documentation will be retained for three years after the protocol has expired. Investigators will also be instructed to maintain research records according to the records management system currently in use by the University.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

Director of the Office of Research Compliance (or designee) is responsible for establishing and implementing processes for making research renewal decisions.

4. APPLICABLE REGULATIONS AND GUIDELINES

TAMU 15.99.01.M1(3.2)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

7. PROCESS OVERVIEW

The IBC Compliance staff will identify those protocols that will require continuing review approximately 60 days prior to the expiration date. An expiration notification will be sent to the Investigator requesting completion of the proper paperwork to update the status of the protocol. A second notice may be sent 30 days prior to the expiration date, if there has been no response to the first notice. If no response is received after two notices, an expiration notice will be sent on the day of expiration giving final notification that the protocol has expired. If the Investigator does not submit a continuing review form indicating completion or the need for renewal, they will be notified that the IBC approval has expired and that no research involving Biohazardous/biohazardous material in the laboratory may continue without new submission. The Investigator will have 10 working days from the expiration date to submit a new Application for IBC Permit. If there is no response, a termination notice will be sent to the investigator, and/or department head and funding sponsor (if funded) stating that the file has been terminated.

It is the responsibility of the Investigator to submit a new Application for IBC Permit in sufficient time for the protocol to be reviewed by the IBC. No research involving Biohazardous/biohazardous material may take place after the expiration date without approval.

In accordance with Institutional policy and procedure, Investigators need to also complete and Annual Review form, which tracks the work completed in the laboratory for the previous year. Because this is the final Annual Review under the previous permit, the

Annual Review will be called a Triennial Review. All current forms are located on the IBSP website: http://researchcompliance.tamu.edu/ibc/ibcrevapp.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBSP Staff	Expiration Notification - Alert notices are generated from database 60 days and 30 days prior to expiration date of protocol. If no response from Investigator another alert notice is sent on the day of expiration stating protocol has expired and PI has 10 working days to submit a new Application for IBC Permit.	Expiration Notification Alert
IBSP Staff	If no response from PI 10 days after protocol expires: Not funded – terminate protocol-send Termination notification. Funded – contact PI, advisor or Dept. Head by telephone – if no response by the following day – terminate protocol – send Termination notification.	Termination Notice
IBSP Staff	When the continuation request is received (Annual Review form) the information is reviewed to ensure complete. If it is complete, determine whether it can be expedited or whether it requires review at a convened meeting. For expedited reviews, follow the expedited review process. For full reviews, distribute to 1 primary and 1 secondary reviewer as well as the other committee members for review.	Continuing Review Form
IBC Member(s)	When the new Application for IBC Permit Form is received, the IBSP staff will ensure the Committee reviewers complete the review of the application and associated materials to determine the status of permit.	
IBSP Staff	Notify the Investigator as to the disposition of the new Application for IBC Permit. If the IBC does not re-approve the research by the specified expiration date, a research suspension letter will be sent. It will also outline the terms of the suspension according to the three regulatory categories (screening, enrollment of new subjects, and continuation of interactions/interventions in already enrolled subjects) as decided by the IBC or reviewer.	Memo Template

IBSP Staff	If the Continuing Review is approved – Approval letter is mailed to the Investigator.	Approval Letter

SOP Number:	**IBSP 300-307**	Revision Number:	**00**	Effective Date:	**5-30-2007**
Title:	**Categories of Action**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:	Institutional BioSafety Program Coordinator		
Supervisor: (Signature)			Date:		
Management: (Printed Name)	Vernon Tesh	Title:	Chair, IBC		
Management: (Approval Signature)			Date:		

1. POLICY

As a result of its review, the IBC may decide to approve or disapprove the proposed research activity, or to specify stipulations required to secure IBC approval of the research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present at a meeting in which a quorum is present, except for those members who are required to recuse themselves from the meeting in accordance with the IBC's conflict of interest policies. When reviewed via expedited review, the Chairperson or designee can make any of the following determinations in the following section except to disapprove a study.

1.1 Determinations

The IBC may make one of the following determinations as a result of its review of research submitted for initial or continuing review:

1.1.1 **Approval**: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IBC or Chairperson or designee in the case of expedited review and expire within one (1) year of the meeting/approval date, but not later than the day preceding the date of review.

The conditions for continued approval, and the timeframe (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

1.1.2 **Pending Approval:** Minor modification of, or addition to, a protocol or accompanying document(s) is required. Required changes will be voted upon during the convened IBC meeting, as well as the terms of approval. The Investigator will be informed by email of the required changes and/or requested information and must provide the IBC with the changes or information. Once the Investigator completes the modifications or provides the requested information, the protocol does not have to return to a convened IBC meeting.

The IBC Chair(s) and/or the primary and secondary reviewers has the authority to review the requested modifications/information via expedited review unless the reviewers requires that the material or information be reviewed by the full IBC. Those Committee members that review the response have the authority to approve those modifications, upon satisfactory review.

1.1.3 **Deferred:** Significant questions are raised by the protocol requiring that reconsideration or substantive changes are required. The Investigator will be notified and asked to provide those substantive changes. When the response is received from the Investigator, it is then forwarded to the next convened meeting agenda.

1.1.4 **Disapproval:** The protocol fails to meet one or more criteria used by the IBC for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IBC. When the IBC suggest substantial clarifications, protocol modifications, or informed consent document revisions the protocol may be disapproved. The Investigator will be informed that a new application will need to be submitted.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

Director of the Office of Research Compliance (or designee) is responsible for ensuring that all IBC decisions and actions are based on institutional and regulatory requirements.

IBC Chairperson (or designee) is responsible for ensuring the appropriateness of all IBC decisions and actions.

4. APPLICABLE REGULATIONS AND GUIDELINES

TAMU 15.99.01.M1(3)

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

Notification of IBC Decision (Sample Letters)

7. PROCESS OVERVIEW

When a response to stipulations is received from the PI, the response and the letter sent from the IBC office should be copied and distributed to the IBC prior to the meeting. In the event that the response is received too late to mail to members, the copies may be distributed at the full board meeting. The response should be reviewed as "Old Business", discussed and a vote taken on whether or not the protocol should receive final approval. If the protocol revisions are approved by the IBC, a final approval letter is prepared and sent to the PI. If not approved, the additional clarifications, protocol modifications, or informed consent revisions should be relayed to the PI. The additional clarifications or modifications,

depending on whether or not simple concurrence or substantive changes are required of the PI, may or may not require full board approval.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBC Compliance Staff	Document IBC decisions in the minutes.	
IBC Program Coordinator	Prepare IBC decision letters	
IBC Chairperson (or designee)	Review and sign all IBC decision letters.	
IBC Compliance Staff	Distribute IBC decisions in a timely manner.	
IBC Program Coordinator	Process responses to IBC requests from Investigators	

REVIEWS REQUIRING

SPECIAL CONSIDERATION

400

SOP Number:	**IBSP 400-401**	Revision Number:	**00**	Effective Date:	**5-30-2007**
Title:	**Use of Live Animals**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Management: (Approval Signature)				Date:	

1. POLICY

The IBC reviews all research on the campus of Texas A&M University as it pertains to the Use of Live Animals. The purpose of this review is to ensure that any and all work with rDNA, Pathogens, and Toxins in live animals are safe for the laboratory personnel and the environment. The Principal Investigator must provide notification of this type work to the IBC through the submission of the Attachment A form of the Application for IBC Permit. Communication between the IBC and the IACUC is a vital component to assist the Principal Investigator in compliance with Federal regulations and guidelines, along with Institutional policy.

For the safe handling of animals on the campus of Texas A&M, the Comparative Medicine Program plays a major role. The Comparative Medicine Program (CMP) is the centrally administered support service for animal research and teaching programs at Texas A&M University, College Station. CMP's facilities and services are available for all Texas A&M University, College Station campus affiliated faculty, staff, and students who have been approved to conduct animal research by the Institutional Animal Care and Use Committee (TAMU IACUC). CMP is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, International) through its affiliation with other AAALAC-accredited TAMU programs.

The CMP facilities offer housing and care for most standard laboratory animals. Specialized housing can be provided for biohazard projects (ABSL 1-3) and hazardous chemical projects. Varying degrees of animal isolation are available. Housing for large animal species is limited; however, various other campus animal care facilities can provide housing for large animals.

CMP also offer a variety of services to institutional personnel. These services include the procurement of animals and animal husbandry supplies, provision of veterinary care, use of CMP surgical facilities, a polyclonal antibody production service, technical support services,

and animal use training services. Representatives from CMP maintain a membership on the IBC to ensure the proper dissemination of information for support in both realms.

Specific Procedures

1.1 Submission of Attachment A

1.1.1 The Principal Investigator will submit a complete Attachment A within the Application for IBC Permit.

1.1.2 The IBSP staff will notify the APP staff of the Attachment A receipt through the completion of the *IBC/IACUC Verification Sheet.*

1.1.3 Both Program Coordinators (IBSP & APP) will verify all pertinent information is included in the submitted Attachment A and the AUP (Animal Use Protocol). APP staff may send the IBSP staff copies of the AUP for uploading into IGPS.

1.1.4 Once the Attachment A has been approved, the Principal Investigator will be notified via

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

Director of the Office of Research Compliance (or designee) is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

IBC Chairperson (or designee) is responsible for ensuring the IBC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

IBC Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

4. APPLICABLE REGULATIONS AND GUIDELINES

N/A

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

N/A

7. PROCESS OVERVIEW

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
IBC Program Coordinator	Maintain and update checklist to conform to applicable regulations and guidelines. Secure prisoner representative for IBC meeting.	Checklist – Requirements for Research Involving Prisoners
IBC Program Coordinator	Select appropriate primary reviewer(s).	
IBC Member (Reviewer)	Complete checklist during review of research and present recommendations at convened meeting.	

SOP Number:	**IBSP 400-402**	Revision Number:	**00**	Effective Date:	
Title:	**Use of Human Subjects and/or Materials**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Vernon Tesh	Title:		Chair, IBC	
Management: (Approval Signature)				Date:	

1. POLICY

The categories of research defined in these policies involve methodologies that might require additional considerations or for which there are federally mandated determinations that IBCs are required to make and document. The IBC will maintain a listing of persons with expertise in these areas and will enlist their services for review of protocols when warranted. These categories of research include, but are not limited to:

- Genetic research
- Protocols lacking plans for human involvement
- Medical records and chart review
- Residual body fluids, tissues and recognizable body parts
- Use of Electronic Equipment
- Hazardous Materials/ Animals

Specific Policies

1.1 Genetic Research

Genetic research may require special considerations.

1.1.2 Subjects of Genetic Research:

At first consideration, most genetic research may appear to meet the criteria for expedited review. These include:

- Pedigree studies, which look for a pattern of inheritance of a gene;
- Positional cloning studies, which are conducted to identify particular genes;

- Diagnostic studies, which gather samples to develop techniques to determine the presence of specific DNA mutations.

However, these studies may create a vulnerable population in that subjects' autonomy may be compromised. The type of IBC review for these studies is dependent on answers to the following questions: Will the samples be made anonymous to maintain confidentiality? If not, to what extent will the results remain confidential; and who will have access to them? Will the samples be used for any additional studies not made explicit at the time of donation, or will the samples be destroyed after specified, one-time use? Will the donor be informed of any and all results obtained from his or her DNA? Will the donor be informed of the results of the entire study? Will family members be implicated in the studies without consent?

Because there is still little regulatory guidance and relatively few ethical precedents, genetic research will require close scrutiny, and the input of experts in this area.

1.2 Protocols Lacking Definite Plans for Human Involvement

Certain types of activities are planned and written with the knowledge that human subjects may be involved, but without definite plans for such involvement. Examples of such proposed activities are:

- Training programs in which individual training projects remain to be selected or designed.
- Research, pilot or developmental studies in which the involvement of human subjects depends on such things as the completion of survey instruments or prior animal studies.
- Institutional Support Programs where the selection of the project is the responsibility of the institution or program administrator. When supporting agencies require review and certification for such programs, protocols are to be submitted to the IBC with as much information as is available. The protocols must include assurances that additional information will be submitted when developed and, in the case of training grants, that all trainees will submit individual protocols if human subjects are to be used.

The IBC can give "General Expedited Approval" to programs like those mentioned above with the understanding that the specific research protocol will be submitted to them once it has been developed. "General Expedited Approval" is not appropriate for individual projects or to meet grant deadlines.

1.3 Medical Records and Chart Review

Studies involving the use of existing public or privately held records may qualify for exempt status or expedited review. However, if the nature of the research could put subjects' confidentiality at risk, the full IBC will review the study. Studies that involve only chart and record review can sometimes pose significant risk to patients.

The most common breach of confidentiality is exposure of possible embarrassing information without the knowledge or consent of the patient. Such studies may also lead to recruitment of patients into future non-therapeutic studies in a manner that

may provoke the patient to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present policy is to require IBC review of studies involving chart review or data collection and analysis.

If identifiers were to be recorded, the research would require IBC review to ensure that, among other things, procedures for protecting privacy and confidentiality are adequate. Furthermore, the Investigator studying cancer risk factors may propose to go on to contact the subjects (if still living) or family members (if the subject is deceased) to gather additional information, which may or may not be subject to the federal regulations.

1.4 Residual Body Fluids, Tissues and Recognizable Body Parts

Body Fluids & Tissues: Research on existing specimens ("on the shelf" or frozen) without identifying information (e.g., no names, initials, hospital number, etc.) may be submitted to the IBC for expedited review, to include a short description of the research and where the tissue is coming from.

1.5 Use of Electronic and Stimuli-Generating Equipment

All equipment used in human subjects research that may be attached for recording purposes or produces any type of stimulus must be calibrated and maintained by a certified medical electronics technician. Such equipment may include, but is not limited to, electrocardiophic monitors (EKG), heat producing, electrical stimulus, noise, light, and/or other electronic devices. This equipment must undergo re-calibration and maintenance each year to ensure participant safety. The Environmental Health and Safety Office will review the equipment and protocols, in addition to the IBC. Investigators must submit all information relating to the equipment and its use (i.e. SOPs), lab use and safety procedures, and certification of calibration and maintenance. First aid procedures for lab personnel and subjects must be included in the protocol application. Investigators and lab personnel must be adequately trained to utilize such equipment. Whenever possible, these types of equipment should be developed and/or purchased from manufacturers who specialize in research and related purposes.

When using these types of equipment in research, investigators should evaluate the level of risk involved. High risk endeavors should be discussed with the IBC office prior to submittal to determine if any alternatives are available. Upon review and approval, the IBC may require continuing review to occur more often than annually.

In case of injury, the IBC must be notified immediately, and the procedures outlined in SOP 603, Adverse Event Reporting, must be followed. Principal investigators are required by regulation and TAMU policy to promptly report any adverse event, regardless of the severity. As appropriate, the event will be reported to the institutional official and to OHRP. Adverse events must also be reported to the federal sponsor, if applicable.

Any questions relating to the use of equipment or electronic devices in research should be directed to the IBC office at (979) 458-4067or IBC@tamu.edu. In addition the Environmental Health and Safety office's Website may be accessed at http://finance.tamu.edu/ehsd/resources.asp and by telephone at (979) 845-2132.

1.6 Hazardous Materials/ Animals

In addition to IBC review, protocols for which hazardous chemicals, biological agents, infusion of radioactive substances, or use of ionizing radiation in a research activity must, at a minimum, be reviewed and approved by the TAMU Institutional Biosafety Committee as appropriate. PIs submitting protocols for these types of procedures must be referred to the Institutional Biosafety Committee (IBC) at (979)458-3624. IBC staff should inform PIs of this requirement at the time of submission or as soon as possible after IBC submission.

The care and use of animals at Texas A&M University and the Texas Agricultural Experiment Station are regulated by federal law and by the University's commitment to adherence to the Public Health Service's *Guide to the Care and Use of Laboratory Animals*. PIs submitting protocols involving the use of animals in teaching and research must be referred to the Institutional Animal Care and Use Committee (IACUC) at (979) 845-1828. IBC staff should inform PIs of this requirement at the time of submission or as soon as possible after IBC submission.

Protocols utilizing these methods and procedures will be flagged (on the original copy) to remind the coordinator of this requirement. After review and approval by the IBC, the requirement to seek appropriate safety committee approval will be added to the list of stipulations for approval sent to the investigator. Final approval for the protocol cannot be granted until a letter of approval from the appropriate committee is received in the IBC office.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

Director of the Office of Research Compliance (or designee) is responsible for maintaining up-to-date review tools for review of research pertaining to these categories based on new and evolving applicable regulations and guidelines.

IBC Chair (or designee) is responsible for ensuring the IBC members are well versed in new and evolving regulations and guidelines pertaining to these categories, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

It is the responsibility of the Program Coordinator to coordinate with other Research Compliance committees (IACUC, IBC, etc.) on research programs to ensure complete compliance with all Federal laws related to research.

IBC Reviewer is responsible for conducting appropriate review of research planned for these categories in consultation with any appropriate experts and resources.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.104
45 CFR 46.101, 46.103, 46.118, 46.119
TAMU 15.01.01.M3

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

IBC Submission Application
Research Related Web Links

7. PROCESS OVERVIEW

Review procedure for areas of research that may require additional considerations and expertise.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Chairperson(or designee)	Identify and invite appropriate consultant(s) who may assist the IBC in its deliberations.	IBC Submission Application
Program Coordinator	Ascertain deliberations of other relevant research review groups (e.g., NIH, Institutional Bio-safety Committee).	Research Related Web Links

SOP Number:	**IBSP 400-403**	Revision Number:	**00**	Effective Date:	
Title:	**Select Agent Plans**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:	Institutional BioSafety Program Coordinator		
Supervisor: (Signature)			Date:		
Management: (Printed Name)	Angelia Raines	Title:	Director, Office of Research Compliance		
Management: (Approval - Signature)			Date:		

1. Policy

Pursuant to 42 CFR 73, any Investigators working with Select Agents on the campus of Texas A&M University, must submit a Security Plan, Biosafety Plan, and Incident Response Plan in the IBC review process. The Investigator must meet with the BioSafety Officer and the University Security Officer to ensure that safety and security assessments are conducted. Results of these assessments are then used to develop the required plans. Upon completion of the plans, the Investigator must submit these plans to the IBC for review and approval before implementation. Submission of the plans must be through the New Application for IBC Permit submission process or the Amendment submission process.

Plans must be reviewed at least annually by the Investigator. Plans must also be reviewed after an incident, and after annual drills. Documentation of the review of the plans must be recorded on the PI Plan Review form, and a copy submitted to the Office of Research Compliance with the Annual Review form. Copies of these will be maintained within the IBC file in the Compliance Office. If the review of the plans yielded the revision of the plan, Investigators must follow the Amendment process, and submit copies of the plan to the IBC for review and approval before implementation. Investigators may create their own plans or use templates made available in the Compliance Office; however, all plans must have the following information:

Specific procedures

1.1 Security Plan

Pursuant to 42 CFR § 73.11 (c), the Security Plan must contain the following information:

- 1.1.1 Describe procedures for physical security, inventory control, and information systems control;
- 1.1.2 Contains provisions for the control of access to select agents and toxins;
- 1.1.3 Contain provisions for routine cleaning, maintenance, and repairs;
- 1.1.4 Establish procedures for removing unauthorized or suspicious persons;

1.1.5 Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes;

1.1.6 Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records;

1.1.7 Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

1.2 Biosafety Plan

Pursuant to 42 CFR § 73.12, the Biosafety Plan (laboratory Standard Operational Procedures) must contain the following:

1.2.1 Must contain sufficient information and documentation to describe the Biosafety and containment procedures;

1.2.1.1 Biosafety and containment procedures must be sufficient to contain the select agent or toxin.

1.2.2 In developing a Biosafety plan, the BMBL, OSHA, and NIH Guidelines should be considered.

1.3 Incident Response Plan

Pursuant to 42 CFR § 73.14 (c), the Incident Response Plan must contain the following:

1.3.1 Must contain the name and contact information for the individual or entity;

1.3.2 Must contain the name and contact information for the building owner and/or manager, where applicable.

1.3.3 Must contain the name and contact information for the tenant offices, where applicable;

1.3.4 Must contain the name and contact information for the physical security official for the building, where applicable;

1.3.5 Must contain personnel roles and lines of authority and communication;

1.3.6 Must contain planning and coordination with local emergency responders;

1.3.7 Must contain procedures to be followed by employees performing rescue or medical duties;

1.3.8 Must contain emergency medical treatment and first aid;

1.3.9 Must contain a list of personal protective and emergency equipment, and their locations;

1.3.10 Must contain site security and control;

1.3.11 Must contain procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge;

1.3.12 Must contain decontamination procedures.

1. SCOPE

This policy applies to all Investigators that work with select agents on the campus of Texas A&M University.

2. RESPONSIBILITY

The Investigator who is working with select agents is responsible for meeting with the BSO and creating the plans pursuant to 42 CFR. The Investigator is also responsible for submitting these plans into the IBC for review and approval before implementation. Submissions without these plans will be deemed incomplete, and will cause delay in IBC review and approval.

3. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR § 73.11 (c), 73.12, & 73.14 (c)

4. REFERENCES TO OTHER APPLICABLE SOPs

5. ATTACHMENTS

PI Plan Review form

6. PROCESS OVERVIEW

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Investigator	Complete Safety Assessment with the BSO to create the agent and facility specific plans.	Plan Templates
Investigator	Through the New Application for IBC Permit process or the Amendment process, submit the plans to the IBC for review and approval.	
IBSP Staff	Will send complete submission to the IBC for review and approval and place on agenda for the next convened IBC meeting.	
IBC	Reviewers review the submission and document comments specifically regarding plans into IGPS.	
IBSP Staff	Provide the IBC's final disposition of submission to the Investigator in written correspondence.	
Investigator	Once approved, at least annually, or after an incident or a drill, the plans must be reviewed and documented.	PI Plan Review form

IBC COMMUNICATION AND NOTIFICATION

500

SOP Number:	**IBSP 500-501**	Revision Number:	**01**	Effective Date:	**07/20/2007**
Title:	**Incident Response Reporting and Investigation Process**				
AUTHORIZATION					
Supervisor: (Printed Name)	Angelia Raines	Title:		Director, Office of Research Compliance	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Fuller Bazer	Title:		Alternate Responsible Official	
Management: (Approval - Signature)				Date:	
Management: (Printed Name)	Richard Ewing			Title:	Responsible Official
Management: (Approval - Signature)				Date:	

1. POLICY

The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).

Specific Procedures

1. **Release – Release** – Occupational exposure (*defined as clinical symptoms confirmed by laboratory evidence or an abnormal event (spill outside biocontainment, needle stick, malfunction of PPE, etc)) in which the agent could have been release outside of the primary bio-containment barrier)* or release of an agent or toxin outside of the primary barriers of the biocontainment area.

    1.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

1.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.

1.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.

1.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.

1.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.

1.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.

1.2 A risk assessment will be conducted immediately upon discovery regarding any release.

1.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will

also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

1.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

1.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

1.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.

1.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.

1.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:

1.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.

1.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.

1.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.

1.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.

1.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.

1.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

2. **Theft** (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.

2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.

2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.

2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.

2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.

2.1.6 The LD/PI will ensure notification to the funding agency

2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.

2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

2.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

2.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

2.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

2.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

3 Investigation

3.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

3.2 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

3.3 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

3.4 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

3.5 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

3.6 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

4 Reporting

4.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

4.1.1 The investigation report, at a minimum, shall include the following information:

4.1.1.1 A detailed description of the incident.

4.1.1.2 A list of all personnel involved in the incident.

4.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

4.1.1.4 An assessment of the safety or security risk of continuing the research.

4.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

4.1.1.6 A recommendation for training, if needed.

4.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

4.3 Events involving rDNA must be reported to the NIH in writing no later than 30 days of the incident.

5 Record- Filing and Retention

5.1 Incident reports and any correspondence generated as a result of the event must be retained for at least three years beyond the life of the protocol.

6 SCOPE

This procedure shall apply to all Select Agent research approved to the IBC.

7 RESPONSIBILITY

The PI is responsible for ensuring all lab personnel are trained on this policy each time it is modified or at least annually.

Each PI will also conduct a safety drill and a security drill at least annually to ensure that the plans (safety and security) are adequate for the research being conducted.

8 APPLICABLE REGULATIONS AND GUIDELINES

NIH Guidelines
42 C.F.R. 73

9 REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

10 ATTACHMENTS

Sample; Form 3

11 PROCESS OVERVIEW

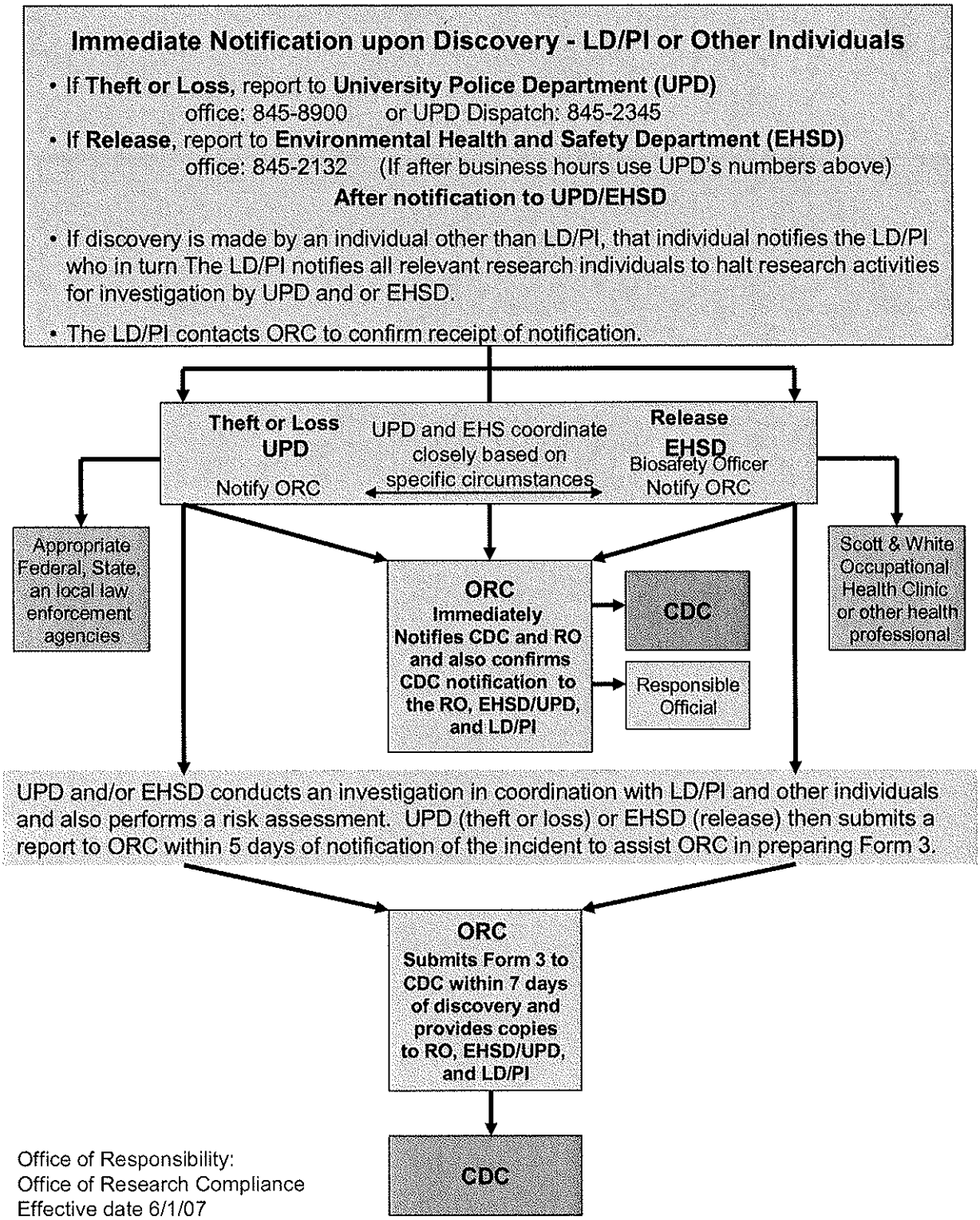
A flow chart has been added to document the process.

12 PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
PI or PI's designee	Notify the Environmental Health and Safety Department's Biosafety Officer or the University Police Department (EHSD/UPD) of the incident (Theft, Loss or Release) immediately. If the incident involves a theft or loss, contact UPD (Bert Kretzschmar). If the incident involves a release, contact the BSO (Brent Mattox)	Phone
PI/Lab Personnel	Immediately halt all work in the lab, while the incident is investigated and until either the EHSD or UPD indicates that work in the lab may resume.	
EHSD/UPD	Notify the Office of Research Compliance (ORC) of the incident and immediately begin an investigation of the event.	Phone

ORC	Notify the Responsible Official (RO), CDC, IBC Chair(s) and other institutional contacts. CDC must be notified immediately. For rDNA, NIH must also be notified.	Phone, email or fax using the SBAT Incident Checklist
EHSD and UPD	With input from the PI, investigate the incident.	
EHSD/UPD	Submit an investigation report to the IBC and RO within 5 days of the event. The report will be used to create the written report (Form 3) that has to be sent to CDC.	
IBC Program Coordinator	Include the incident report on the next available IBC agenda.	
ARO/Director of the Office of Research Compliance	Based on the information supplied by the EHSD/UPD in the incident report, complete the CDC Report of a Theft, Loss or Release Form (Form 3). Provide a draft of the report to the PI, EHSD/UPD for review and input. After all input in received, submit to CDC RO, IBC and institutional contacts. The report must submitted to CDC no later than 7 days from the initial notification	Fax, or email Form 3
CDC	Respond to the Form-3 submission	Letter
ARO/Director of the Office of Research Compliance	Notify the RO, PI, BSO/UPD IBC and other institutional contacts of any additional information required by the CDC or final CDC disposition	
ARO/Director of the Office of Research Compliance	Continue to follow up with the RO, PI, EHSD/UPD IBC, CDC and other institutional contacts until CDC indicates that no further action or information is needed.	
IBC Program Coordinator	File the incident report as well as all other supporting documentation with the IBC minutes and in the Incident Reporting section of the Select Agent registration file.	

Theft, Loss, or Release of Select Agents and Toxins (SBATs) Notification and Reporting Procedures



Office of Responsibility:
Office of Research Compliance
Effective date 6/1/07

SBAT Incident Response
Emergency Contact Numbers

PI Information		
PI Adams Office – 979 845-5092 Mobile – 979 255-1657	**PI Davis** Office – 979 862-4113 Mobile – 979 229-9774	**PI Ficht** Office – 979 845-4118 Mobile – 979 574-9466
PI Tesh Office – 979 862-4113 Mobile – 979 229-9774	**PI Samuel** Office – 979 862-1684 Mobile – 979 220-8269	**Lab Director Ihrig** Office - 979 845-7433 Mobile - 979 229-2696

Building Manager			
972 = David Carlson	**1197-Thomas Ficht**	**1504= George Martin**	**1220-28= Frank Stein**

Incidents involving Theft or Loss
University Police Department (UPD) contact
Bert Kretzschmar
Office – 979 845-8900
Mobile – 979 777-9033
Home – 979 774-0017).

Incidents involving a Release (or Occupational Exposure)
Environmental Health and Safety Office contact

Between 8:00 a.m. and 5:00 p.m.
Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO)
Office – 979 865-2132
Mobile – 979 450-0662

After hours 5:00 pm
Contact the University Police Department contact
Lt. Bert Kretzschmar
Office – 979 845-8900
Mobile – 979 777-9033
Home – 979 774-0017

Other Contact information		
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or 979 229-1479 (Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or 979 324-7364 (Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or 770 789-3456 (Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or 979 229-2696 (Mobile)
	Elizabeth Browder	979 845-7433 (Office) or 979 777-0132 (Mobile)
	Frank Stein	979 845-6488 (Office) or 979 218-0642 (Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or 979 574-9466 (Mobile)
	Vernon Tesh	979 862-4113 (Office) or 979 229-9774 (Mobile)
	Tiffany Agnew	979 458-3624 (Office) or 706 414-7133 (Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911
	Medical Emergency	9-911
	College Station Fire	979 764-3700 or 9-911
	Radiological Emergency	979 832-1111
	University Maintenance	979 845-4311

SOP Number:	**IBSP 500-502**	Revision Number:	**00**	Effective Date:	
Title:	**Adverse Events involving a Biohazard/Reports of Non-Compliance NOT INVOLVING SELECT AGENTS**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew		Title:	Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines		Title:	Director, Office of Research Compliance	
Management: (Approval - Signature)				Date:	

1. POLICY

Principal investigators conducting research using Biohazardous agents are required by regulation and TAMU policy to promptly report any adverse event, regardless of the severity or significant problem which includes violation of the National Institutes of Health (NIH) Guidelines or other issues of non-compliance, immediately to the Institutional Biosafety Committee (IBC).

An **adverse event** involving a biohazard is any event that involves contamination of personnel and/or the environment with a biohazard that has the potential to cause illness or one that may cause significant concern to the general public. Examples of adverse events are personnel injury, exposure, theft or loss of the materials.

Please note: Individuals who are exposed to a Biohazardous agent with the potential to cause illness must immediately contact Occupational Health for an evaluation.

Non-compliance is defined as failure to manage the safety of the laboratory staff to ensure that the required safety practices and techniques are employed, failure to report and investigate (with input from the Biosafety Officer) any significant problems pertaining to the operation and implementation of containment practices and procedures, failure to remedy any problems that could result in the release of Biohazardous materials, or any violation of the *NIH Guidelines* that results in personal injury.

The *NIH Guidelines* contain requirements for reporting of significant problems (Sections IV-B-1-j, IV-B-2-b-(7), and IV-B-7-e(2)].

All research conducted under the Texas A&M University IBC requires the Principal Investigator to immediately report problems to the Biosafety Officer and to the

Biosafety Committee. A subcommittee headed by the Biosafety Officer will then investigate the incident. Incidents requiring immediate reporting to NIH or other regulatory agencies will be submitted by Biosafety Committee (through the Responsible Official).

If the research involves a select biological agent and/or toxin, the investigator and the event involves a theft, release (including occupation exposure) or loss, the incident report process for the lab must be followed.

After initial notification occurs, a written report must be filed within 24 hours of occurrence and submitted to the Institutional Biosafety Committee through the Institutional Biosafety Officer.

The report must include details of the event.

The Biosafety Officer or IBC chair will review the report and forward it to the IBC for review. The IBC and Responsible Official (through the Office of research Compliance) will determine whether a report must be sent to the NIH Office of Biotechnology Activities.
If required, the report must be submitted to NIH within 30 days after the occurrence.

If the event involves the release, theft or loss of a select agent, CDC will be immediately notified by the Office of Research Compliance. Within 7 days of the notification, the ORC will submit Form 3 to the CDC. The process used to report and investigate all incidents involving a select agent are located in policy IBC 601 for SBAT incident reporting.

IBC Investigation Committee

1. The Investigation Committee will be headed by the Institutional Biosafety Officer (BSO) as well as designated members of the IBC who do not have a conflict of interest.
2. The PI and all administrators will communicate with the BSO and vice versa, i.e., there will be only one line of communication.
3. The Committee will investigate the event as quickly as possible but no later than 72 hours of the report.
4. Once the Committee has determined the response and informed the IBC, the PI will receive a written response as well as the Responsible Official.
5. In reports involving significant harm to human welfare, the entire IBC Committee will meet within 7 days of the investigation to recommend the course of action. At that time PI will be given the opportunity to address the committee. In other cases, the investigation Committee will present the report and its investigation at a regularly scheduled IBC meeting.

1.2 Reporting

All reports of adverse events are reported in the minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO or IBC Chair at the next convened meeting.

Incidents involving SBAT will be immediately reported to the CDC with a written report (form 3) submitted within 7 days.

Events involving rDNA will be reported to the NIH within 30 days.

1.3 Filing and Retention

Adverse event reports and any correspondence generated by the IBC in response to the event must be filed with and retained for three years beyond the life of the protocol.

2. SCOPE

These policies and procedures apply to all research submitted to the IBC.

3. RESPONSIBILITY

IBC Compliance Staff is responsible for entering the adverse event into the database and forwarding to Program Coordinator for review.

The IBC investigations committee, headed by the BSO is responsible for review of the adverse event and initiating appropriate action.

4. APPLICABLE REGULATIONS AND GUIDELINES

NIH Guidelines
42-CFR-73

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

Adverse Event Form
Adverse Event Acknowledgement Memo

7. PROCESS OVERVIEW

The IBC Compliance staff responsible for adverse event processing will check the email each workday morning for any reported event. If any, the IBC Compliance staff will record all pertinent information, such as principal investigator name, protocol number, a description of the event, date of occurrence, and any other information provided by the PI. This email "starts the clock" as to when a written report is required to be submitted. The written report must be submitted to the IBC office within 5 days of the event.

Upon receipt of a completed IBC Adverse Event report, the IBC Compliance staff will enter the report into the database, pull the file, attach the report and submit to the Program Coordinator. The file is then sent for review by the Biosafety Officer and or member(s) of the investigation committee. The BSO will lead the investigation and determine what action is required. If the event involved a select agent, all research will stop until the investigation is complete or the BSO authorizes the work to continue.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
PI	Notify the IBC /BSO of the adverse event/incident	Phone, email, fax
PI	If the incident involves a select agent, follow the SBAT incident reporting process, which is incorporated in each laboratory's Incident Response Plan (report the event immediately to the BSO and ORC	SBAT Incident Report Procedure
PI	For SBAT ensure that all work should stop until the BSO authorize continuing.	
ORC/BSO	Upon notification, immediate notify the IBC chair. If the event involves an SBAT, immediately notify the Responsible Official (through the Director of the Office of Research Compliance) and CDC.	Phone, email, fax
BSO	Within 72 hours of notification, initiate an investigation on behalf of the IBC and institution.	
BSO	Submit investigation report to the IBC and RO within 5 days of the event.	
ARO/Director of the Office of Research Compliance	Submit form 3 to CDC if the incident involves an SBAT no later than 7 days from the initial notification	Form 3
IBC Compliance Staff, BSO or IBC	Receive adverse event report and enter into database.	Adverse Event Form
IBC Program Coordinator	Review adverse event report for appropriate action	Adverse Event Form
IBC Program Coordinator	Place on agenda for committee review	IBC Agenda/Minutes Template

IBC Chair (or designee)	Acknowledge receipt of adverse event report	Adverse Event Acknowledgement Memo

IBC - Adverse Event and Non-Compliance to *NIH Guidelines* Reporting Form

File this report within 24 hours of the event with the Biosafety Officer or with the IBC through the Office of Research Compliance. This form is used to report research-related adverse events only.

Type of event A = Adverse Event NC = Non- Compliance	**Date of event**	**Location of Event**	**Bio-hazardous agent involved**	**Nature of the event** (e.g., exposure, spill, etc)
Below, please include a description of the events that occurred				

Exposure risk to people and the environment

_____

_____

Action taken:

_____

_____

Report submitted by:_____ **Date:**_____

For Official Use only:

Date received:_____

Institutional Action Taken:_____

_____ _____

Institutional Biosafety Officer or IBC Chair Date

SOP Number:	**IBSP 500-503**	Revision Number:	**00**	Effective Date:	
Title:	**Monthly Select Agent BioSafety Program Report**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Richard Ewing	Title:		Vice President for Research	
Management: (Approval - Signature)				Date:	

1. POLICY

In order to effectively communicate the critical activities of the BioSafety program, the BSO is required to compile and distribute a monthly report to key institutional officials.

Specific Requirements

1.1 The "Monthly Select Agent Security Report" will contain the following information in summary form:

D. Details of all SBAT facilities inspected. Including,

a. Date
b. Location/Lab Inspected
c. Principle Investigator
d. Number of Items Reviewed
e. Number of Findings
f. Response Due Date
g. Date of Response
    i. Include if PI has already responded

E. Safety and/or security issues identified

a. Inspection date
b. Location/Lab Inspected
c. Principle Investigator
d. Summary of safety or security issue identified.

F. Incident Summary

a. Incident Date

b. Location/Lab Inspected

c. Principle Investigator

d. Brief description of incident

e. Determination of need for external reporting

f. Date external report issued, if applicable

G. BSO Certification of Report

a. BSO will sign the report attesting to the completeness and accuracy.

1.2 The following shall be included with the summary report upon distribution.

D. Complete SBAT lab inspection reports.

E. Incident reports

a. Internal and External

1.3 Distribution

A. Distribution is to occur on or before the 10th day of the month for the prior month's report.

B. The Summary Report with all attachments itemized in 1.2 will be distributed as follows:

a. Responsible Official (RO)

b. Director of Research Compliance

c. Institutional BioSafety Program Coordinator

i. The IBC Coordinator will issue a complete copy of the report to all members of the IBC at their next regularly scheduled meeting.

ii. The IBC Coordinator will issue a complete copy of the report to the IBC upon receipt.

QUALITY ASSURANCE

600

SOP Number:	**IBSP 600-601**	Revision Number:	**00**	Effective Date:	
Title:	**Quality Assurance/Quality Control Program**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:	Institutional BioSafety Program Coordinator		
Supervisor: (Signature)			Date:		
Management: (Printed Name)	Angelia Raines	Title:	Director, Office of Research Compliance		
Management: (Approval Signature)			Date:		

1. POLICY

Quality assurance and control of the daily operations of the IBC ensure effective support of the IBC's mandate. Therefore, the QA/QC program consists of three components:

- Training and continuing education of IBC Compliance Staff
- Interactions with the IBC community outside the Texas A&M Community
- Regular review and assessment of procedures

Specific Policy

The Director of the Office of Research Compliance, the Institutional Official or the IBC Chair has the authority to implement a QA/QC program and to act on identified deficiencies by implementing corrective action which may include implementing revisions to the Standard Operating Policies and Procedures.

2. Audits of IBC Records and Database

Arrangements will be coordinated by the Program Coordinator to schedule an internal audit of the IBC records and database on an annual basis. For audits of the database, the auditors will compare data contained in the IBC protocol files with the information contained in the IBC database. For audits of IBC protocol files (records), the presence of the following documents in a sampling of IBC files will be verified:

Original and approved IBC Protocol
Original and approved Consent Form (if applicable)
Final protocol approval letter to PI
Continuing Review Forms for every year past the initial approval period
Acknowledgement of adverse event reports by designated members
Approvals for amendment/modification requests

Verification of documentation of amendments/modifications, adverse events, and continuing review will be accomplished by checking the Report of Administrative Actions of the IBC.

An audit plan will be developed by the Program Coordinator and presented to and approved by the Chair(s) and Director of Research Compliance by March 1st of each year. The annual audit will by completed by August 31st of each year. A report of the findings shall be forwarded to the Director of Research Compliance. Discrepancies will be corrected immediately and, if required, reported to the Office for Human Research Protections.

3. SCOPE

These policies and procedures apply to all IBCs in the Texas A&M University system.

4. RESPONSIBILITY

Director of the Office of Research Compliance (or Program Coordinator) in conjunction with the Institutional Official or the IBC Chair is responsible for the establishment, implementation and oversight of the QA/QC program.

5. APPLICABLE REGULATIONS AND GUIDELINES

6. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

7. ATTACHMENTS

8. PROCESS OVERVIEW

IBC personnel and the research community are responsible for maintaining and ensuring continuing quality and standards for all IBC procedures.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Director of the Office of Research Compliance (or Program Coordinator)	Review IBC operations at least annually. Develop and implement quality improvements as indicated by periodic assessments.	

SOP Number:	**IBSP 600-602**	Revision Number:	**00**	Effective Date:	
Title:	**Audits By Regulatory Agencies**				
AUTHORIZATION					
Supervisor: (Printed Name)	Tiffany Agnew	Title:		Institutional BioSafety Program Coordinator	
Supervisor: (Signature)				Date:	
Management: (Printed Name)	Angelia Raines	Title:		Director, Office of research Compliance	
Management: (Approval - Signature)				Date:	

1. POLICY

Texas A&M University acknowledges that certain regulatory agencies have the authority to audit the operations of IBCs, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Entities that may audit IBCs include: CDC, NIH, DOD, DHS, and other appropriate agencies. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

Specific Policies

1.1 Preparing for an Audit

1.1.1 For external audits involving OHRP or FDA, the following must be notified immediately:

- The Directory of the Office of Research Compliance, who in turn will notify
- The Institutional Official
- IBC Chair,
- other organizations as needed
- The IBC Compliance Staff designated to participate in the audit are required to follow the steps outlined by this institution for preparing the site for an audit.

1.2 Participating in an Audit

1.2.1 IBC Compliance Staff are expected to know and follow the procedures outlined by this Institution for the conduct of a regulatory audit.

1.2.2 Prior to being granted access to IBC documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IBC documents, and no entity other than those listed on the consent forms may have access to any document that includes subject identifiers.

1.2.3 Auditors will be provided with adequate working area to conduct an audit and IBC Compliance Staff and members must make every reasonable effort

to be available and to accommodate and expedite the requests of such auditors.

1.2.4 Documents may be copied and taken off-site only by individuals authorized in writing by the Director of the Office of Research Compliance or Program Coordinator.

1.3 Follow-up after an Audit

Reports of the audit, either verbal or written, should be addressed by the Institutional Official, (with the assistance and support of the Office of Research Compliance), as soon as possible after the audit.

2. SCOPE

These policies and procedures apply to all IBCs in the Texas A&M University system.

3. RESPONSIBILITY

Institutional Official is responsible for serving as the responsible institutional official in all regulatory agency matters regarding regulatory compliance, participating as needed in regulatory agency audits, and providing support in responding to and correcting audit findings.

Director of the Office of Research Compliance (or designee), with input from IBC Chair, Institutional Official and Office of Research Compliance, is responsible for all formal regulatory agency correspondence and interactions, establishing logistical support during regulatory agency audits, serving as key institution contact during such audits, and drafting responses to regulatory agency correspondence received following such audits.

IBC Chair, members and staff are responsible for participating in regulatory agency audits as determined by the Director of the Office of Research Compliance (or Program Coordinator), and in fully cooperating with government officials during their participation in such audits.

IBC Chair is responsible for assisting the Director of the Office of Research Compliance (or Program Coordinator) in formal responses to regulatory agency audits and in implementing policy and procedure changes indicated by such audits.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115
45 CFR 46.115
TAMU 15.99.01
FDA Compliance Program Guidance Manual 7348.809, Institutional BioSafety Committees

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

N/A

7. PROCESS OVERVIEW

Guidelines concerning preparation for regulatory audits of the IBC and appropriate behavior toward regulators will be adhered to continually.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
Director of the Office of Research Compliance (or Program Coordinator)	Upon being notified of an impending audit, notify all IBC Compliance Staff, and staff of any other institutional entity designated, including the IBC Chair, Institutional Official, and the Director of the Office of Research Compliance	Internal Audit Plan Audit Report Policy
	Using the Audit Preparation Checklist, assign responsibilities as indicated on the checklist.	

IBC Application and Related Forms

Institutional Biosafety Committee
Registration Document

For Research Involving Recombinant DNA,
Infectious Agents/Biological Toxins

Please keep the following information for your records.

The Texas A&M University Institutional Biosafety Committee (IBC) maintains a registry of all laboratories and personnel working with **human pathogens** and **biological toxins**. A pathogen is defined in the NIH and CDC Guidelines as *any organism know to or suspected of causing infection in humans*. A biological toxin is defined as a *proteinaceous poison which is toxic to humans.*

Additionally, the IBC reviews proposed work with **recombinant DNA** molecules and **genetically modified animals**. Proposed work must be reviewed and approved prior to the initiation of research. (Please consult the NIH Guidelines for Research Involving Recombinant DNA Molecules for information needed to complete this registration form.)

The Principal Investigator (PI) is responsible for completing all appropriate parts of this registration document and for notifying the IBC when information submitted in this document changes, such as personnel, location, procedures, funding, etc. If such changes occur, the PI will be required to fill out an Amendment Form (located online).

All IBC laboratory permits are currently approved for the duration of three (3) years, but these protocols must undergo mandatory laboratory inspections. Once a year, an investigator will be required to submit an Annual Review to renew the protocol (located online). At the completion of the three (3) years, Principal Investigators will be asked to submit a Triennial Review, and the permit will be terminated. If the work is not completed, Principal Investigators will be asked to submit a Triennial Review and a new Application for IBC Permit, for which the Committee will conduct a complete review, and a new IBC permit number will be issued.

Only typed forms will be accepted. For your convenience, each required form is fillable on line. Only the most current forms will be accepted and reviewed; therefore we ask that you access our website for all submissions. The application must be completed, signed by all appropriate personnel, and submitted to the **IBC** at **MS 1186** through the Office of Research Compliance, **prior** to initiation of research. At the time of submission, you are asked to also submit all grant proposals pertaining to your research. Failure to provide all information requested, including requested signatures, will lead to a delay in processing your request. If further instructions are necessary, please contact the IBC at IBC@tamu.edu or call (979) 458-3624.

If you are using a biological agent or toxin requiring BSL 3 containment, please contact the Office of Research Compliance office at (979) 458-3624 for further instructions. Definitions of Biosafety Levels may be found in ***Appendix 1***, which may be accessed on our website at www.researchcompliance.tamu.edu/ibc. You may also access the ***APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins*** list from this site.

Routing # _____
AUP # _____
IRB # _____

FOR INTERNAL USE ONLY
IBC # _____

APPLICATION for IBC PERMIT
Part I
Checklist and Table of Contents for Institutional Biosafety Protocols

The following is a table of contents of the items included in application for an IBC permit. In order for research to be approved, you must provide all applicable sections to the IBC, and a copy of the grant proposal. **Please check and attach all items that apply to your research.**

Parts I and Attachment D are required and must be completed then submitted. Parts II through Attachment C are subsequent attachments; they should be completed and submitted as applicable. **Only typed applications will be processed for review.** You need not submit blank or not-applicable pages to the IBC.

Please send completed Applications for IBC Permits to **VPR – Office of Research Compliance, MS 1186**. The office may be contacted at (979) 458-3624 or by email at IBC@vprmail.tamu.edu.

Your protocol will be delayed if it is missing any required information. **Please allow sufficient time for processing of your application. It may take 30-60 days to obtain IBC approval.**

- ☐ Part I: Investigator Identification **(required of all investigators)**
- ☐ Part I: Risk Assessment **(required of all investigators)**
- ☐ Part I: Investigator Assurance **(required of all investigators)**
- ☐ Part II: Use of Biological Toxins
- ☐ Part III: Use of Pathogens
- ☐ Part IV: Use of Recombinant DNA
- ☐ Attachment A: Use of Live Animals
- ☐ Attachment B: Use of Humans and/or Human Materials
- ☐ Attachment C: Use of Plants
- ☐ Attachment D: Personnel Information **(required of all investigators)**
- ☐ Grant Proposal **(required of all investigators)**
- ☐ *If your research involves the Use of Select Agents from the CDC, USDA, or overlap lists* – (See Appendix 2 of this document for a listing of select agents and include a copy of your laboratory's BioSafety Plan, Security Plan, and Incident Response Plan)

PART I
Principal Investigator Identification

All Principal Investigators must complete this part.

A. Principal Investigator Information

Name _____

Department _____ Campus Mail Stop _____

Office location (building, room number) _____

Laboratory locations (building, room number (s)) _____

Address _____
City State Zip

Phone: _____ _____ _____
Office Laboratory Emergency/after hours

Fax: _____ Email: _____

B. Funding Source (Please check all that apply)

☐ NIH ☐ NSF ☐ DOD ☐ USDA ☐ Other: _____

C. Routing Agency

☐ TAMU ☐ Research Foundation ☐ TEES ☐ TAES

D. Research Objectives

Briefly describe your research objectives. Justify the use of biological toxins, pathogens, and/or rDNA in your goals (Use an additional sheet of paper if necessary).

PART I
Risk Assessment
All investigators must complete this part.

A. Risk Management Matrix

Evaluate the impact of the inappropriate or accidental release of the most hazardous agent used in your laboratory.

Green Zone – 1 **Yellow Zone – 2 through 3** **Red Zone – 4 through 5**

		Probability That Something Will Go Wrong			
		A Likely to occur immediately or in a short period of time, expected to occur frequently	**B** Probably will occur in time	**C** May occur in time	**D** Unlikely to occur
Seriousness of Risk	**I** May result in death			4	3
	II May cause severe injury, major damage or loss, and/or result in negative publicity for the participant involved			3	2
	III Participation presents a minimal threat to safety, health and well-being of participants		3	2	1
	IV No more than minimal risk	3	2	1	1

Does your protocol fall in the Yellow Zone (2 through 3) or Red Zone (4 through 5)?
☐ No. ☐ Yes.

B. Will you be using an agent classified as a Risk Group 3 or 4? (See Appendix 1 of this document for Risk Group Classifications.)
☐ No. ☐ Yes.

C. Will you be using an agent listed on the CDC, USDA, or overlap lists of Select Agents?
☐ No. ☐ Yes. (See Appendix 2 of this document for a listing of select agents and include a copy of your laboratory's BioSafety Plan, Security Plan, and Incident Response Plan)

D. *Risk Group (RG): _____ *BioSafety Level (BSL): _____
*See **Appendix 1** for determination of risk group and Biosafety level.

FOR COMMITTEE ACTION ONLY

This application, including the Risk Assessment, has been reviewed and approved and the investigator's assurance has been accepted.

Signature of IBC Chair	Date	Signature of BioSafety Officer	Date
_____	_____	_____	_____

PART I
Investigator Assurance

All investigators must complete this part.

- I agree to use lab practices that meet the Biosafety level (BSL) required by my work. (For definitions of Biosafety levels, please see Appendix 1of this document.)
- I have read the NIH Guidelines and I acknowledge my responsibility for the conduct of this research in accordance with Section IV-B-7 of the NIH Guidelines.
- I have the knowledge and training required to safely handle the materials described.
- I agree to conduct these experiments in accordance with all TAMU and IBC policies.
- I acknowledge my responsibility to secure and control the biological agents used in this project.
- Entry doors to the laboratory will be closed and locked when the laboratory is unattended.
- I agree to provide all personnel working in the laboratory notification, information and training on the hazards, laboratory security and emergency policies and procedures associated with working in my laboratory. **I agree to inform all personnel working in the laboratory that potentially all microorganisms can be pathogens under certain conditions. When necessary, work procedures and protocols are in place to prevent aerosols and exposure to microorganisms. All personnel are provided training in sterile technique, the use of automatic pipetters and the proper disposal of bacterial cultures. All personnel are advised that if they are in an immunocompromised/ immunosuppressed condition that they are at risk for infection from the general environment and susceptible to infections that would normally not be a problem for an immunocompetent individual. All personnel are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health.**
- I agree to contact the Office of Environmental Health & Safety before the transfer of any select agents. EH&S can be contacted at (979) 845-2132 or by email at ehsd@tamu.edu.

PART I
Investigator Assurance - continued

All investigators must complete this part.

_____ _____

Signature of Principal Investigator Date

_____

Typed/Printed Name

_____ _____

Signature of Unit Head Date

_____

Typed/Printed Name

PART I
Risk Assessment
All investigators must complete this part.

A. Risk Management Matrix

Evaluate the impact of the inappropriate or accidental release of the most hazardous agent used in your laboratory.

Green Zone – 1 **Yellow Zone – 2 through 3** **Red Zone – 4 through 5**

Seriousness of Risk	Probability That Something Will Go Wrong			
	A Likely to occur immediately or in a short period of time, expected to occur frequently	**B** Probably will occur in time	**C** May occur in time	**D** Unlikely to occur
I May result in death			4	3
II May cause severe injury, major damage or loss, and/or result in negative publicity for the participant involved			3	2
III Participation presents a minimal threat to safety, health and well-being of participants		3	2	1
IV No more than minimal risk	3	2	1	1

Does your protocol fall in the Yellow Zone (2 through 3) or Red Zone (4 through 5)?
☐ No. ☐ Yes.

B. Will you be using an agent classified as a Risk Group 3 or 4? (See Appendix 1 of this document for Risk Group Classifications.)
☐ No. ☐ Yes.

C. Will you be using an agent listed on the CDC, USDA, or overlap lists of Select Agents?
☐ No. ☐ Yes. (See Appendix 2 of this document for a listing of select agents and include a copy of your laboratory's BioSafety Plan, Security Plan, and Incident Response Plan)

D. *Risk Group (RG): _____ *BioSafety Level (BSL): _____
*See **Appendix 1** for determination of risk group and Biosafety level.

FOR COMMITTEE ACTION ONLY

This application, including the Risk Assessment, has been reviewed and approved and the investigator's assurance has been accepted.

Signature of IBC Chair	Date	Signature of BioSafety Officer	Date
_____	_____	_____	_____

FOR INTERNAL USE ONLY

IBC # _____

PART II
Use of Biological Toxins

Complete this part if your work will involve the use of biological toxins.

A. Identification of Toxins Used

1. List all toxins used in your laboratory.

Toxin – generic name	Chemical name (if available)	Source organism	Risk group*	BSL*

*See **Appendix 1** for determination of risk group and Biosafety level.

2. Acquisition and storage – list all sources for each toxin. (example: vendor, private/off-campus laboratory, clinical collection, culture, other – specify)

Toxin	Source(s)	Storage location(s) – building name, number, and room number	Use location(s) – building name, number, and room number

B. Laboratory Procedures

1. Briefly describe in lay terms the experimental procedures using toxins.

2. Which experimental manipulations do you intend to use that have a potential for generating aerosols or splashes? Please check the applicable boxes. Then choose the biosafety containment level for each from the drop-down menu.

☐ Homogenization	N/A	☐ Centrifugation	N/A
☐ Sonication	N/A	☐ Pipetting	N/A
☐ Dissection	N/A	☐ Other (Specify.)	N/A

C. Medical Risks

1. Describe health risks associated with the use of all toxins in your laboratory and list the symptoms/disease that may occur.

Agent	Health Risks/Symptoms/disease/target organ(s)

2. What are the treatment options/plans available in case of a potential exposure to toxins?

3. Is there a process in place to inform personnel of potential hazards of working with toxins and of increased risks of infection for individuals with immunocompromised/ immunosuppressed conditions? Please choose applicable answer from the dropdown menu.

   N/A.

D. Exposure Control

1. Indicate the personnel protective equipment you will use. Please check the applicable boxes.

☐ Face Mask	☐ Gloves	☐ Shoe Covers	☐ Head covers
☐ Boots	☐ N 95 (HEPA)	☐ Eye protection	☐ Double gloves
☐ Lab coats	☐ Face shield	☐ Disposable outers	☐ N100 (HEPA)
☐ Other (Specify:)			

2. Indicate the protective equipment you will use. Please check the applicable boxes.

☐ Automatic pipettors	☐ Safety blender
☐ Low aerosolization pipette tips	☐ Chemical fume hood
☐ Centrifuge with safety cups	☐ Biological safety Cabinet
☐ Other (Specify.)	

3. Indicate the type of Biological Safety Cabinet(s) (BCS) you intend to use. Please check applicable box.

   ☐ Class II A (recirculating)
   ☐ Class II B1 (70% exhausted – ducted outside)
   ☐ Class II B2 (100% exhausted – ducted outside
   ☐ None
   ☐ Other (Specify:)

Is the biological safety cabinet(s) certified annually? Please choose answer from dropdown menu. Provide dates of most recent certification if answer is "Yes".

N/A

Dates

Note: Research activities involving BSL4 containment are currently prohibited on the TAMU Campus.

E. Transport

Will there be any transport in or out of your laboratory of contaminated materials, including those from human, animal, and plant sources, that present potential hazards for personnel or environment? Choose Yes or No from dropdown menu. Complete table if answering "Yes".

N/A

Type of material	Potential hazard	Anticipated transport (from – to)	Packaging/handling precautions

- All transport must meet requirements of state, federal, and University policies.
- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for transport information.
- Contact the Office of Environmental Health & Safety for instructions regarding all **Select Agent** transport.

F. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

1. Indicate the type of waste that will be generated and indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste (see next page for suggested temperature and exposure times).

Type of waste	Potential hazard	Decontamination/sterilization/disposal procedures
Liquids		
Solids		
Glassware		
Biological Materials		
Animals		

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guideline are:

Liquids *121°C (250°F) 1 hour, (each gallon)*
Laundry *121°C (250°F) 30 minutes*
Trash *121°C (250°F) 1 hour*
Glassware *121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

a. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.
   - ☐ I give assurance that the method indicated above will be used.
   - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.
   a. ☐ The autoclave is departmentally operated
      Contact name:_____ Phone No: _____
      Building Location: Building No.: _____/Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)
   b. ☐ The autoclave is individually operated (supervised by Principal Investigator)
      Building Location: Building No.: _____Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

3. A commercially available test indicator kit that uses bacterial spores (Bacillus stearothermophilus) is the recommended method of testing autoclave efficiency.
   a. Please give assurance that you will use the recommended method or provide scientific rationale for using an alternate method.
      - ☐ I give assurance that the method indicated above will be used.
      - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

4. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.
   - ☐ I give assurance that the method indicated above will be used.

- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for more information on disposal of hazardous materials or instructions regarding **Select Agent** disposal.

FOR INTERNAL USE ONLY

IBC # _____

PART III
Use of Pathogens

Complete this part if your work will involve the use of pathogens.

A. Identification of Pathogens Used

1. List all pathogens used in your laboratory.

Pathogen – generic name	Genus, species	Strain	Risk group*	BSL*

*See **Appendix 1** for determination of risk group and Biosafety level.

2. Acquisition and storage – list all sources for each pathogen. (example: vendor, private/off campus laboratory, clinical specimen, other – specify)

Pathogen	Source(s)	Storage location(s) – building name, number, and room number	Use location(s) – building name, number, and room number

B. Laboratory Procedures

1. Briefly describe in lay terms the experimental procedures using pathogens.

2. Do you intend to culture any pathogens? Choose "Yes" or "No" from dropdown menu. Complete table if answering "Yes."

N/A

Organism	Greatest concentration/volume expected on hand at any one time	If inactivated or lysed before experimental manipulations, specify method

3. Will any experimental procedures result in acquisition of new characteristics such as enhanced virulence, infectivity, drug resistance, or change in host range?

☐ No.
☐ Yes. Explain.

4. Which experimental manipulations do you intend to use that have a potential for generating aerosols or splashes? Type an "X" in the applicable box. Select the biosafety containment level for each from the dropdown menu.

☐ Homogenization	N/A	☐ Centrifugation	N/A
☐ Sonication	N/A	☐ Pipetting	N/A
☐ Dissection	N/A	☐ Other (Specify:)	N/A

C. Medical Risks

1. Describe health risks associated with the use of all pathogens used in your laboratory and list the symptoms/disease that may occur.

Agent	Health risks/symptoms/disease/target organ(s)

2. What are the treatment options/plans available in case of a potential exposure to pathogens?

3. Do any of the pathogens you intend to work with require pre-project serum samples, immunization, medical monitoring, and/or health surveillance (e.g. Orthopoxvirus vaccination)?

☐ No.
☐ Yes. Describe the health monitoring and/or immunization program that will be employed for safe conduct of your protocol.

4. Is antibiotic resistance expressed with any pathogen(s) used?

☐ No.

☐ Yes. Indicate the specific antibiotic resistance that is expressed.

Pathogen	Antibiotic resistance(s)

5. Is there a process in place to inform personnel of potential hazards of working with pathogens and of increased risks of infection for individuals with immunocompromised/immunosuppressed conditions? Please check the applicable box.

☐ No

☐ Yes. Describe the informational process(es).

D. Exposure Control

1. Indicate the personnel protective equipment you will use. Please check the applicable boxes.

☐ Face Mask ☐ Gloves ☐ Shoe Covers ☐ Head covers

☐ Boots ☐ N 95 (HEPA) ☐ Eye protection ☐ Double gloves

☐ Lab coats ☐ Face shield ☐ Disposable outers ☐ N100 (HEPA)

☐ Other (Specify:)

2. Indicate the protective equipment you will use. Please check the applicable boxes.

☐ Automatic pipettors ☐ Safety blender

☐ Low aerosolization pipette tips ☐ Chemical fume hood

☐ Centrifuge with safety cups ☐ Biological safety Cabinet

☐ Other (Specify:)

3. Indicate the type of Biological Safety Cabinet(s) (BSC) you intend to use. Please check the applicable boxes.

☐ Class II A (recirculating)

☐ Class II B1 (70% exhausted – ducted outside)

☐ Class II B2 (100% exhausted – ducted outside

☐ None

☐ Other (Specify:)

Is the biological safety cabinet(s) certified annually? Please check the applicable box.

☐ No.

☐ Yes. Provide date(s) of most recent certification.

Note: Research activities involving BSL 4 containment are prohibited on the TAMU Campus.

E. Transport

Will there be any transport in or out of your laboratory of infected/contaminated materials, including those from human, animal, and plant sources, that present potential hazards for personnel or environment? Please choose "Yes" or "No" from the dropdown menu. Complete table if answering "Yes."

N/A

Type of material	Potential hazard	Anticipated transport (from – to)	Packaging/handling precautions

- All transport must meet requirements of state, federal, and University policies.
- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for transport information.
- Contact the Office of Environmental Health & Safety for instructions regarding all **Select Agent** transport.

F. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

Will your work generate infected/contaminated waste materials, including those from human, animal and plant sources that present potential hazards for personnel or environment? Please choose "Yes" or "No" from the dropdown menu. Complete table if answering "Yes."

N/A

1. Indicate the type of waste that will be generated and indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste (see next page for suggested temperature and exposure times).

Type of waste	Potential hazard	Decontamination/sterilization/disposal procedures
Liquids		
Solids		
Glassware		
Biological Materials		
Animals		

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guideline are:

Liquids	*121°C (250°F) 1 hour, (each gallon)*
Laundry	*121°C (250°F) 30 minutes*
Trash	*121°C (250°F) 1 hour*
Glassware	*121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

a. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.
   - ☐ I give assurance that the method indicated above will be used.
   - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.
   a. ☐ The autoclave is <u>departmentally</u> operated
      Contact name:_____ Phone No.: _____
      Building Location: Building No.: _____ Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)
   b. ☐ The autoclave is <u>individually</u> operated (supervised by Principal Investigator)
      Building Location: Building No.: _____ Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

3. A commercially available test indicator kit that uses bacterial spores (Bacillus stearothermophilus) is the recommended method of testing autoclave efficiency.
   a. Please give assurance that you will use the recommended method or provide scientific rationale for using an alternate method.
      - ☐ I give assurance that the method indicated above will be used.
      - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

4. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.

   ☐ I give assurance that the method indicated above will be used.

- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for more information on disposal of hazardous materials or instructions regarding **Select Agent** disposal.

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IBC # _____

PART IV
Use of Recombinant DNA

Complete this part if your work will involve the use of rDNA.

Please mark the appropriate box if your research falls into any of the following categories:

☐ **Section III-F-1.** Those that are not in organisms or viruses.

☐ **Section III-F-2.** Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

☐ **Section III-F-3.** Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

☐ **Section III-F-4.** Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

☐ **Section III-F-5.** Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), *Major Actions*). See Appendices A-I through A-VI, *Exemptions Under Section III-F-5--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt from the *NIH Guidelines*.

☐ **Section III-F-6.** Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-6* for other classes of experiments which are exempt from the *NIH Guidelines*.

☐ **N/A.** Please check this box if your research does not fall into one of the aforementioned categories.

A. Biological System Identification

1. Host-Vector System(s): The vectors and cells used for propagation of rDNA.

Complete the following table.

Host cells – genus, species, strain	If E. coli, indicate if it is a K12 strain (Yes or No)	Vector(s)	DNA source organism	Gene(s)	Function of gene(s) and/or hazards of exposure/contamination
	N/A				
	N/A				
	N/A				
	N/A				
	N/A				

2. Viral Vectors

a. Is a viral vector being used? (Choose the applicable answer from the dropdown menu and follow instructions.0

N/A

b. What is the viral vector system being used?

c. Is the virus replication competent? (Please check the applicable box.)

☐ No. Answer questions **d** and **e**.
☐ Yes. Answer question **f**.

d. Describe the genome organization of the viral vector. Include information about what genes or genome regions have been removed. Indicate what percent of the original viral genome remains in the vector.

e. The possibility of homologous recombination with endogenous viruses exists. Indicate the reversion rate and the recombination event of such a possibility. Describe methods you will use to ensure that replication competent viruses are excluded.

f. Are assay systems used to measure the titer of replication competent viruses that may be present? N/A

3. Target System(s): The biological system into which the rDNA is introduced for functional assessment. Complete the following table.

Target system –organism, cell line, phage, virus, etc	Describe any anticipated clinically significant side effects to genetic alteration(s) including acquired drug resistance	Risk group*	BSL*

*See **Appendix 1** for determination of risk group and Biosafety level.

B. Biological Containment

1. List all laboratory and containment locations.

Location(s) of storage and use: building name, number, and room number	rDNA(s) used/stored at this location	Security measures – room locks, container locks, BSC, etc	BSL

2. Do you intend to perform environmental testing or release of genetically altered target(s)? Please check applicable box.

☐ No.
☐ Yes. Complete the following table.

Target System	Testing/Release Plan*	Containment Plan

* If field testing is planned, attach appropriate permits.

C. Cloning of toxic products

Will there be deliberate cloning of genes for toxic products? Please choose applicable box.

☐ No.
☐ Yes. Complete the following table.

Toxin Product	LD 50 of Toxin

D. Medical Risks

Does your work with rDNA involve any human health risks? (Please check the applicable box.)

☐ No.
☐ Yes. Complete the following table.

rDNA used	Health risks	Have personnel been informed of health hazards and appropriately trained?	Is employee health surveillance needed?

E. Transport

Will there be any transport in or out of your laboratory of genetically altered materials, including those from human, animal, and plant sources, that present potential hazards for personnel or environment? (Please check the applicable box.)

☐ No.
☐ Yes. Complete the following table.

Type of material	Potential hazard	Anticipated transport (from – to)	Packaging/handling precautions

- All transport must meet requirements of state, federal, and University policies.
- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for transport information.
- Contact the Office of Environmental Health & Safety for instructions regarding **Select Agent** transport.

F. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

1. Indicate the type of waste that will be generated and indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste (see next page for suggested temperature and exposure times).

Type of waste	Potential hazard	Decontamination/sterilization/disposal procedures
Liquids		
Solids		
Glassware		
Biological Materials		
Animals		

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guideline are:

Liquids	*121°C (250°F) 1 hour, (each gallon)*
Laundry	*121°C (250°F) 30 minutes*
Trash	*121°C (250°F) 1 hour*
Glassware	*121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

a. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.
   - ☐ I give assurance that the method indicated above will be used.
   - ☐ Other (Please attach an explanation and include scientific rationale for the use of an alternative method)

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.

   a. ☐ The autoclave is <u>departmentally</u> operated
      Contact name:_____ Phone No.: _____
      Building Location: Building No.: _____/Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

   b. ☐ The autoclave is <u>individually</u> operated (supervised by Principal Investigator)
      Building Location: Building No.: _____/Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

3. A commercially available test indicator kit that uses bacterial spores (Bacillus stearothermophilus) is the recommended method of testing autoclave efficiency.
    a. Please give assurance that you will use the recommended method or provide scientific rationale for using an alternate method.
        ☐ I give assurance that the method indicated above will be used.
        ☐ Other (Please attach an explanation and include scientific rationale for the use of an alternative method.)

4. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.
    ☐ I give assurance that the method indicated above will be used.

- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for more information on disposal of hazardous materials or instructions regarding **Select Agent** disposal.

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IBC # _____

ATTACHMENT A
Use of Live Animals

Complete this attachment if your work involves the use of live animals.
Note: Use of live animals also requires approval by the Institutional Animal Care and Use Committee (IACUC). Contact IACUC at (979) 845-1828 or AnimalCompliance@vprmail.tamu.edu .

I. Use of Biological Toxins in Live Animals

A. Will you use biological toxins in live animals? Please check applicable box.

☐ No. Go to **Part II of this attachment**.
☐ Yes. Complete the following tables and questions.

B. List all toxins used on animals.

Toxin	Source organism	Recipient animal	Amount (Conc/vol)	Route	Anticipated effect(s) on animal	Excretion route

C. Where will you house and work with animals receiving toxins?

Animal	Toxin	All housing/procedure sites at which treated animals may be present – building #/room #

D. How will toxin-treated animals be identified (cage cards, tattoos, etc)?

E. Which of the following animal sources (if any) present exposure risks to the research staff and/or animal care personnel? Please check the applicable boxes.

☐ None ☐ Feces/Urine ☐ Bedding
☐ Saliva ☐ Blood ☐ Animal carcasses/tissues
☐ Animal bite/scratch ☐ Other (Specify.)

II. Use of Pathogens in Live Animals

A. Will you use pathogens in live animals? Please check applicable box.

☐ No. Go to **Part III of this attachment**.
☐ Yes. Complete the following tables and questions.

B. List all pathogens used in animals.

Pathogen	Recipient animal	Amount (Conc/vol)	Route	Anticipated effect(s) on animal	Excretion route

C. Where will you house and work with animals receiving pathogens?

Animal	Pathogen	List all housing/procedure sites where treated animals may be present – building name, number, and room number

D. How will infected animals be identified (cage cards, tattoos, etc.)?

E. Which of the following animal sources (if any) present exposure risks to the research staff and/or animal care personnel? Please check the applicable boxes.

☐ None ☐ Feces/Urine ☐ Bedding
☐ Saliva ☐ Blood ☐ Animal carcasses/tissues
☐ Animal bite/scratch ☐ Other (Specify.)

III. Use of Genetically Modified Animals

A. Will you obtain genetically modified animals from a **non-commercial** source (private laboratory, other academic institution, individual, etc.) or **perform genetic alterations** on live animals? Type an "X" in place of the applicable box.

☐ No. Please complete Sections IV. and V. of this attachment.
☐ Yes. Complete the following tables and questions.

B. List genetically modified species.

Species	Source –if obtained off campus	Genetic alteration(s)	Anticipated clinically significant side effects

C. Where will you house and work with genetically modified animals?

Animal	Genetic Strain	List all housing/procedure sites where treated animals may be present – building name, number, and room number

D. What measures are in place to assure containment of genetically altered animals?

IV. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

A. Indicate the type of waste that will be generated and indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste (see suggested temperature and exposure times).

Type of waste	Potential hazard	Decontamination/sterilization/disposal procedures
Liquids		
Solids		
Glassware		
Biological Materials		
Animals		

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guideline are:

Liquids	*121°C (250°F) 1 hour, (each gallon)*
Laundry	*121°C (250°F) 30 minutes*
Trash	*121°C (250°F) 1 hour*
Glassware	*121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

1. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.
   ☐ I give assurance that the method indicated above will be used.

☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

B. Autoclaves should be tested before being placed into service and then periodically for effectiveness.

1. ☐ The autoclave is departmentally operated
   Contact name:_____ Phone No.: _____
   Building Location: Building No.: _____/Room No.: _____
   a. Indicate testing frequency:
      ☐ Minimum - 1 time per week (BL3)
      ☐ Minimum - 1 time every other week (BL2)
      ☐ Minimum - 1 time per month (BL1)
      ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

2. ☐ The autoclave is individually operated (supervised by Principal Investigator)
   Building Location: Building No.: _____Room No.: _____
   a. Indicate testing frequency:
      ☐ Minimum - 1 time per week (BL3)
      ☐ Minimum - 1 time every other week (BL2)
      ☐ Minimum - 1 time per month (BL1)
      ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

C. A commercially available test indicator kit that uses bacterial spores (Bacillus stearothermophilus) is the recommended method of testing autoclave efficiency.

1. Please give assurance that you will use the recommended method or provide scientific rationale for using an alternate method.
   ☐ I give assurance that the method indicated above will be used.
   ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

D. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.
   ☐ I give assurance that the method indicated above will be used.

- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **ehsd@tamu.edu** for more information on disposal of hazardous materials or instructions regarding **Select Agent** disposal.

V. Animal Disposition Upon Termination of Project

☐ Sold
☐ Returned to colony, herd or owner
☐ Transferred to another project (Note AUP# & PIs Name: _____)

- [ ] Other (please specify: _____)
- [ ] Euthanized (please answer below):
    - [ ] Rendered (No restrictions on use)
    - [ ] Incinerated
- [ ] Biodigested
- [ ] Other (please specify: _____)

FOR INTERNAL USE ONLY

IBC # _____

ATTACHMENT B

Use of Human Subjects and/or Materials

Complete this attachment if your work will involve human subjects, cell lines, and/or materials.
Note: Use of human subjects, cell lines, and/or materials also requires approval by the Institutional Review Board (IRB). Contact the IRB office at (979) 458-4067 or IRB@tamu.edu.

I. Use of Biological Toxins in Humans/Human Materials

A. Will you use biological toxins in human subjects, cell lines or unfixed tissues? Please check applicable box.

☐ No. Go to **Part II of this attachment.**
☐ Yes. Complete the following tables and questions.

B. List all toxins used in humans or human materials.

Toxin	Source organism	Recipient type	Amount (Conc/vol)	Route	Anticipated effect(s) on human subjects – if applicable	Excretion route – if any

C. Where will you administer toxins to humans/human materials?

Recipient type	Toxin	All locations at which toxins will be administered – building name, number, and room number

D. Which of the following (if any) present exposure/contamination risks to the research staff and/or human subjects? Please check the applicable boxes.

☐ None ☐ Feces/Urine ☐ Blood ☐ Unfixed tissues
☐ Cell culture plates/media ☐ Saliva ☐ Other (Specify.)

II. Use of Pathogens in Humans/Human Materials

A. Will you use pathogens in human subjects, cell lines or unfixed tissues? Please check applicable box.

☐ No. Go to **Part III of this attachment.**
☐ Yes. Complete the following tables and questions.

B. List all pathogens used in humans or human materials.

Pathogen	Recipient type	Amount (Conc/vol)	Route	Anticipated effect(s) on human subjects – if applicable	Excretion route – if any

C. Where will you administer pathogens to humans/human materials?

Recipient type	Pathogen	All locations at which pathogens will be administered – building name, number, and room number

D. Which of the following (if any) present exposure/contamination risks to the research staff and/or human subjects? Please check applicable boxes.

☐ None ☐ Feces/Urine ☐ Cell culture plates/media ☐ Blood
☐ Saliva ☐ Body fluids other than blood
☐ Other (Specify). ☐ Unfixed tissues

III. Use of rDNA in Humans/Human Materials

A. Will you obtain genetically modified human cell lines from a **non-commercial** source (private laboratory, other academic institution, individual, etc)? Please check applicable box.

☐ No. Go to question **C**.
☐ Yes. Complete the following table.

B. List all genetically modified cell lines.

Cell line description/name	Source	Genetic alteration(s)	Method(s) of secure storage

C. Will you perform genetic alterations on human subjects and/or human cell lines? Please check applicable box.

☐ No. Go to question **E**.
☐ Yes. Complete the following table.

D. List all genetically altered cell lines or human subjects.

Target – cell line(identify) or human subject	Source – if using cell line(s)	Genetic alteration(s)	Method(s) of secure storage – altered cell lines

E. Which of the following (if any) present exposure/contamination risks to the research staff and/or human subjects? Please check the applicable boxes.

☐ None ☐ Feces/Urine ☐ Cell culture plates/media ☐ Blood
☐ Saliva ☐ Body fluids other than blood
☐ Other (Specify). ☐ Unfixed tissues

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IBC # _____

ATTACHMENT C
Use of Plants

Complete this attachment if you will use genetically modified plants or induce genetic modifications in plants.

See NIH Guidelines for *Research Involving Recombinant DNA Molecules* for information on biological containment requirements. The following sections identify the physical containment requirements and related requirements to experiment with plant rDNA: Sections III-D-5 and Section II-E-2, entitled *Experiments Involving Whole Plants*, and Section IV-B-4, *Plant, Plant Pathogen, or Plant Pest Containment Expert*.

In addition, Appendix P, entitled *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, identifies the Biosafety levels and the requirements for each level.

I. List all genetically modified plants used in your laboratory, information about the types of genetic modifications being produced and all locations for storage and use (**complete both tables**).

PLANT NAME	SOURCE OF ORGANISM(S) DNA TO BE INTRODUCED	HOST AND VECTOR SYSTEMS USED IN CONSTRUCTION?	STORAGE AND USE LOCATION(S)		
			BLDG. NAME	BLDG. NO.	ROOM NO.

PLANT NAME	WILL THE INTRODUCED GENES BE EXPRESSED? (choose "Yes" or "No" from the dropdown menu)	IF SO, WHAT PROTEINS WILL BE PRODUCED?	ARE THERE ANY KNOWN ADVERSE EFFECTS OF THIS PROTEIN? (Answer "Yes" or "No"; If "Yes", explain)
	N/A		N/A
	N/A		N/A
	N/A		N/A
	N/A		N/A
	N/A		N/A

II. From the dropdown menu, choose the Biosafety level required for containment of your most hazardous work.

N/A

III. Does your research facility meet the requirements for the indicated Biosafety level (as defined in Appendix P on the NIH Guidelines *Physical and Biological Confinement for rDNA Research Involving Plants*)? Please check applicable box.

☐ No. Please explain.
☐ Yes.

IV. Describe the physical and/or biological containment practices for all genetically modified plants used in your laboratory. Describe practices to ensure control of altered plants and undesirable species (e.g., weed, rodent, arthropod pests and pathogens).

Plant name	BSL	Containment/control practices

V. Do you plan to field test any transgenic plant or plant inoculated with a modified virus? Please check applicable box.

☐ No. No planned field work testing or release is scheduled.
☐ Yes. Submit a copy of APHIS* permit for field testing.

* Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at ehsd@tamu.edu for assistance in obtaining release forms.

VI. Describe how experimental organism(s) (i.e., transgenic plants and hosts/vectors used in their construction) will be rendered biologically inactive before disposal.

A. Disposal, Autoclave Testing, Autoclave Efficacy and Recordkeeping

1. Indicate the type of waste that will be generated and indicate the methods and laboratory procedures that are in place for decontamination and disposal of contaminated waste (see next page for suggested temperature and exposure times).

Type of waste	Potential hazard	Inactivation/Decontamination/Sterilization/Disposal Procedures
Liquids		
Solids		
Glassware		
Biological Materials		
Other		

Suggested temperatures and exposure times for autoclaving from NIH Biohazards Guideline are:

Liquids *121°C (250°F) 1 hour, (each gallon)*
Laundry *121°C (250°F) 30 minutes*

Trash	*121°C (250°F) 1 hour*
Glassware	*121°C (250°F) or 160°C (320°F) 1 hour to 4 hours (dry heat)*

a. Please provide assurance that you will use the guidelines listed above or provide scientific rationale for using an alternate method.
   - ☐ I give assurance that the method indicated above will be used.
   - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

2. Autoclaves should be tested before being placed into service and then periodically for effectiveness.
   a. ☐ The autoclave is <u>departmentally</u> operated
      Contact name:_____ Phone No_____
      Building Location: Building No.: _____/Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)
   b. ☐ The autoclave is <u>individually</u> operated (supervised by Principal Investigator)
      Building Location: Building No.: _____Room No.: _____
      i. Indicate testing frequency:
         - ☐ Minimum - 1 time per week (BL3)
         - ☐ Minimum - 1 time every other week (BL2)
         - ☐ Minimum - 1 time per month (BL1)
         - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

3. A commercially available test indicator kit that uses bacterial spores (Bacillus stearothermophilus) is the recommended method of testing autoclave efficiency.
   a. Please give assurance that you will use the recommended method or provide scientific rationale for using an alternate method.
      - ☐ I give assurance that the method indicated above will be used.
      - ☐ Other (Please attach explanation and include scientific rationale for the use of an alternative method)

4. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the <u>date of treatment</u>, the <u>amount of waste treated</u>, the <u>method/conditions of treatment</u>, and the <u>printed name</u> and <u>initials of the person performing the treatment</u>. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.
   - ☐ I give assurance that the method indicated above will be used.

- Contact the Office of Environmental Health & Safety at (979) 845-2132 or by email at **chsd@tamu.edu** for more information on disposal of hazardous materials or instructions regarding select agent disposal.

FOR INTERNAL USE ONLY

IBC # _____

ATTACHMENT D
Personnel Information

Personnel List

Each Principal Investigator is responsible for submitting one (1) Personnel List per laboratory permit. List must include Principal Investigator.

Name of Personnel	Location of Laboratory		Position/Title (Role in study)	Email Address	Will personnel be working with Select Agents? *Yes* or *No*
	Building	Room			

FOR INTERNAL USE ONLY

IBC # _____

ATTACHMENT D
Personnel Information

Signature Page

By my signature below, I certify that I have read and understand the laboratory security and emergency policies and procedures for working with _____ in laboratory building _____ and room(s) _____ under the direction of_____.

I further certify that I understand the hazards of working with _____; the indications of infection or intoxication by this biological material; the reporting system for potential exposure and accidents; how to seek evaluation and therapy; the standard microbiological practices for this laboratory; the special Biosafety practices required for Biosafety level _____ work, in accordance with the Biosafety in Microbiological and Biomedical Laboratories Guidebook and the standard operating procedures for this laboratory.

Finally, I certify that any transfer of this biological material will be done in accordance with TAMU policies and regulations and under the supervision of the TAMU Office of Environmental Health and Safety Department. In addition, I ensure that the detailed records of information necessary to account for all activities related to this agent will be maintained.

_____ _____

Signature Date

_____ _____

Printed name Position/Title

Have you undergone training for this specific laboratory and materials?

☐ **Yes** ☐ **No**

_____

Date and location of training

_____

Email address

_____ _____

Laboratory director/Supervisor's signature Date

_____

Laboratory director/Supervisor's printed name

(Please reproduce this page as needed to cover all personnel.)

APPENDIX 1
Definitions of Risk Group and Biosafety Level(s)

Please keep the following information for your records.

As researchers, it is extremely important to consider all the possible health risks (real and theoretical) associated with the use of infectious agents. The result of careful planning prior to the initiation of a project using these agents will allow the researcher to select the proper physical containment application(s) (referred to as Biosafety Levels), thereby decreasing the risk of an accidental exposure to the staff, general public, and the environment. Therefore, one of the top priorities of a researcher should be to familiarize him/herself with the terminology and definitions commonly applied to these two important areas – Risk and Containment. These definitions are provided for you below.

Risk Group is classified into four categories (according to NIH Guidelines for Research Involving Recombinant DNA Molecules):

- **Risk Group 1 (RG1)** agents are not associated with disease in healthy adult humans.
- **Risk Group 2 (RG2)** agents are associated with human disease, which is rarely serious, and for which preventive or therapeutic interventions are often available.
- **Risk Group 3 (RG3)** agents are associated with serious or lethal disease for which preventive or therapeutic interventions may be available.
- **Risk Group 4 (RG4)** agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Biosafety Level is classified into the following groups (according to the Biosafety in Microbiological and Biomedical Laboratories guidebook):

- **Biosafety Level 1 (BL1)** is suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.
- **Biosafety Level 2 (BL2)** is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, (2) access to the laboratory is limited when work is being conducted, (3) extreme precautions are taken with contaminated sharp items, and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.
- **Biosafety Level 3 (BL3)** is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents, which may cause serious or potentially lethal disease as a result of exposure, by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents. All procedures are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.
- **Biosafety Level 4 (BL4)** is required for work with dangerous and exotic agents, which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Restrictions apply to personnel training, lab accessibility and construction, and the use of protective equipment and clothing. There is No BSL4 facility at Texas A&M University.

INSTITUTIONAL BIOSAFETY COMMITTEE
AMENDMENT FORM

INSTRUCTIONS

Complete the following form if you need to make changes in your approved Texas A& M University Institutional BioSafety Committee (IBC) Permit. This form should be used to request approval for changes to the original permit (e.g., addition or deletion of personnel, changes in procedures or in the use of Biological Toxins, Pathogens, rDNA, Live Animals, Human and/or Human Materials, Plants or Select Agents).

Please check the portion of the Amendment Form that applies to your proposed revisions, and provide a description of the proposed changes. You should provide the same level of detail, including justifications, for amendment requests that would be included on an *Application for IBC Permit* form. **Only typed forms will be processed for review**. In addition, please provide the modified section of the *Application for IBC Permit.*

If your permit includes the use of SBAT and the amendment proposes changes to procedures relating to their use or handling, you will also need to complete the following steps:

1. Contact the BSO and have him/her complete a Safety Pre-Review Form to determine the impact of the proposed changes. This form should be submitted with your Amendment Form.
2. Complete the Safety, Security and Incident Response Plan Review Form (Part II–A) and include it with your Amendment Form submission. In order to complete this form, you will need to do the following:
    a. Review the Incident Response Plan and determine what, if any, changes need to be made to accommodate the amendment. Send a copy of the plan with revisions highlighted with the amendment application.
    b. Review the Security Plan and determine what, if any, changes need to be made to accommodate the amendment. Send a copy of the plan with revisions highlighted with the amendment submission.
    c. Review the Safety Plan and determine what, if any, changes need to be made to accommodate the amendment. Send a copy of the plan with revisions highlighted with the amendment application.
3. Assist Office of Research Compliance in completing the APHIS/CDC Form 1. The ORC will contact you after you have submitted your applications for assistance, if necessary.

Please submit your completed Amendment Form and required documentation to the Institutional BioSafety Program (IBSP) compliance office via campus mail at MS 1186.

If you have any questions, please contact the IBSP compliance office at (979) 458-3624 or IBC@vprmail.tamu.edu.

IBC Permit Amendment Form

Amendment Number: (To be Assigned by IBC)
_____

TEXAS A&M UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE

AMENDMENT FORM

Date:

_____

Investigator: _____

Department: _____

Mail Stop: _____

IBC Permit #: _____

1. **CHANGES REQUESTED.** Please select all that apply **and** complete the applicable section of the IBC permit found at http://researchcompliance.tamu.edu/ibc/ibcrevapp. Submissions that do not include the applicable section will be considered incomplete and will not be processed.

   Additionally, please provide a description of the proposed revisions requested in Section 2 on Page 2 of the Amendment Form.

   ☐ Part I: Investigator Identification

   ☐ Part I: Risk Assessment

   ☒ Part I: Investigator Assurance

   ☐ Part II: Use of Biological Toxins

   ☐ Part II-A: (SBAT Only) Safety, Security and Incident Response Plan Review Form
   ☐ (SBAT Only) Copies of Safety, Security and Incident Response Plans with revisions highlighted

   ☐ Part III: Use of Pathogens

   ☐ Part IV: Use of Recombinant DNA

   ☐ Attachment A: Use of Live Animals

   ☐ Attachment B: Use of Humans and/or Human Materials

   ☐ Attachment C: Use of Plants

   ☒ Attachment D: Personnel Information

Investigator: _____

IBC Permit #: _____

2. **DESCRIPTION OF PROPOSED CHANGES.** Please provide a detailed description of the proposed changes, including justification. Provide the same level of detail requested in the original IBC Permit.

3. _____ _____
SIGNATURE - PRINCIPAL INVESTIGATOR **DATE**

****FOR COMMITTEE USE ONLY****

☐ The Proposed Amendment has been reviewed and approved by the IBC.

☐ The Proposed Amendment has been denied by the IBC (Action: _____) .

☐ The IBC Acknowledges PI's request to terminate protocol.

_____ _____
Signature Date

_____ _____
Signature Date

IBC Annual Review Form

ANNUAL REVIEW FORM

INSTRUCTIONS

The following Annual Review must be completed and returned for consideration by the Institutional Biosafety Committee (IBC). Please be aware that under IBC procedures you must have this approval renewed each year and a complete review is required every 3 years during the term of your experimental study. Triennial Reviews (3rd year) will require the submission of a "new" application. The IBC bases the review dates on the approval date of the original application. The IBC office will notify you by e-mail of the protocol number that needs review.

If you have any questions, please contact the IBC office at 979/458-3624.

Please return the form to the Institutional Biosafety Committee at Mail Stop 1186. The original document with original signature must be submitted for approval. **Only typed forms will be processed for review.**

TEXAS A&M UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE

ANNUAL REVIEW FORM

1. **PRINCIPAL INVESTIGATOR IDENTIFICATION**

Name _____ **Date** _____

Department _____ **Campus Mail Stop** _____

Office location (building, room number) _____

Laboratory location(s) (building, room number (s)) _____

Address _____ _____ _____
City State Zip

Phone _____ _____ _____
Office Laboratory Emergency/after hours

Fax _____ **Email** _____

2. **A. LIST ALL FUNDING SOURCES**

B. RESEARCH ADMINISTRATOR (check all that apply):

☐ TAMU ☐ Research Foundation ☐ TEES ☐ TAES ☐ Other: _____

3. **PROTOCOL STATUS.** Please indicate by marking the status of this project.

Request Protocol Continuance
A. ☐ Active - project ongoing.
B. ☐ Currently inactive - project was initiated but is presently inactive.
C. ☐ Inactive - project was never initiated but anticipated start date is _____.
D. ☐ Inactive - project pending sponsor award.

Request Protocol Termination
E. ☐ Inactive - project never initiated.
F. ☐ Currently inactive - project initiated but project has not/will not be completed.
G. ☐ Completed - no further research will be done.

Investigator:

IBC Permit #:

4. **PROBLEMS/ADVERSE EVENTS (THIS QUESTION MUST BE ANSWERED)**

If the status of this project is 3A (Active - project ongoing) or 3B (Project was initiated, but is presently inactive), describe any unanticipated adverse events and how these problems were resolved. If NONE, this should be indicated.

5. **PROPOSED CHANGES**

Any proposed changes (e.g. investigator, agent, location, acquisition, storage, medical risk, transport, or disposal) in Parts I through VI and Attachments A through D of the IBC application must be reported in writing to the IBC for approval. Committee approval of the proposed changes is required prior to proceeding with the revised research protocol.

Check all boxes that apply. If no changes are planned, an approved Annual Review authorizes the continuation of the project, as previously approved by IBC. ***If minor changes are planned, please enclose a completed Amendment requesting the modifications. If major changes are planned, please enclose a revised application to address the remainder of the protocol's proposed research.***

Part I: Principal Investigator Identification
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Part II: Risk Assessment
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Part III: Investigator Assurance
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Part IV: Use of Biological Toxins
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Part V: Use of Pathogens
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Part VI: Use of Recombinant DNA
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Attachment A: Use of Live Animals
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Attachment B: Use of Humans and/or Human Materials
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Attachment C: Use of Plants
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Attachment D: Personnel Information
☐ Not applicable ☐ No changes ☐ Minor changes ☐ Major changes

Investigator:

IBC Permit #:

6. LAB CERTIFICATION AND RISK GROUP IDENTIFICATION

Based on your approved application, please indicate the following:

BioSafety Level Risk Group Level

Are there any changes to the BSL noted above? ☐ No ☐ Yes
If you answered 'yes', please describe:

Are there any changes to the RGL noted above? ☐ No ☐ Yes
If you answered 'yes', please describe:

7. RECERTIFICATION OF THE PRINCIPAL INVESTIGATOR

Signature certifies that the investigator will continue to conduct this research in accordance with the BMBL guidelines, Section IV-B-7 of the NIH guidelines, and the TAMU Environmental Health & Safety guidelines found at http://finance.tamu.edu/ehsd/resources/biosafety.asp. [Signature further certifies that the proposed work does not unnecessarily duplicate previous experiments.]

_____ _____
Signature - Principal Investigator Date

****FOR COMMITTEE USE ONLY****

Inspections

Date of last laboratory inspection by EHSD _____

Date of last autoclave inspection by EHSD _____

IBC Adverse Event and Non-Compliance Reporting Form

IBC - Adverse Event and Non-Compliance to *NIH Guidelines* Reporting Form

File this report within 24 hours of the event with the Biosafety Officer or with the IBC through the Office of Research Compliance. This form is used to report research-related adverse events only.

Type of event A = Adverse Event NC = Non- Compliance	**Date of event**	**Location of Event**	**Bio-hazardous agent involved**	**Nature of the event** (e.g., exposure, spill, etc)
Below, please include a description of the events that occurred				

Exposure risk to people and the environment

Action taken:

Report submitted by:_____ **Date:**_____

For Official Use only:

Date received:_____

Institutional Action Taken:_____

_____ _____

Institutional Biosafety Officer or IBC Chair Date

Select Agent Specific Forms

FOR INTERNAL USE ONLY

IBC # _____

PART II-A
Safety, Security and Incidence Response Plan Review
(For use with SBAT Amendment Applications)

Instructions

Carefully review the Safety, Security and Incident Response Plans currently in place to determine whether additional measures, considering proposed changes, are necessary to ensure the safety and security of all persons. If changes are need, revise the plans. In your Amendment Application packet, you should include a copy of all plans with any changes highlighted.

Part I – Safety Plan

Date of Review –

Based on my review of this plan and the amendment being proposed, I have determined the following:

☐ The current Safety Plan is sufficient to accommodate the changes proposed by the amendment and does not need to be revised. Include copy of plan in the Amendment Application packet.

☐ The current Safety Plan must be revised to accommodate the changes proposed by the amendment. Include a copy of the revised plan with changes highlighted in the Amendment Application packet.

Part II – Security Plan

Date of Review –

Based on my review of this plan and the amendment being proposed, I have determined the following:

☐ The current Security Plan is sufficient to accommodate the changes proposed by the amendment and does not need to be revised. Include copy of plan in the Amendment Application packet.

☐ The current Security Plan must be revised to accommodate the changes proposed by the amendment. Include a copy of the revised plan with changes highlighted in the Amendment Application packet.

Part III – Incident Response Plan

Date of Review –

Based on my review of this plan and the amendment being proposed, I have determined the following:

☐ The current Incident Response Plan is sufficient to accommodate the changes proposed by the amendment and does not need to be revised. Include copy of plan in the Amendment Application packet.

☐ The current Incident Response Plan must be revised to accommodate the changes proposed by the amendment. Include a copy of the revised plan with changes highlighted in the Amendment Application packet.

Part IV – Certification

I have carefully reviewed and considered the Safety, Security and Incident Response Plans as they relate to the changes proposed to this IBC permit. In order to protect all persons, I have made any necessary changes. I have also attached a copy of the plans to be followed upon approval of this amendment. Any changes made to the plans are highlighted.

_____ _____

Lab Director's Signature **Date**

TEXAS A&M UNIVERSITY
VICE PRESIDENT FOR RESEARCH - OFFICE OF RESEARCH COMPLIANCE

SBAT PERSONNEL CHANGES

Date:_____
Laboratory Director: _____
Lab Location: _____

_____
Signature of Lab Director

A. Please complete the following section if REMOVING personnel:

Last Name	First Name	CDC UIN	Reason for removal

B. Please complete the following section if ADDING personnel or MODIFYING the name of personnel. In addition, please attach FBI form 961 with Sections III and IV completed:

Last Name *(If modifying, include Previous Last Name)*	First Name	Birth date (mm/dd/yyyy)	Building number(s)	Lab/Room numbers(s)	Identify Role: (e.g. research assistant, researcher, visiting scientist)	Email address	*If transferring, please indicate the name of the originating institution

***NOTE:** *If adding personnel or modifying the name of personnel who are already approved at another institution, FBI FD-961 form must still be completed. We will also need to know their Security Risk Assessment (SRA) approval date and number.*

CONFIDENTIAL

Training Certification

Trainer(s): _____

_____

The following employee(s) received training regarding _____(e.g., safety, security, lab procedures, incident response and reporting)

Name	Please sign to indicate that you understood the training and have no questions	Date

The following information represents the topics covered:

_____
_____
_____
_____
_____
_____
_____

Include enough details to indicate the information covered and the method used to assess understanding.

FEDERAL BUREAU OF INVESTIGATION
BIOTERRORISM PREPAREDNESS ACT: ENTITY / INDIVIDUAL INFORMATION

Section I: Entity Information (Identical to that indicated on the CDC or APHIS registration application)

Legal Name of Entity: Texas A&M University

2. Address: (**Not** a post office box) Street: 1112 TAMU | City: College Station, | State: Texas | Zip Code: 77843-1112

3. Type of Entity:

☑ Public ☐ Government

☐ Other (i.e. Non-Profit, Private Academic, and Commercial)

*** **Indicate if you are a ☐ corporate officer, ☐ board of director, and/or ☐ stock holder.**

Section II: Individual Information

4. Full Name (Last, First, Middle) 4a. Aliases/Maiden Name:	5. Date of Birth (Month, Day, Year)	6. Social Security Number
7. Residence Address: (No., Street, City, State, Zip Code)		8. Sex: ☐ Male ☐ Female
9. Place of Birth (City, State or Foreign Country) *If not born in the United States please complete questions on page 2 titled Foreign Born Information.	10. Race: ☐ White ☐ Black or African ☐ Hispanic or Latino ☐ Asian/ Native Hawaiian ☐ American Indian or Alaska Native ☐ Pacific Islander	
11. Unique Identifier Number (Supplied by APHIS or CDC):		
12. Certifications (All questions must be answered "Yes" or "No" in the box provided) *Title 18 Section 1001 of the U.S. Code provides that knowingly falsifying or concealing a material fact is a felony that may result in fines or imprisonment for not more than 5 years or both.		
12a. Are you under indictment or information in any court for a felony, or any crime, for which the judge could imprison you for more than one year? ☐ Yes ☐ No	12b. Have you been convicted in any court for a crime, for which the judge could have imprisoned you for more than one year, even if you received a shorter sentence including probation? ☐ Yes ☐ No	
12c. Are you a fugitive from justice? ☐ Yes ☐ No	12d. Are you an unlawful user of any controlled substance (as defined in Section 102 of the Controlled Substance Act [21 U.S.C. 802])? ☐ Yes ☐ No	
12e. Have you ever been adjudicated as a mental defective or been committed to any mental institution? If yes, a complete copy of medical records regarding the commitment will be required. ☐ Yes ☐ No	12f. Are you an alien illegally or unlawfully in the United States? ☐ Yes ☐ No	
12g. Are you an alien who has been lawfully admitted for permanent residence or a naturalized citizen? If yes, please complete page 2 of the application. ☐ Yes ☐ No	12h. Have you been discharged from the Armed Services of the United States under dishonorable conditions? ☐ Yes ☐ No	
I certify that the above answers are true, correct and complete. I understand that the making of a false oral or written statement is a crime. Signature		Date:

Foreign Born Information

This page must be completed by any individual answering YES to question 12g of page 1. All questions **MUST** be answered. Be sure to include all alien or admission numbers for question 9.

13. Country of Citizenship:

14. Mother's Full Name:

15. Father's Full Name:

16. Date of Entry to the United States:

17. Place of Entry:

18. Immigration Status at Entry:

19. Current Immigration Status:

20. Date Status Expires, if Applicable:

21. Alien Number or Admission Number (9-11 digits):

Alien registration numbers are issued by the Bureau of Immigration and Customs Enforcement for individuals who are granted permanent legal resident or a naturalized citizen status in the U.S. Other situations that individuals would have an alien registration number include the following: Employment Authorization cards, Temporary Resident cards, Border Crossing cards, I-94 or Visa numbers. If this number is not available please provide an explanation. If born to US citizen serving a military or diplomatic post in a foreign country please provide a copy of the US born abroad birth certificate.

Section III: Consent

By signing this form, I hereby authorize the U.S. Department of Justice to obtain any information relevant to assessing my suitability to access, possess, use, receive or transfer select agents and toxins from any relevant source, including, but not limited to, individuals, public sources, and government sources. This information may include, but is not limited to, biographical, financial, law enforcement and intelligence information.

I further authorize any individuals having information pertinent to such an assessment to release such information to a duly accredited representative of the U.S. Department of Justice. The authorization set forth in this paragraph is valid for five (5) years from the date on which this form is signed.

I further authorize the U.S. Department of Justice to disclose any records, results or information relating to, or obtained in connection with, my security risk assessment to: the U.S. Department of Agriculture; the Department of Health and Human Services; any agency contractors assisting in the determination of risk; and responsible officers or other appropriate personnel of pertinent entities.

I further authorize the release of records, results or information relating to, or obtained in connection with my security risk assessment to any law enforcement or intelligence authority or other federal, state or local entity with relevant jurisdiction where such information reveals a risk to human, animal and/or plant health or national security.

I further authorize disclosure of records results or information relating to, or obtained in connection with my security risk assessment to organizations or individuals, both public and private, if deemed necessary, in the sole discretion of the U.S. Department of Justice, to elicit information or cooperation from the recipient for use in assessing my suitability to access, possess, use, receive or transfer select agents and toxins.

I further authorize release of records, results or information relating to, or obtained in connection with my security risk assessment to laboratories, universities, individuals, or other entities, both public and private, responsible for making security assessments, employment and/or licensing determinations and suitability or security decisions when the information is relevant to an assessment of my suitability to access, possess, receive, use, or transfer agents or toxins

I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecution or other legal action.

_____ _____

PRINTED NAME DATE

_____

SIGNATURE

GUIDANCE DOCUMENT FOR REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

A select agent or toxin may only be transferred under the conditions described in 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to transfer. Upon receipt of a transfer request (APHIS/CDC Form 2) from the intended recipient, the sending entity's Responsible Official (RO) or facility director must obtain approval from APHIS or CDC prior to transfer of a select agent or toxin. To request approval, the sender must submit this form (APHIS/CDC Form 2) to either APHIS (facsimile: 301-734-3652) or CDC (facsimile: 404-718-2096).

PURPOSE

The purpose of this form is to request prior authorization of a transfer of select agent(s) or toxin(s) and to provide a method for the documentation of the transfer. The form must be completed for each transfer of select agents or toxins and maintained for three years.

INSTRUCTIONS

Prior to transferring a select agent or toxin:

(A) Recipient Responsibilities:

1. Completes Section A and blocks 30 (including strain designation if known) and 37 (information should match the information submitted for the entity's certificate of registration). The recipient's RO then sends the form to the sender.
2. Transfer of select agents or toxins may require the intended recipient to obtain a valid USDA and/or PHS permit prior to the transfer (See 7 CFR Part 330.200, 9 CFR Part 122.2, and 42 CFR Part 71.54) The application and instructions for obtaining USDA transport or import permits are available through the APHIS website at: http://www.aphis.usda.gov/vs/ncie/ or the PPQ website at: http://www.aphis.usda.gov/ppq/permits/ or by calling 301-734-5960. The application and instructions for obtaining PHS import permits are available through the CDC website at: http://www.cdc.gov/od/ohs/biosfty/imprtper.htm or by calling 404-718-2077.
3. For importation of select agents, the recipient's RO completes Sections A and B as instructed; completes Sections C and D for sender, placing the "APHIS Permit Number or PHS Permit Number" in block 3 of the form; and transmits the form via facsimile to APHIS (FAX: 301-734-3652) or CDC (FAX: 404-718-2096).

(B) Sender Responsibilities:

1. Completes Section B and blocks 31-36. If known, please provide characterization of agent (e.g., strain designation, GenBank Accession number, publication citation, molecular characterization data, etc.). Provide additional information on attached sheet if needed. The sender's RO or facility director transmits the form via facsimile to APHIS (FAX: 301-734-3652) or CDC (FAX: 404-718-2096).
2. Clinical and diagnostic laboratories that transfer select agents and toxins after identification (See 7 CFR 331, 9 CFR 121, and 42 CFR 73) are required to submit this form for approval prior to transferring the select agent or toxin to a registered entity (see also APHIS/CDC Form 4, "Report of the Identification of a Select Agent or Toxin").

(C) APHIS/CDC Responsibilities: APHIS or CDC will FAX the form back to the sender and/or recipient with an approval authorization number after verification of the information on the form.

After authorization of transfer:

(A) Sender Responsibilities: Must ship the material to the recipient only after the sender has received the approval authorization number from APHIS or CDC. The approval authorization number will be **valid for only 30 days** after issuance. If the sender has a suspicion that the agent may not be used for the requested purpose, then the sender should consult with APHIS or CDC prior to the transfer. The sender completes blocks 38-40. Select agents and toxins must be packaged, labeled, and shipped in accordance with all federal and international regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents and toxins being shipped. A copy of the completed form must be maintained for 3 years.

(B) Recipient Responsibilities: Upon receipt of the shipment, the recipient's RO must complete blocks 41 and 42 and FAX or mail the form to both the sender's RO and APHIS or CDC **within 2 business days of receipt**. The recipient's RO must immediately report to APHIS or CDC and complete APHIS/CDC Form 3, "Report of Theft, Loss, or Release of Select Agents and Toxins", if the select agent or toxin has not been received within 48 hours after the expected delivery time or the package received containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred. A copy of the completed form must be maintained for 3 years.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or the CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

REQUEST TO TRANSFER SELECT AGENTS AND TOXINS (APHIS/CDC FORM 2)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the report. Answer all items completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096

FOR APHIS/CDC USE ONLY

APHIS/CDC AUTHORIZATION NUMBER: _____

DATE: _____ **INI:** _____ **EXP DATE:** _____

SECTION A – RECIPIENT (REQUESTOR) INFORMATION			
1. Entity name:	2. Entity registration number:	3. a. APHIS Permit #: b. US PHS#:	
4. Recipient name (authorized personnel) First: MI: Last: Signature:	5. Date:	6. Phone:	7. FAX:
8. Principal investigator name (if different from line above) First: MI: Last: Signature:	9. Date:	10. Phone:	11. FAX:
12. Responsible Official name First: MI: Last: Signature:	13. Date:	14. Phone:	15. FAX:
SECTION B – SENDER (TRANSFEROR) INFORMATION			
16. Entity name:	17. ☐ Entity registration number: _____ ☐ Clinical/diagnostic laboratory ☐ Other: _____		
18. Sender name First: MI: Last: Signature:	19. Date:	20. Phone:	21. FAX:
22. Principal investigator name (if different from line above) First: MI: Last: Signature:	23. Date:	24. Phone:	25. FAX:
26. Responsible Official name First: MI: Last: Signature:	27. Date:	28. Phone:	29. FAX:

FOR APHIS/CDC USE ONLY

APHIS/CDC AUTHORIZATION NUMBER: _____

DATE: _____ **INI:** _____ **EXP DATE:** _____

SECTION C – LIST OF SELECT AGENTS AND TOXINS SHIPPED (attach additional sheets if necessary)

	RECIPIENT	**SENDER**					
	30. Select agent or toxin:	31. Characterization of agent or toxin (*see instructions*):	32. Number of vials:	33. Form (e.g., powder/liquid/ slant):	34. Vol or wt per vial (e.g., ml, mg):	35. Total quantity:	36. Concentration/ vial (e.g., 10^8 cfu/ml):
a							
b							
c							
d							
e							
f							
g							
h							
i							
j							
k							
l							
m							

37. Proposed Use: ☐ Research ☐ Diagnostics ☐ Production ☐ Storage Only ☐ Other (explain):

SECTION D – SHIPPING INFORMATION (attach additional sheets if necessary)

38. Number of primary receptacles per outer package:____ Number of outer packages: _____ Carrier waybill (tracking) #(s):

39. Sender (Responsible Official or Facility Director) ensures select agents or toxins listed in section C were shipped First: MI: Last: Signature:	40. Date shipped:
41. Recipient (Responsible Official) ensures select agents or toxins listed in section C were received First: MI: Last: Signature:	42. Date received:

AGENT VERIFICATION FORM

Agent/Species _____

Location: Building # _____ **Room#** _____ **Freezer/Cabinet I.D.** _____

Date	Container Label	Location Box/Slot	Conc/Sample Size	On Inventory List	On Access Log	Amount/ Location Verified	Discrepancy Justification (Lost, Stolen, Wasted, Transferred[1])

[1] If transferred, enter the quantity transferred, date of transfer, and to whom transferred.

Revised: 07/08/05

R.O. / A.R.O. _____

Monthly Select Agent BioSafety Security Program Report
Month _____ Year _____

This report will be completed monthly by the BSO and submitted to the RO by the 10th of the following month. The purpose of this report is to notify the RO of the following:

(1) inspections completed during the month
(2) findings and action items documented as a result of inspections
(3) any safety or security issues identified
(4) incidents

Part I – Inspections and Findings Summary*

Inspection Date	Location/Lab Inspected	Principle Investigator	Number and Type of Items Reviewed	Number of Findings	Response Due Date

* A copy of all inspection reports must accompany this summary report

Part II – Safety and/or Security Issues Identified

Inspection Date	Location/Lab Inspected	Principle Investigator	Safety or Security Issue Identified

Part III – Incident Summary**

Incident Date	Location/Lab	Principle Investigator	Brief Description of Incident	External Reporting Required?	Date External Report Issued

** A copy of all incident reports, both internal and external, must accompany this summary report

Part IV – Distribution

This report and all supporting documents will be issued to the following:

1 – Responsible Official (RO)
2 – Director of Research Compliance
3 – Institutional BioSafety Program Coordinator***

*** The IBSP Coordinator will distribute the complete report to all IBC members at the next regularly scheduled meeting and to the IBC Chair upon receipt.

Part V - Certification

The above information accurately summarizes the activities and findings of the Select Agent BioSafety Security Program. All reports indicated above have been filed and distributed according to the BioSafety Program Standard Operating Procedures #602.

_____ _____

Signature, BioSafety Officer Date

Incident Tracking Number:_____

SBAT Incident Tracking Sheet

Date _____/time_____ Received by Mail____ Email___ Phone____

Notified by:_____

Lab Director/Principal Investigator	Incident Type (Check one)	Location of Incident
	Theft: _____ Loss: _____ Release: _____	Building:_____ Room(s)_____

Summary of the incident:

Initial notification by ORC			Follow up Notification by ORC			Follow up Notification by ORC		
Initial all that apply:	Date/Time	Type of contact (Mail, Email, Phone)	Initial all that apply:	Date/Time	Type of contact (Mail, Email, Phone)	Initial all that apply:	Date/Time	Type of contact (Mail, Email, Phone)
___ RO			___RO			___ RO		
___CDC			___CDC			___CDC		
___BSO			___BSO			___BSO		
___PI			___PI			___PI		
___UPD			___UPD			___UPD		
___HSC			___HSC			___HSC		
___Other			___Other			___Other		

Document Submitted/Received

Document Type	Date Submitted	Date Received	CC's
Form 3			
CDC Response			
Updated Security Plan			
Updated Safety Plan			
Updated Incident Plan			
Other_____			
Other_____			

SBAT Incident tracking sheet must be attached to each incident file.
Version: 7/26/2007

Inspection Procedures for Select Agent Inventories

On an annual basis, the RO or his designee will authenticate the Agent Access Log using the following process:

Using the Agent Verification Form the RO or his designee will randomly check inventories of select agents and toxins to verify the accuracy of such records. Ten (10) % of available cultures will be checked to determine that inventory records, including agent access records, are accurate. In cases where large stocks are present, the inspector may choose less than 10%, but no fewer than ten (10). Each inspection shall require the use of an Agent Verification Form and must be signed by the RO or his designee. Any discrepancies, including extra or unaccounted for agents, will be reconciled by the PI in collaboration with the RO or his designee. The results of the reconciliation will be accounted for and documented on the Agent Verification Form. A copy of the completed form will be provided to the PI with the original on file with the RO or his designee.

A ENT ACCESS LOG – WRITE LEGIBLY

Agent/Characteristics _____

Location: Building #_____ **Room#**_____ **Freezer/Cabinet I.D.**_____

Date *(mm/dd/yy)*	**Container Label** *(e.g. Containers Vials, Tubes, etc)*	**Source** *(e.g. Clinical, Environ-mental, or Other)*	**Purpose of Use** *(Research-R, Destruction-D Transport-T)*	**Concentration/ Sample Size**	**Agent Removal**		**Method of Removal**	**Return to Storage**	
					Amount Removed (Qty)	**Removed by Whom**		**Amount Returned (Qty)**	**Returned by Who**

[1] If transferred, enter the quantity transferred, date of transfer, and to whom it was transferred.

Select Agent Templates

BIOSAFETY PLAN/
STANDARD OPERATIONAL PROCEDURES TEMPLATE
for

Location of Laboratory
Room Number(s)
COLLEGE STATION, TX

PI: PI's name

The Department of Health and Human Services (HHS) has issued a final rule regarding possession, use, and transfer of Select Agents and toxins (42 CFR Part 73). The final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is designed to protect public health and safety.

42 CFR 73 requires that an individual or entity required to register, must develop and implement a written safety plan. The plan must be written in a manner that is commensurate with the risk of the agent or toxin, given its intended use. The Biosafety Plan/Standard Operational Procedures must contain sufficient information and documentation to describe the Biosafety and containment procedures.

The Biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.*, physical structure and features of the entity, and operational and procedural safeguards).

The CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL), including all appendices, will be used when developing Biosafety plans/Standard Operational Procedures.

All DOJ Authorized Persons accessing areas with Select Agents or visiting facilities with Select Agents will adhere to the safety and security standards set forth in this plan so as to ensure that the requirements of Title 42, CFR, Part 73 are met. Additionally, all DOJ Authorized Persons will complete the required training and certifications prior to entering areas with Select Agents.

This Biosafety Plan/Standard Operational Procedures will be reviewed at least annually and revised as necessary to ensure that it is adequate for current conditions and consistent with other facility-wide policies and procedures.

Drills or exercises will be conducted at least annually to test and evaluate the effectiveness of this plan. This plan will be reviewed and revised, as necessary, after any drill or exercise and after any incident

Entry Procedures:

By using the BMBL, please enter the entry procedures for your particular laboratory. The follow is merely an example:

Sign up to use the BSL-3 by writing your name, date, and time of entry into the suite on the dry erase board located in lab location, room lab room number.

Before entering the BSL-3 suite, the operator must first enter all details required in the Facility Access Log book outside the anteroom (name, date, time in). If the individual is not DOJ approved, they must be escorted by a DOJ approved personnel. The escort must also provide an entry in the Facility Access Log book.

Once inside the anteroom the operator dons a laboratory gown/coat and 2 pairs of gloves.

Biosafety Cabinet Use:

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

Before working in the Biosafety cabinet, the UV light is turned off, the fluorescent light is switched on, and a biohazard bag, a paper towel, a Wexide squeeze bottle and a fresh absorbent sheet (if needed) are placed in the cabinet.

All materials needed to complete the experiment are placed in the cabinet to limit the number of times hands pass through the air barrier. Equipment is not to be placed on the intake grills at the front of the cabinet, nor blocking the exhaust opening at the back of the cabinet.

The outer (second) pair of gloves is always removed before withdrawing hands from the biosafety cabinet. A new outer pair of gloves is then donned before proceeding with other work in the BL-3.

A biohazard bag should be present in the cabinet. Absorbent material (such as paper towels) is placed in the bottom of the biohazard bag. This bag is used for discarding solid waste (gloves, plastic waste, pipette tips). Once the bag is full, it is closed, wiped with Wexide and taken out of the cabinet to be collected into a larger covered waste container next to the cabinet.

Liquid waste should be put into a special container inside the biosafety cabinet with sufficient concentrated hypochlorite bleach to achieve a final concentration of not less than 10% and allowed to react overnight before disposal. Wipe the outside of the container with Wexide or 10% chlorine bleach before removing it from the cabinet. The liquids are then disposed of down the sink using large amounts of water.

Contaminated pipettes and plastic inoculating loops should be submerged in a container filled with the appropriate concentration of Wexide solution. The contaminated pipette tray must remain in the hood until the operator is ready to autoclave it.

Anything removed from the BSC during the work session is to be decontaminated by wiping with Wexide while still in the BSC. Ethanol (70%) is then used to remove the Wexide.
At the end of each work session, culture tubes, DNA tubes, racks and other material to be removed from the cabinet are decontaminated by wiping with Wexide while still within the cabinet. Ethanol (70%) is then used to remove the Wexide.

The absorbent sheet and other absorbent materials used during cleaning along with the gloves are placed into a biohazard bag while still within the cabinet. The bag is closed with autoclave tape while still in the cabinet. Wipe the outside of the bag with Wexide. Do not twist or tie the bag as it will blow open in the autoclave. Place the bag into a larger covered waste container next to the cabinet.

A fresh pair of gloves is donned and the hood is now wiped down completely with Wexide followed by 70% ethanol (the ethanol serves to remove the Wexide). Nothing should be left in the Biosafety cabinet when leaving the facility.

All tissue or cell culture related materials should be disposable whenever possible. Only disposable plastic pipettes and plastic inoculating loops are to be used in the BSL3 lab.

Exiting Procedures:

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

If autoclaving is necessary, the operator is to follow autoclaving procedures detailed below.

Once done with working outer gloves are removed and put in the general biohazard container. The inner pair of gloves must be removed in the anteroom.

Finally, you must wash and dry your hands with microbicidal soap before exiting the anteroom.

The operator exits through the outer door and notes his/her time out in the log book.

Decontamination Procedures:

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

All waste material leaving the BSL3 facility must first be autoclaved for at least an hour except for the liquids decontaminated with bleach as noted above.

A double-door autoclave is located in the laboratory next to the anteroom.

Do not autoclave materials containing chlorine bleach, volatile chemicals or radioactive materials.

On a monthly basis, Wex-cide 128 (1 gal) will be poured down floor drains to ensure periodic decontamination. A record of this activity will be documented and maintained by the laboratory manager.

Decontamination Procedures for Spills

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

- *Allow aerosols to settle in the room*
- *Dress in protective clothing (e.g., lab coat, gloves)*
- *Gently cover spill with paper towels and apply 1% sodium hypochlorite (bleach), starting at perimeter and working towards the center*
- *Allow sufficient contact time (30-60 min) before clean up*
- *Decontaminate all wastes before disposal: autoclave*
- *Spill procedure notice displayed in suite*

Personnel Protective Equipment

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

1. When in the lab location, worker must wear protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls. Any clothing that

is reusable must be decontaminated before being laundered. Clothing must be changed when overtly contaminated.

2. Gloves must be worn in lab locationwhen handling any materials, animals, and equipment contaminated with Agent.

3. It is recommended that when in lab location, personnel frequently change their gloves, along with hand washing. Disposable gloves must never be reused.

4. In lab location, all manipulations of materials infected with Agent, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III Biological safety cabinet.

5. When a procedure or process in lab location cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) must be used.

6. Personnel working in lab location are required to utilize respiratory and face protection when in rooms containing infected animals.

Long-term Inventory Records:

All long term inventory records will be kept on the document Agent Access Log, which will be maintained in the laboratory. Inventory will be reconciled *(how Often and describe the process)*

Special Practices:

By using the BMBL, please enter the entry procedures for your particular laboratory. The following is merely an example:

All doors are kept locked.

Dr. enter PI's name controls access to the suite.

Laboratory personnel receive appropriate training and instruction on the potential hazards associated with work in the laboratory, along with the necessary precautions to be taken.

As part of an Occupational Health Plan, workers with access to Agent will participate in a periodic serologic analysis for response to Agent. A serologic sample will be taken prior to work with virulent Agentas a baseline sample. Scott and White Clinics, the Occupational Health Plan provider, will notify workers of reportable serologic responses. Personnel will be advised of the opportunity to

consult with Scott and White clinicians about the relationship between serological titer, clinical disease, and treatment options. Personnel reporting to the PI with clinical symptoms consistent with acute symptoms associated with exposure/infection will be advised of the opportunity to consult Scott and White clinicians.

All personnel working with Agent in lab location have demonstrated proficiency in standard microbiological practices and techniques as well as practices specific to the laboratory.

Incident Response:

The Incident Response Plan will be utilized in conjunction with the University Crisis Management Plan in the event of an emergency.

Note to the PI: Your plan should be detailed enough to ensure the safe handling of the agent and operation of the lab. Please modify the template so that it covers all areas of lab safety and your lab SOP

CONFIDENTIAL

SECURITY PLAN

TEXAS A&M UNIVERSITY
FACILITIES AND RESEARCH LABORATORIES WITH SELECT AGENTS

Principal Investigator's Name
Location of the facility
Month & Year of Plan

Responsible Official:
Richard E. Ewing, Ph.D.
Vice President for Research

The Department of Health and Human Services (HHS) has issued a final rule regarding possession, use, and transfer of Select Agents and toxins (42 CFR Part 73). The final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and is designed to protect public health and safety.

42 CFR 73 requires that an individual or entity required to register, must develop and implement a written security plan. The security plan must be sufficient to safeguard the Select Agent or toxin against unauthorized access, theft, loss, or release. The plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the Select Agent or toxin.

All DOJ Authorized Persons accessing areas with Select Agents or visiting facilities with Select Agents will adhere to the safety and security standards set forth in this plan so as to ensure that the requirements of Title 42, CFR, Part 73 are met. Additionally, all DOJ Authorized Persons will complete the required training and certifications prior to entering areas with Select Agents. Each individual with DOJ authorized access to a Select Agent will be familiar with security and emergency procedures. Their knowledge and understanding will be documented.

All DOJ Authorized Persons must understand and comply with the security procedures. Each individual with access to a Select Agent will adhere to this plan to minimize opportunities for accidental or intentional unauthorized removal of any Select Agent.

This security plan will be reviewed by faculty and laboratory directors at least annually and revised as necessary to ensure that it is adequate for current conditions and consistent with other facility-wide policies and procedures. This could involve a check of keys, locks and alarms.

Drills or exercises will be conducted at least annually to test and evaluate the effectiveness of this security plan. This plan will be reviewed and revised, as necessary, after any drill or exercise and after any incident.

Principal investigators and laboratory supervisors responsible for laboratories and other facilities where select agents are used or stored must adopt these procedures and develop a security plan that is

facility-specific. Both safety and security experts should be consulted in the evaluations and development of individual facility-specific recommendations.
This security plan includes the following major components:

a) Physical Security;
b) Information Systems Control;
c) Personnel Security;
d) Access Control;
e) Inventory Control;
f) Shipping, Receiving, & Transferring Select Agents;
g) Incident Reporting & Breaches in Security;
h) Emergency Response Plan;
i) Policies that address Breaches in Security;

Note: Any deviations to the above approved plans must be requested in writing by the Principal Investigator and approved in advance by the Responsible Official or his designated Alternate Responsible Official.

A. Physical Security:

The physical security systems have been tailored to address site-specific characteristics and requirements, ongoing programs, operational needs, and to achieve acceptable protection levels using current technology. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Biosafety Plan**. Safety and security experts must be involved in any evaluations and development of security recommendations.

- Each BSL-3 laboratory shall post entry requirement procedures. All visitors shall follow the facilities entry requirements.

- A background check and/or security risk assessment (SRA) is required before new employees are assigned to the facility or laboratory area. Guests must be escorted or cleared for entry using the same procedures as for regular workers.

- Before entering the laboratories, check the reading of the room pressure monitor. Do not enter the laboratory if the monitor indicates a red light. If the monitor indicates a red light (negative room pressure), the laboratory director must be contacted immediately. Laboratory personnel must verify that the direction of the airflow is going into the BSL-3 laboratory. Read and follow all entry procedures. Biohazard door signs, entry requirements and procedures must be posted.

- Entry into the facility is restricted to DOJ Authorized Personnel. All persons entering the BSL-3 facility must be advised of the potential biohazards and informed of laboratory procedures.

- Keep facility and laboratory doors closed at all times to prevent unauthorized entry. Establish procedures for securing the laboratory, room, or area when approved individuals (under HHS 42 CFR part 73.8, e.g., card access system, key pads, locks, etc.) are not present

- When no one is present, lock facility and laboratory doors.

- DOJ Authorized Persons are always required to swipe their ID card when entering and leaving the suite, even if the door has already been opened by another user. DOJ Authorized Persons are also responsible for making sure that non-authorized persons do not enter the laboratory after an authorized person has opened the door with a card key. **SHARING OF CARD ACCESS AND/OR ENTRY CONTROLS BY ANY INDIVIDUAL IS NOT PERMITTED.**

- Access to BSL 3 labs to those who do not have written authorization to enter the suite is not permitted. Visitors must sign in and out in the lab log book and must be escorted at all times by an authorized individual. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents. Visitors who are not United States citizens are required to have written authorization before entering labs.

- Proper training of all staff (including students) that uses the BSL3 suite will be provided by **Principal Investigator**.

- Laboratories, facilities, and storage equipment (refrigerators, freezers, cabinets, incubators, and other containers) that contain a Select Agent need to be separate from the public areas of the buildings.

- Select Agents and toxins requiring freezers, refrigerators, cabinets, and other containers where they are stored will be secured against unauthorized access (e.g., card access system, lock boxes, etc.).

- Lock all equipment (e.g. freezers, cabinets, incubators, scintillation counters) that contain hazardous materials and are locked in hallways or areas outside of facilities or laboratories.

- Laboratories, storage areas, and equipment (e.g. freezers, refrigerators, cabinets, etc.) will be locked when the Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are not in direct view of authorized staff (e.g. when located in unattended storage areas).

- Protocols for changing access numbers or locks following staff changes are included in the **Biosafety Plan**.

- Emergency contact signs will be placed on facility and laboratory doors, including 24-hour contact numbers. Emergency contact signs include the names and contact information such as work telephone and alternate telephone numbers of the Principal Investigator, Biosafety Officer, and the person(s) responsible for the building or facility. Also, included are telephone numbers for the University Police Department and College Station Fire Department. (Emergency contact information is found in the **Incident Response Plan**.)

B. Information Systems Control:

The facility will systematically integrate cyber security into management and work practices at all levels so that missions are accomplished while protecting electronic information and electronic information systems. This is to be accomplished through effective integration of cyber security management into all facets of work planning and execution. The overall management of

cyber security functions and activities will become an integral part of mission accomplishment. If sensitive electronic data are present in the facility or laboratory, information technology specialists should assess the security of hardware and software products in addition to the security of local area networks. Hard copies of security sensitive records (e.g., inventory records, etc.) will be properly secured and accessed only by individuals with authorized access approval (under HHS 42 CFR part 73.8). Information Services will be used as a resource for data security.

C. Personnel Security:

Only DOJ Authorized Persons (cleared by the US Department of Justice as indicated in HHS 42 CFR Part 73.8) will have access to Select Agents. These policies are required for compliance with the HHS/CDC and USDA regulations for Select Agents. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Biosafety Plan**.

- All visitors shall be escorted in the BSL-3 facility by a DOJ Authorized Person. Visitors must sign in and out in the Facility Access Log. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- DOJ Authorized Persons will receive laboratory safety and security training when initial DOJ Select Agent access approval is granted; annually thereafter and when new requirements are implemented. Visitors will receive laboratory safety and security training prior to the first entry to a secured area or laboratory containing Select Agents; annually thereafter and when new requirements are implemented. Additionally, as the Principal Investigator, I will mentor and assess scientific/lab skills with persons working within their labs on an ongoing basis. All training should be documented on the Security and Safety Training Certificate.

- All other individuals, including maintenance workers and visitors, understand security requirements will be trained and equipped to follow established procedures.

- Below is a description of the minimum education and experience criteria for DOJ Authorized Persons with access to Select Agents or toxins, physical security, and cyber security.
  Describe the minimum education and experience criteria here:

  Enter any additional requirements specific for your laboratory.

  - All DOJ Authorized Persons, as well as workers and new employees, will be known to facility and laboratory personnel.

  - All DOJ Authorized Persons approved for access to Select Agents (including students) will wear a visible identification badge that includes, at a minimum, a photograph, the wearer's name, and an expiration date.

  - Visitors should be issued an identification badge including their name and an expiration date.

  - Visitors will be escorted at all times when in an area where Select Agents are present.

- Police, fire, and other emergency responders will be informed as to the types of biological materials that are in use in the laboratory areas.

- Security procedures will be reviewed whenever an incident occurs or a new threat is identified.

    - Procedures for reporting and removing unauthorized persons are described in the **Incident Response Plan**.

- Approach any visitors that appear wandering in the facility or laboratory areas and ask if you can help direct them. Suspicious or unexplained behavior will be reported immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and Responsible Official or designee as described in the **Incident Response Plan**.

D. Access Control:

Standard Operating Procedures, establishing the following requirements, at minimum, to control access to areas where hazardous materials are used and stored, or outlined in the **Biosafety Plan**, and the **Incident Response Plan**.

- Provide provisions that allow unescorted access only to DOJ Authorized Persons (HHS 42 CFR Part 73.8) who are performing a specifically authorized function during hours required to perform the defined job.

- It is best to use the "buddy system" when working with hazardous materials in a facility or laboratory. However, if it is necessary to work in the facility or laboratory alone during non-routine hours, let someone know where you will be and how long you expect to be in the facility or laboratory. Arrange for someone to check on you at least hourly.

- Only DOJ Authorized people (workers, students, visiting scientists, etc.) required to perform a job should be allowed in a facility or laboratory and animal housing areas at hours (when laboratory employees are present) required to perform their particular job (including routine cleaning, maintenance, repairs, and delivery to outside shipping agent for transportation in commerce).

- Access during non-routine work hours should be limited to authorized personnel. Allow individuals not approved for access (HHS 42 CFR Part 73.8) from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, and other activities not related to Select Agents or toxins only when continually escorted and monitored by approved individuals (Part 73.8). Access for routine cleaning, maintenance, and repairs should be limited to hours when DOJ Authorized Persons are present. DOJ Authorized Persons must maintain visual contact with the visitor(s) at all times. At no point, may a visitor(s) be left unattended while in secured areas or laboratories containing Select Agents.

- Maintain a logbook to record entries of all visitors, maintenance workers, repairmen, and others needing one-time or occasional entry into an area where Select Agents are present. The means of identification should include a current valid picture driver's license or state identification card or passport. This information should be documented on the Facility Access Log.

- Provide provisions for the control of access to containers where Select Agents (stocks of biological agents, hazardous chemicals or radioactive materials) are stored by requiring laboratories, storage areas, equipment, freezers, refrigerators, cabinets, and other containers where stocks of Select Agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of a DOJ Authorized Person (e.g. when located in unattended storage areas), and by using other monitoring measures as needed. Access control to areas where Select Agents are present could include card access (preferred), combination keypad, use of lock boxes to secure materials, video surveillance cameras, etc. A protocol for periodically changing combination keypad access numbers should be developed.

- Maintain a current list of authorized persons who possess door keys or those who have knowledge regarding the keypad access numbers or the security entry system.

- Each DOJ Authorized Person is prohibited from sharing with any other person their unique means of accessing a Select Agent or toxin (e.g., keycards or passwords).

- Procedures for loss or compromise of keys, passwords, combinations, change of authorization, reassignment of personnel, or staff changes are described below:

  Enter specific procedures for loss or compromise of keys, passwords, combinations, change of authorization, reassignment of personnel, or staff changes that are specific to your labortatory.

E. Inventory Control:

The Responsible Official and/or Responsible Official's designee will maintain records created in pursuance to Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121 and will implement a system to ensure that such records are accurate and that the authenticity of records may be verified. Standard Operating Procedures establishing the following requirements, at minimum, are described in the **Biosafety Plan**. Records will be maintained for a period of three (3) years in accordance with Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121. If the select agent is also registered with USDA, the following will be referenced: "USDA Security Policies and Procedures for Biosafety Level-3 Facilities", http:/www.usda.gov/ocio/directives/DM/DM9610-001.htm. Standard Operating Procedures establishing the following requirements, at minimum, have been included in the **Biosafety Plan.**

At minimum, records should include:

1) The name of the agent (scientific and common name and strain where applicable);
2) Amount (number of vials or contains inventoried);
3) Biosafety Level, agent type;
4) Storage location;
5) Site of usage (building and room numbers);
6) Storage methods and conditions (refrigerator, freezer type, etc.);
7) Date of change of status (i.e. removal, change of custody, transfers, etc.);
8) Disposition (including shipping) when removed from inventory;
9) Method, amount, and date of destruction (when applicable);
10) Scientist with contact information (telephone number and address of researcher or diagnostician).

- Access to Select Agent inventory will be limited to Enter the Principal Investigator and a designated alternate. Both enter Principal Investigator and the designated alternate must be a DOJ Authorized Person. An Authorized Person will then record removal, placement and/or access data into the inventory record in accordance with Title 42, CFR, Part 73, Title 7, CFR Part 331 and Title 9, CFR, Part 121. The Principal Investigator and/or the designated alternate will maintain and document the current and accurate inventory of each Select Agent held on the Agent Verification Log, which shall be secured at all times and viewed only by DOJ approved personnel.

- Enter Principal Investigator must provide requirements and procedures for the termination of the use of a Select Agent or toxin in this **Security Plan**.

- Any working cultures that become new repository stocks must be added to the inventory. New pathogens (not already in inventory) identified in diagnostic or experimental samples or generated through recombinant technologies must be added to the repository and inventory database.

- Scientists are responsible for the accuracy of databases and laboratory records, which are subject to review by their supervisor, director, and authorized personnel. .

F. Shipping, Receiving, & Transferring Select Agents:

All shipping, receiving, and transfers (internal & external) of Select Agents will meet the provisions set forth in HHS 42 CFR Part 72 and Part 73.14. If the Select Agent is also registered with USDA, reference "USDA Security Policies and Procedures for Biosafety Level-3 Facilities." Standard Operating Procedures establishing the following requirements, at minimum, are listed below:

- **Note:** *Shipments must be packed by a DOT/IATA trained and certified person. Environmental Health and Safety Department (EHS, 845-2132) will be contacted for assistance before arranging shipments in or out of campus.*

  Only persons trained and certified for dangerous goods shipping will pack or ship infectious materials. Certificates of completion of DOT/IATA training must be made available upon request.

  Infectious substances affecting humans and animals will be stored in locked freezers. The agents will be packaged for shipment according to DOT/IATA regulations and shipped by freight handlers under supervision of their dangerous goods specialists and under computerized shipping surveillance.

- The Environmental Health & Safety Department (EH&S), with the assistance of the University Police Department (UPD), will inspect all suspicious packages before they are brought into or removed from the area where Select Agents or toxins are used or stored. The recipient or receiving facility should be known to the sender and the sender should make an effort to ensure the materials are shipped to a facility or laboratory equipped to handle those materials safely. Contaminated or possibly contaminated materials should be decontaminated before they leave the facility or laboratory areas. All unexpected or suspicious packages will be inspected by visual or noninvasive techniques before they are brought into, or removed

from, the area where Select Agents or toxins are used or stored. Guidelines for recognizing suspicious packages have been provided by the U.S. Postal Service and can be found at: http://www.usps.com/news/2001/press/pr01_1010tips.htm. If unexpected or suspicious Packages are received, then the sender should be contacted to verify that the package is legitimate. If any individual observes suspicious packages being transported out of the laboratory (for example, packages that have an unusual weight or size), then they should immediately notify UPD and wait for an officer to respond.

- All intra-facility transfers or external shipments (send/receive) of Select Agents must be documented and reported to the Responsible Official or designee (contact the Office of Research Compliance, 458-3624, and the Environmental Health and Safety Department, 845-2132). Transfers will remain under the supervision of a DOJ Authorized Person, including chain-of-custody documents and will remain in the possession of the Authorized person in order to safeguard against theft, loss, or release.

- The DOJ authorized person will inspect all packages upon entry to and exit from the area. All packages will be screened (visual and/or x-ray) before being brought into the laboratory area. If a suspicious or unexpected package is delivered to the facility or laboratory, **do not open it.** Contact the University Police Department (emergency 9-911; non-emergency 845-2345).

- The following protocol will be used to **receive** all Select Agents or toxins based in HHS 42 CFR 73.8:

    - Enter name of Principal Investigator will request the receipt of a Select Agent, by completing Section A-Recipient (REQUESTOR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2).** (*Electronic copies of the form may be found at:* http://www.selectagents.gov/resources/APHIS-CDC%20Form%202.pdf).
    - Enter name of Prinicpal Investigator will inform EH&S of request to receive Select Agents or toxins.
    - Enter the name of Prinicpal Investigator will complete all necessary blocks of Section A and submit the completed form to the Office of Research Compliance (ORC) for the signature of the Responsible Official/Alternate Responsible Official (RO/ARO).
    - Upon receipt of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2),** the ORC will confirm that enter the name of the Principal Investigator has the appropriate Institutional Biosafety Committee (IBC) approvals in place and is listed on the University's registration for the Select Agent or toxin.
    - When the signature of the RO/ARO has been obtained, the ORC will coordinate efforts with enter the name of the Principal Investigator to ensure all information is correct.
    - The ORC will send the document to the Sender for them to complete Section B of the form.
    - Once the form is complete, it is the responsibility of the Sender (Transferor) to then fax the document to the CDC.
    - The CDC will fax an approval to the (RO) of both the Sender and Receiver. The approval will then be forwarded to the ORC.
    - Upon receipt, the ORC will contact EH&S, who will contact the transferring (RO) and Principal Investigator to verify shipping date and confirm shipping address.
    - EH&S will notify enter the name of the Principal Investigator of shipment arrival and

arrange transfer of package to user laboratory.
- Packages will be opened in the laboratory in the presence of EH&S.

- The following protocol will be used to **send** all Select Agents or toxins based in HHS 42 CFR 73.8:

  - Enter name of Principal Investigator will complete Section B- Sender (TRANSFEROR) Information of the **Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)** upon receipt of form from the Recipient.
  - Enter name of Principal Investigator will send the completed form to the ORC to obtain the RO/ARO signature.
  - Enter name of the Principal Investigator will inform EH&S. EH&S and enter the name of the Prinicipal Investigator will coordinate to arrange the shipment of the package. EH&S will contact the transferring RO and Principal Investigator to verify shipping date and confirm shipping address.
  - Once the signature has been obtained, the ORC will fax the completed form to the CDC for approval.
  - The CDC will fax an approval to the RO of both the Sender and Receiver. The approval will then be forwarded to the ORC.
  - Notification of approval will be sent to the ORC, and the ORC will inform Enter the name of Prinicpal Investigator and EH&S of the approval.
  - EH&S will assist enter the name of the Principal Investigator with the shipment and arrange transfer of package to user laboratory.
  - EH&S will complete blocks 38-40 of Section D- Shipping Information of the form, and return completed form to the ORC.
  - A copy of the Dangerous Goods manifest and air bill is maintained by EH&S.
  - EHS/Principal Investigator notifies the receiving institution that the package has been shipped.

EHS and laboratory staff to validate contents of shipment against EA-101 form.

- APHIS/CDC Form 2 is dated (Section D) and signed by EH&S staff to confirm volume and number of vials shipped against the inventory.
- A copy of the completed APHIS/CDC Form 2 is faxed to CDC Select Agent Program and to the transferring RO and Principal Investigator.
- Destruction of Select Agent is recorded on the APHIS/CDC Form 2 and is faxed to CDC.
- Hardcopy of file is retained in archive files for a minimum of 3 years.

G. Incident Reporting and Breaches in Security:

Standard Operating Procedures regarding this particular area have been developed and are located in the **Incident Response Plan,** to include:

- The University Police Department, the Responsible Official or designee, and Environmental Health and Safety will be notified in the event of:
  1) Any loss or compromise of keys, passwords, combinations, etc.;
  2) Any suspicious persons or activities;
  3) Suspicious packages;
  4) Any loss or theft of Select Agents or toxins;
  5) Missing chemicals;

6) Any release of Select Agents or toxins;
7) Any sign that inventory and use records of Select Agents or toxins have been altered or otherwise compromised;
8) Cyber security breach;
9) Non-biological incident such as violence against person;
10) Unusual or threatening phone calls;
11) Undocumented visitors;
12) Severe weather and natural disasters.

- Upon discovery of a theft or loss of a Select Agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the Select Agent or toxin is subsequently recovered or the responsible parties are identified. (42 CFR 73.19)

- Establish procedures for removing unauthorized or suspicious persons.

H. Incident Response Plan:

The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies. Reference: http://finance.tamu.edu/ehsd/resources/gensafety/Emergency_Ref.asp.

Involve facility administrators, laboratory directors, principal investigators, laboratory workers, facility safety office, and facility law enforcement officials in emergency planning. Control of access to facility and laboratory areas can make an emergency response more difficult.

- Police, fire, and other emergency responders should be informed as to the types of biological materials that are in use in the laboratory areas and special access control devices that are in use (e.g. card-key, etc.).

- Police, fire, and other emergency responders should assist in planning their responses to emergencies in the laboratory areas.

- The emergency response plan includes provisions for immediate notification of (and response by) laboratory directors, laboratory workers, safety office personnel, or other knowledgeable individuals when an emergency occurs.

- The emergency response plan must address the following:
  1) The hazards associated with the use of the Select Agents and toxins;
  2) Any hazards associated with response actions that could lead to a spread of a Select Agent or toxin;
  3) Planning and coordination with outside parties;
  4) Personnel roles, lines of authority, training, and communication;
  5) Emergency recognition and prevention;
  6) Safe distances and places of refuge;
  7) Site security and control;
  8) Evacuation routes and procedures;

9) Decontamination;
10) Personal protective and emergency equipment; and
11) Special procedures needed to address the hazards of specific agents.

PIs must complete the following:
In the event that a Select Agent must be relocated, enter the Principal Investigator will contact enter the name of the alternate institution that will allow storage of the agent, who has agreed to offer their assistance in the storage of the agent. In the event of an emergency, with the approval of CDC and assistance from EHS, the agent will be moved using proper transport/shipping requirements.

I. Policies that address Breaches in Security

The Security Plan must contain procedures that require each individual approved under HHS 42 CFR Part 73.8 to report any of the following immediately to the Responsible Official:

1) Any loss or compromise of their key, passwords, combinations, etc:
2) Any suspicious persons or activities;
3) Any loss or theft of select agents and toxins:
4) Any release of select agents or toxins; and
5) Any sign that inventory and used records of selected agents or toxins have been altered or otherwise compromised.

- Report suspicious or unexplained behavior immediately to the University Police Department (emergency 9-911; non-emergency 845-2345) and the Responsible Official.

- If possible, program speed dial of emergency contacts (e.g., 9-911, facility or laboratory director, University Police 845-2345, etc.) on the phones in the facility or laboratory.

INCIDENT RESPONSE PLAN (TEMPLATE)

Building name and number
PI – *Insert name(S)*

Texas A&M University, College Station, TX 77843
to ensure compliance with
42 CFR Part 73.14 – Select Agents and Toxins

1. Purpose

1.1 General. This is the incident response plan for the possession and use of *insert agent(s)* at Texas A&M University main campus (College Station, TX). This incident response plan meets the requirements of 42 CFR Part 73 and 9 CFR Part 121. This plan covers the use of these select agents when used in *insert building name/number*.

1.2. This plan describes the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage. This plan is coordinated with the University-wide incident response plans in place at TAMU.

2. Roles and Responsibilities

2.1 Principal Investigator (PI). The Principal Investigator, *insert name(s)*, has primary responsibility for the implementation of the select agent program within a particular laboratory or select agent work area. Where possible, all incidents covered in this plan must be reported directly to *insert name*. The PI is responsible for ensuring all incidents regarding theft, loss or release are immediately reported to the proper institutional officials. This document outlines response actions concerning any theft, loss, or release from select biological agents and toxins (SBAT) facilities, including illness of personnel or visitors in SBAT facilities. Certain actions outlined below are performed in parallel rather than sequentially (see attached flowchart).

2.2 All lab personnel (including the PI) are responsible for immediately reporting an incident to the University Police Department (UPD) for theft or loss or to the Institutional Biosafety Officer (BSO) for release (including occupational exposure).

2.3 UPD – Responsible for immediately contacting the Alternate Responsible Official (ARO) and beginning an investigation of the incident. A written investigation report will be submitted to the Institutional Biosafety Committee (IBC), the PI and the ARO within 5 days of the incident. UPD will also work with the PI to conduct a security assessment following any incident involving loss or theft.

2.3 BSO - Responsible for immediately contacting the Alternate Responsible Official and beginning an investigation of the incident. A written investigation report will be submitted to the IBC, the PI and the ARO within 5 days of the incident. The BSO will also work with the PI to conduct a safety assessment following any incident involving a release (including occupational exposure.

2.4 ARO - Responsible for immediately contacting the Responsible Official, CDC, NIH (if rDNA) and other key institutional contacts regarding the incident. The ARO will work with the BSO, UPD and the PI to insure that the written report is correct and that the report will be submitted to CDC, NIH (if rDNA) and other key institutional contacts.

2.5 Responsible Official – Is responsible for compliance to the Select Agent regulations and insuring requirements (registration, investigations, etc) are properly carried out.

2.6 Contact information is found on the Emergency contact list. The list is attached to this document and is posted throughout the lab.

2.7 Annual Program Review. The Responsible Official or Alternate Responsible Official will audit the incident response program on an annual basis. This review will include drills and exercises to ensure the effectiveness of the incident response plan. Based on the outcome of drills, exercises or reported incidents, this incident response plan will be reviewed and updated as necessary.

3. Description of Work

This plan covers all work being performed at TAMU. Each lab will be responsible for providing information specific to the work being performed as follows:

Lab	Work description	Unique features of Agent	Biological Use Authorization	Biosafety Level
Please complete chart				

Additional information concerning the laboratories and the select agent use is contained in the facility's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or Environmental Health and Safety Office.

4. Response to theft:

4.1 Determination of Loss or Theft – The following are examples of events that may be considered a loss or theft. Possible loss or theft of the select agent will be reported initially to the Principal Investigator if any of the following have occurred:

- 4.1.1 The lock on the Select Agent storage area has been found open or appears to have been tampered with;
- 4.1.2 Evidence of forced entry into the laboratory or storage areas has been found;
- 4.1.3 A discrepancy in the Select Agent inventory that can not be reconciled;
- 4.1.4 An employee reports cultures or samples missing;
- 4.1.5 A package containing select agents fails to arrive in the laboratory at the time indicated on CDC Form 2;
- 4.1.6 An infected animal is missing from its microisolator cage.

4.2 Report/Investigation Process:

Theft (unauthorized removal) or **Loss** (failure to account for) a select agent or toxin

4.2.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected theft or loss of SBATS to UPD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345). Based on circumstances, UPD will notify EHSD.

If the release is discovered and UPD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the person shall then notify the LD/PI.

After notification to UPD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or

toxin to temporarily halt research activities for investigation. The LD/PI will also contact ORC.

4.2.1.1 Upon notification of discovery of a theft or loss, UPD will immediately notify ORC.

4.2.1.2 Upon notification from UPD, ORC will immediately notify the Responsible Official (RO) and Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, and UPD.

4.2.1.3 UPD (and ESHD, based on circumstances) will immediately investigate the incident. The investigation will include coordination with the LD/PI and others approved with access or visiting SBAT facilities. UPD will submit a written report to ORC within 5 days of being notified about the discovery of the theft or loss. If the investigation provides evidence that a theft or loss did not occur, circumstances will be documented in UPD's investigation report.

4.2.1.4 Based on the UPD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss or Release of Select Agents and Toxins) with CDC. ORC will maintain an official copy of information submitted to CDC and will provide a copy of the submission to the RO, UPD/EHSD, and LD/PI.

4.2.1.5 UPD will notify the appropriate Federal, State, or local law enforcement agencies.

4.2.1.6 The LD/PI will ensure notification to the funding agency

4.2.2 A risk assessment will be conducted immediately upon discovery of a loss or theft. The risk assessment will be a part of the investigation report.

4.2.2.1 In addition to the investigation, upon notification of a theft or loss, UPD (with input from EHSD and the LD/PI) will conduct a risk assessment to determine if the laboratory is operating in a safe and secure manner and to attempt to determine the cause of the theft. This risk assessment shall include, but not be limited to a comprehensive laboratory survey, review of access logs, review of inventory records, and verification that all equipment is operating within normal parameters (e. g. biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of theft will also be reviewed and modified, as warranted. If deficiencies in safe and secure practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

4.1.2.2 If deemed necessary, the EHSD/UPD will contact Biosafety Program Coordinator to convene a special meeting of the Institutional BioSafety Committee (IBC).

4.1.2.3 Documentation of the risk assessment will be maintained by UPD with a copy sent to the LD/PI, EHSD and ORC.

4.1.2.4 Security Risk Assessments will be completed by UPD, with input from the LD/PI (and EHSD, based on circumstances). The results of the risk assessment and findings, including any requirements for post theft procedures, medical surveillance, and alterations made to laboratory

protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI, EHSD, and ORC.

4.1.2.5 The ORC will contact CDC, and if needed, a copy of the assessment will be submitted. ORC will also update the RO.

4.2.3 UPD will establish and maintain a specific file for each theft or loss incident, with all pertinent information.

4.2.4 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected loss or theft to UPD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

5. Investigation

5.1 The Investigation Committee for all releases will be headed by the EHSD's Institutional Biosafety Officer (BSO) with input from UPD and the PI. UPD will lead investigations involving theft or loss, with input from the BSO and PI.

5.1.1 The BSO/UPD will investigate the event as quickly as possible, but no later than 24 hours of the initial report or the incident.

5.1.2 The investigation should include a review of all materials related to the research, including access logs, inventory logs, laboratory notes and laboratory plans (security, safety and incident response)

5.1.3 Once the investigation is complete, the BSO or UPD will submit an investigation report to the IBB and RO.

5.1.4 Once the Committee has determined the response and informed the RO and IBC (through the Office of Research Compliance), the IBC will review the report and make a recommendation to the RO of any additional actions that they believe are needed.

5.1.5 After the RO has approved of the recommended actions, the PI will receive a written response from the IBC.

6. Reporting

6.1 All incident reports are included in the IBC agenda minutes for review by the full board at the next convened meeting. Serious events should be specifically presented to the IBC by the BSO/UPD or IBC Chair at the next convened meeting.

6.1.1 The investigation report, at a minimum, shall include the following information:

6.1.1.1 A detailed description of the incident.

6.1.1.2 A list of all personnel involved in the incident.

6.1.1.3 A description of what occurred and what has or needs to be done to prevent any future incident.

6.1.1.4 An assessment of the safety or security risk of continuing the research.

6.1.1.5 A recommendation of any changes that need to be made to the plans (safety, security or incident response), medical surveillance or laboratory procedures to reduce the risk of a reoccurrence.

6.1.1.6 A recommendation for training, if needed.

6.1.2 Incidents involving SBAT will be immediately reported to the CDC with a written report (Form 3) submitted within seven (7) days.

6.1.3 Events involving rDNA must be reported to the NIH immediately in writing but no later than 30 days of the incident.

7. Release of a Select Agent or Toxin.

Examples of a possible release (including occupational exposures of the agent or toxin include but are not limited to the following:

7.1 A package containing the Select Agent or toxin that has been received which has been damaged in transit such that the primary containment vessel appears to have been compromised;

7.2 Simultaneous complete power failure of the Biosafety cabinet and negative pressure in the BSL-3 suite during work in the Biosafety cabinet with open cultures;

7.3 Simultaneous spill of cultures outside the Biosafety cabinet and failure of negative pressure in the Biosafety Level 3 suite. In case of a spill, a spill kit containing absorbent material and disinfectant will be located in a designated lab for each Principal Investigator;

7.3.1 Personnel are advised to immediately leave the lab after removing any contaminated clothing and to return in Tyvek suits with full face respirators after the air has been scrubbed clean by air handlers (approx. one hour).

7.4 In case release of the Select Agent or toxin outside the BSL-3 laboratory is suspected, the Principal Investigator will notify the BSO laboratories on the first floor of the VRB, as well as the Responsible Official, and the building manager.

7.5 Exposure of laboratory personnel to cultures. The following incidents may result in unintentional exposure to the Select Agent that can result in a laboratory-acquired infection. In any of these cases, personnel should report the exposure to the Principal Investigator and report to TAMU Occupational Health, where they will be given the option to initiate post-exposure prophylaxis. The exposure will be reported by the Principal Investigator to the BSO who reports immediately to the Responsible Official, who will notify CDC of the exposure. The following are examples of unintentional exposure:

7.5.1 A spill of live culture outside the Biosafety cabinet;
7.5.2 Failure of the Biosafety cabinet during work with a select agent;
7.5.3 Needle stick or cut with sharps contaminated with a select agent;
7.5.4 If a bite from a select agent--infected animal penetrates the double gloves and breaks the skin;
7.5.5 A centrifuge accident that results in aerosolization of a select agent..

8. Process of reporting and investigating a Release:

Release – Occupational exposure (clinical symptoms confirmed by laboratory evidence or an abnormal event in which the agent could have been release outside of the primary bio-containment barrier.) or release of an agent or toxin outside of the primary barriers of the biocontainment area.

8.1 All individuals approved for access or visiting SBAT facilities shall upon discovery immediately report any actual or suspected release to the Environment Health and Safety Department (EHSD). Based on circumstances, EHSD will notify the University Police Department (UPD). During normal business hours, call EHSD at 845-2132. If it is outside of normal business hours, call UPD who will notify EHSD. UPD contact numbers are as follows: office (845-8900) and Dispatch (845-2345).

If the release is discovered and EHSD is notified by an individual other than the Lab Director (LD) or Principal Investigator (PI), the individual shall then notify the LD/PI.

After notification to EHSD by the LD/PI or other individual, the LD/PI will immediately notify all individuals with approved access to the select agent or toxin to temporarily halt research activities for investigation. The LD/PI will also contact the Office of Research Compliance (ORC).

8.1.1 Upon notification of discovery of a release, EHSD will immediately notify Scott & White Occupational Health Clinic and ORC.

8.1.2 Upon notification from EHSD, ORC will immediately notify the Responsible Official (RO) and the Centers for Disease Control and Prevention (CDC) via fax, email or phone call. ORC will confirm notification of CDC to the RO, LD/PI, EHSD, and UPD.

8.1.3 EHSD (and UPD, based on circumstances) will immediately investigate the incident. The investigation will include the coordination with the LD/PI and others approved with access or visiting SBAT facilities. EHSD will submit a written report to ORC within 5 days of being notified about discovery of the release. If the investigation provides evidence that a release did not occur, circumstances will be documented in EHSD's investigation report.

8.1.4 Based on the EHSD report, ORC will prepare and file Form 3 (Guidance Document for Report of Theft, Loss, or Release of Select Agents and Toxins) with the CDC within seven calendar days of the discovery of the release. ORC will maintain an official copy of information submitted to the CDC and will provide a copy of the submission to the RO, EHSD, and LD/PI.

8.1.5 EHSD will obtain confirmation from health care providers that reports to other state or federal health agencies have been submitted. The LD/PI will ensure notification to the funding agency.

8.2 A risk assessment will be conducted immediately upon discovery regarding any release.

8.2.1 In addition to the investigation, upon notification of a release, EHSD (under the direction of the Biological Safety Officer (BSO)) will conduct a risk assessment to determine if the laboratory is operating in a safe manner and attempt to determine the cause or most likely route of the release. This risk assessment shall include but not be limited to a comprehensive laboratory survey, review of access logs to determine potential occupational exposures, review of inventory records, and verification that all equipment is operating within normal parameters (e.g., biological safety cabinets, centrifuges, or aerosolization units). Research protocols in use at the time of the release will also be reviewed by EHSD and modified, as warranted, in consultation with the LD/PI. If deficiencies in safe practices are discovered, all work in the laboratory will cease until corrective actions have been taken.

8.2.2 If deemed necessary based on the risk assessment, the BSO will contact ORC to convene a special meeting of the Institutional BioSafety Committee.

8.2.3 Documentation of the risk assessment will be maintained by EHSD with a copy sent to the LD/PI and the ORC.

8.2.4 Risk assessments will be completed with input from the LD/PI. The results of the risk assessment and findings, including any requirements for post decontamination procedures, medical surveillance, and alterations made to laboratory protocols or plans (Safety, Security or Incident) will be documented. A copy of the information will be sent to the LD/PI and ORC.

8.2.5 ORC will contact CDC, and if needed, a copy of the risk assessment will be submitted. ORC will also update the RO.

8.3 The following additional steps will also be taken immediately upon discovery regarding an actual or suspected occupational exposure:

8.3.1 EHSD will direct the LD/PI to notify laboratory personnel and visitors that a potential exposure has occurred and refer them to Scott & White Occupational Health for consultation. EHSD will obtain access logs and other information to determine a complete list of potentially exposed personnel. EHSD will then follow-up with potentially exposed personnel to ensure notification.

8.3.2 Individuals will be encouraged to contact Occupational Health at Scott & White Clinic, or to immediately identify to medical personnel, the agent they were potentially exposed to if treatment is sought. Scott & White Occupational Health Clinic or the attending physician will screen for the organism (e. g. Brucella species), and begin prophylaxis as deemed appropriate by the attending physician.

8.3.3 If an occupational exposure is confirmed through appropriate medical tests or as determined by a physician, all personnel and potentially exposed individuals will be immediately referred to Scott & White for screening, testing, or preventive prophylaxis as determined by the attending physician. If personnel or visitors are at remote locations (other university facilities, traveling), they should immediately report to a physician of choice and explain that a positive occupational exposure to a specific organism has occurred and specific treatment or screening is desired. Personal physicians should be encouraged to contact either EHSD or Scott and White Occupational Health if they have any questions.

8.3.4 EHSD, in consultation with Scott & White, will perform periodic follow-up with the group of exposed or potentially exposed personnel for a period of time as appropriate for the organism.

8.4 EHSD will establish and maintain a specific file for each release incident, with all pertinent information.

8.5 The LD/PI shall train all individuals approved for access or visiting SBAT facilities to immediately report any actual or suspected release to EHSD and the LD/PI. Documentation for completion of training shall be maintained by the LD/PI.

9. Security Breach:

A security breach will be determined to have occurred if any of the following are observed:

9.1 The access control system has failed, leaving the BSL-3 suite accessible to unauthorized persons;
9.2 An unauthorized person is observed unaccompanied in the BSL-3 suite;
9.3 A lost or stolen card was used to access the BSL-3suite;
9.4 An unauthorized person has accessed the computer used to control entry to the BSL-3 suite;
9.5 An unexpected or suspicious package arrives in the laboratory.

If any of the above occurrences is observed, it must be reported immediately to the Principal Investigator. The Principal Investigator will then notify the Responsible Official of the security breach and take steps to correct the problem. Corrective procedures will be secured immediately,

but no later than 24 hours; an inventory will be performed of all samples and animals in the laboratory and in Select Agent storage. Any missing Select Agent samples or animals will be reported to CDC using Form 3. Regardless of the outcome of the security breach, the Principal Investigator and the Responsible Official will review the incident to determine whether changes to the Security plan are required to avoid similar occurrences in the future.

10. Severe weather or natural disasters.

The most likely occurrences in this area are severe thunderstorms, floods or tornadoes.

10.1 If severe weather (thunderstorms or flooding) is predicted, experiments with Select Agents should be suspended until the severe weather has passed to avoid power outages during the work. All samples should be secured inside the locked -80°C freezer or the locked +4°C storage.

10.2 If an earthquake is felt, workers should immediately leave thesuite-if possible, shedding gloves and lab coat on the way out of the BSL-3 suite. Cleanup, if necessary, can be performed once it is safe to re-enter the building.

10.3 Power to the BSL-3 suite may be affected if the emergency generator is flooded. In this case, all samples should be secured inside the -80°C freezer. If the vivarium is threatened by flooding, animal cages should be fastened shut, put into secondary containers (biohazard bag or large Tupperware) and transported to LARR (CMP) for secure holding until the threat of flooding has passed. If it becomes necessary to evacuate the College Station area, all animal experiments will be terminated before evacuation by euthanizing the animals and storing the carcasses in the secure select agent storage in room.

10.4 In case of a power outage, if there is no immediate danger to the building, secure all infectious samples inside a -80°C freezer, the +4°C refrigerator, or the incubators. The Biosafety cabinets and air handling system of the BSL-3 suite are on emergency backup power, which will prevent exposure to infectious samples in case of a power outage. Follow standard procedures for leaving the laboratory and return once the power has been restored to resume work.

11. Fire, Gas leak, Steam leak, Explosion, Bomb threat:

11.1 If work is being performed in the Biosafety cabinet, cap all samples, dispose of gloves and outer laboratory coat, and leave the labaoratory immediately. If the fire is within the BSL 3 laboratory, and the worker feels (s)he can safely extinguish the fire, then the fire extinguisher located in the interior hall may be used. If a worker feels his or her safety threatened, (s)he should leave the laboratory immediately without stopping to decontaminate or secure any work, using the designated escape routes (through the locker rooms or the exterior "airlock" door on the west side of the building). Upon leaving the building, personnel should assemble outside the VRB in the assigned spot (southern corner of corner of Parking lot 13) and report to the Lab Safety Officer for attendance.

11.2 Notify the appropriate emergency responders: Fire 9-911 or 911 from mobile phones, the Principal Investigator and the Biosafety Officer. For steam and gas leaks, notify TAMU Operations and Maintenance.

11.3 In case a bomb threat is received by telephone, follow TAMU procedure to notify the University Police immediately by calling the emergency number, 9-911 or 911. Also inform the Principal Investigator and Responsible Official. Always be sure to give the number and location of the building and your name and telephone extension number.

11.3.1 The University Police Department will assign personnel to investigate the call and take whatever police action they may deem necessary and reasonable for the

safety of the campus community. The University Police will conduct a search of the building, or of specific locations in or around the building. When judged prudent and feasible to do so, the search will be conducted with the assistance and cooperation of the Principal Investigator and/or Responsible Official. After an evaluation/assessment of the content of the bomb threat, the decision to evacuate or close building shall be made jointly, whenever possible, by the Police and the Principal Investigator and/or Responsible Official.

11.3.2 Any unusual or suspicious object should be reported immediately to the University Police or to any immediate supervisor or administrative officer. Suspected objects or materials should NOT be touched or disturbed. Every bomb threat or incident of a suspected explosive device should be considered valid until all reasonable precautions for public safety have been taken or until the danger to life and property is terminated.

12. Failure of Select Agent Storage Freezer:

12.2 If the -80°C freezer in VRB 127 that is used to store *Brucella* strains fails, the strains will be moved to a temporary backup location, which is either the other -80°C Revco freezer located in room 127, or in secure freezer in a locked BSL-2 laboratory. This freezer will be locked in order to limit access to personnel authorized to work with select agents.

13. Workplace violence:

13.1 Incidents of disruptive or threatening behavior on the part of an employee, student or visitor should be reported immediately to the Principal Investigator, who will report the incident to the Department Head, the Responsible Official and the Workplace Violence Response Team, as proscribed by the TAMU Personnel and Procedures manual section 290-09. If the individual accused of disruptive or threatening behavior is authorized for access to select agents, this person's access will be suspended pending the results of an investigation by the Workplace Violence Response Team. If an act of violence or a physical assault has occurred, or the threatening activity occurs within the BSL-3 laboratory, the person feeling threatened should call the police immediately to report the incident. If the person accused of violence has access to select agents, the person's access will be suspended pending the outcome of the investigation. Suspension of select agent access will be reported to the Responsible Official and a suspended individual's access will be inactivated within 24 hours.

14. Entry of emergency responders into the BSL-3 laboratory.

14.1 In a case in which a life-threatening injury or medical condition (i.e. heart attack) occurs inside the BSL-3 laboratory, emergency responders will be allowed to enter the laboratory. If possible, upon feeling ill the laboratory worker should immediately exit the suite to facilitate treatment by emergency responders. Personnel protective equipment, including Tyvek suits, N95 masks, HEPA-filtered respirators and gloves, are located inside the entries (locker rooms) to the BSL-3 suite. A spill kit containing absorbent materials and disinfectant is located under the bench in each of the labs. A First Aid kit is located inside the lab. If responders are required to enter an area where a spill has occurred, they will be referred to Scott and White Clinic and offered post-exposure prophylaxis.

14.1.1 Entry procedure for the BSL-3 laboratory: Dress yourself in a Tyvek suit, gloves, shoe covers and respiratory protection (N95 mask) before entering the laboratories.

14.1.2 Providing first aid and emergency medical treatment in the BSL-3 laboratory: A person working inside the Biosafety hood is not considered to be contagious unless a spill has occurred. The person's gloves may be contaminated, and may be removed to facilitate treatment. If there is no space within the labs to put the person on the floor, move the person to the interior hallway to administer treatment.

14.1.3 Exit procedure from the BSL-3 laboratory: Emergency responders should remove Tyvek suit, mask, shoe covers and gloves before exiting and leave them behind in the BSL-3 laboratory. Hands should be washed immediately upon exit from the BSL-3 laboratory.

14.1.4 Decontamination procedures for medical equipment and clothing: Emergency responders should decontaminate equipment before leaving the laboratory by one of the following methods:

14.1.4.1 Autoclaving. Autoclaves are located within the BSL3 suite or on the 2nd floor of the VRB.

14.1.4.2 Wiping surfaces with 10% bleach followed by 1% Virkon-S.

15. Incident Response Plan Testing (Drills)

15.1 Drills or tabletop exercises will be conducted annually to test the effectiveness of the Biosafety plan. The drills or exercises will be coordinated with the TAMU Police Department and will include, but not be limited to, the Principal Investigator or designee, BSO, TAMU Fire Department representative and the Campus Emergency Planner.

15.2 The drill or exercise will include, but not be limited to, accessibility to restricted space, attempted or unauthorized entry into restricted spaces challenge, animal room security, staff knowledge of hazard/emergency protocols for their work location(s) and other situations that are deemed appropriate for each work location.

15.3 Following the drill or exercise, which will test the various components of the incident response plan for completeness, those involved will critique their findings for each drill/exercise location. The Principal Investigator working with the Responsible Official and Biosafety Officer will implement changes as necessary changes to the plan. Results of the drill or exercise will be reviewed by the Biological Safety Administrative Advisory Committee (Institutional Biosafety Committee).

16. Texas A&M University Crisis Management Plan

16.1 The entity crisis management plan is contained in a separate document and is referenced in the individual laboratory emergency response plan.

16.2 Additional information concerning the laboratory emergency response plan is contained in the laboratory's CDC select agent application for registration on file at the CDC's Select Agent Program office. A copy is also securely stored at the entity's Office of Research Compliance or the Environmental Health & Safety Department.

16.3 The Responsible Official and Biosafety Officer should be contacted immediately in the case of any emergency in a select agent lab. The Responsible Official will coordinate access and information issues with campus police, fire, and emergency responders.

16.4 If necessary, the Responsible Official will coordinate the emergency relocation of select agents to another secure location.

17. Site security and control are described in detail in the Select Agent Security Plan

17.1 The buildings are secured by a keyed lock. Sharing of keys with other personnel is not permitted.

17.2 Individuals not authorized for access to Select Agents must be accompanied by approved personnel at all times while in the buildings.

17.3 Data that could enable access to select agents by unauthorized personnel should be located on password-protected computers.

17.4 If approved personnel are observed violating security or Biosafety procedures, this observation should be reported immediately to the Principal Investigator. The Principal investigator will investigate the allegation and determine whether the violator should have his/her Select Agent access suspended or revoked. Suspension of Select Agent access will be reported to the Responsible Official and the individual's key card access will be terminated within 24 hours.

18. Inventory Discrepancies:

18.1 Inventory discrepancies will be documented on the agent access form.

18.2 All discrepancies will be immediately reported to the Principal Investigator.

18.3 If the discrepancy is believed to be a result of loss or theft, the incident response procedures for loss or theft and release will be followed.

18.4 If the discrepancy is a result of a transfer, the transfer form will be documented.

19. References

19.1 42 CFR Part 73

19.2 7 CFR Part 331

19.3 9 CFR Part 121

19.4 Biosafety in Microbiological and Biomedical Laboratories, Centers for Disease Control and Prevention, National Institutes of Health, Fourth Edition, May 1999

19.5 Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents (Revised BMBL, Appendix F), published in Morbidity and Mortality Weekly Report, December 6, 2002.

SBAT Incident Response
Emergency Contact Numbers

PI Information
PI insert name Office – 979 insert number Mobile – 979 insert number Home – (979) insert number
Building Manager Insert name and contact info
Department Head Insert name and contact info
Incidents involving Theft or Loss University Police Department (UPD) contact Bert Kretzschmar Office – 979 845-8900 Mobile – 979 777-9033 Home – 979 774-0017).
Incidents involving a Release (or Occupational Exposure) Environmental Health and Safety Office contact Between 8:00 a.m. and 5:00 p.m. Brent Mattox, Biosafety Officer (BSO) Alternate Responsible Official (ARO) Office – 979 865-2132 Mobile – 979 450-0662 After hours 5:00 pm Contact the University Police Department contact Lt. Bert Kretzschmar Office – 979 845-8900 Mobile – 979 777-9033 Home – 979 774-0017

Other Contact information		
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or 979 229-1479 (Mobile)
	Fuller Bazer (ARO)	979 693-2876 (Office) or 979 324-7364 (Mobile)
	Angelia Raines (ARO)	979 847-9362 (Office) or 770 789-3456 (Mobile)
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or 979 229-2696 (Mobile)
	Elizabeth Browder	979 845-7433 (Office) or 979 777-0132 (Mobile)
	Frank Stein	979 845-6488 (Office) or 979 218-0642 (Mobile)
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or 979 574-9466 (Mobile)
	Vernon Tesh	979 862-4113 (Office) or 979 229-9774 (Mobile)
	Tiffany Agnew	979 458-3624 (Office) or 706 414-7133 (Mobile)
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911
	Medical Emergency	9-911
	College Station Fire	979 764-3700 or 9-911
	Radiological Emergency	979 832-1111
	University Maintenance	979 845-4311

Decontamination Procedures for Spills of Cultures
(Please customize for specific laboratories.)

1. Signal others in the BL3 labs of any spill outside the biological safety cabinet. All personnel should change out of contaminated clothing and wash any exposed skin with a disinfectant, such as Purell. Clothes must be removed within the BL3 area and will be autoclaved by those cleaning up.
2. Put on a clean scrub suit and go to the shower on the first floor animal facility. Shower thoroughly with soap.
3. Return to the lab for cleanup: Put on a full face respirator and tyvek suit (contained in the SPILL KIT). Put on double gloves and shoe covers.
4. Use paper towels to cover the spill. Prevent creation of contaminated aerosols.
5. Saturate all materials with 10% bleach solution (see previous section for description).
6. Allow to soak 15 minutes while remaining in the room. Clean up debris and other contaminated materials and place in autoclave bags.
7. Disinfect all exposed surfaces using 1X Wexcide or 1% Virkon (surface disinfectant solution).
8. Wipe surface of full-face respirator with 1% Virkon or 1X Wexcide, being careful to avoid skin contact with Wexcide.
9. Remove all clothing and place in autoclave bag.
10. Remove full face respirator and spray off all surfaces in the lab with 1% Virkon or 1X Wexcide.
11. Make sure that all contaminated material is autoclaved, surface-disinfected or incinerated.
12. Inform others not to work in the lab until the air handling system is able to clear any residual organisms from the air (3h).
13. Return to the lab after 3 hours and perform another decontamination of all lab surfaces with 1% Virkon or 1X Wexcide.
14. Report accident to the Principal Investigator, who will report it to other officials.

Contents of spill kit located in BL-3 labs:
Full-face respirator, Tyvek suit, clean scrub suit, absorbent material, Purell skin disinfectant, towel, copy of decontamination procedures for spills.

Texas A&M University - VPR Office or Research Compliance

Institutional Biosafety Committee (IBC) - New IBC Application Process

Research Compliance Website- *http://researchcompliance.tamu.edu*

New IBC Application- *http://researchcompliance.tamu.edu/ibc/ibcrevapp*

New Application for IBC Permit

***Reminder**: You need only submit one application listing all agents/toxins to work with these materials for three years

PI reviews and completes Application for IBC Permit.
(PI must also complete Attachment D and all other Parts and Attachments applicable to their research.)

PART I – Investigator Identification

Risk Assessment
APPENDIX 1 lists definitions of Risk Group and Biosafety Levels

Investigator Assurance
PI must complete **ASSURANCE STATEMENT.** (Original signatures required from PI and Unit Head.)

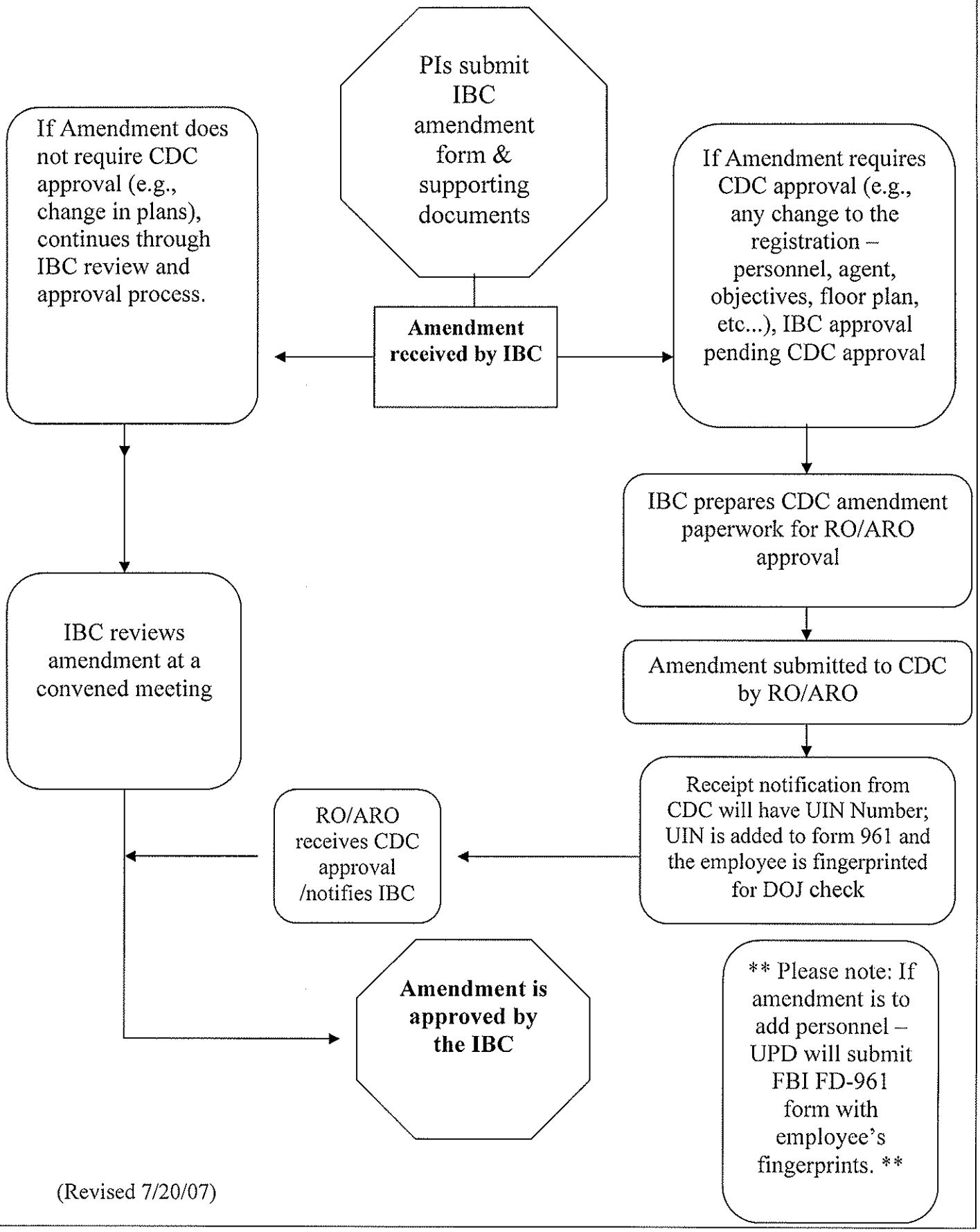
- If work involves the use of Biological Toxins, **PART II** must be completed.
- If work involves the use of Pathogens, **PART III** must be completed.
- If work involves the use of Recombinant DNA, **PART IV** must be completed.

- If work involves the use of animals, **ATTACHMENT A** must be completed.
- If work involves the use of humans and/or human material, **ATTACHMENT B** must be completed.
- If work involves the use of plants, **ATTACHMENT C** must be completed.
- All PIs are asked to submit copies of all grant proposals that reflect their research.
- If work involves the use of Select Agents, PLEASE CONTACT THE OFFICE OF RESEARCH COMPLIANCE @ 458-3624. If your lab has **not** been registered to work with a select agent, you **must** also contact Brent Mattox, Environmental Health and Safety, at bsmattox@tamu.edu and Ms. Angelia Raines, Research Compliance Director, at araines@vprmail.tamu.edu.

Submit completed Application for IBC Permit to the Office of Research Compliance at MS 1186

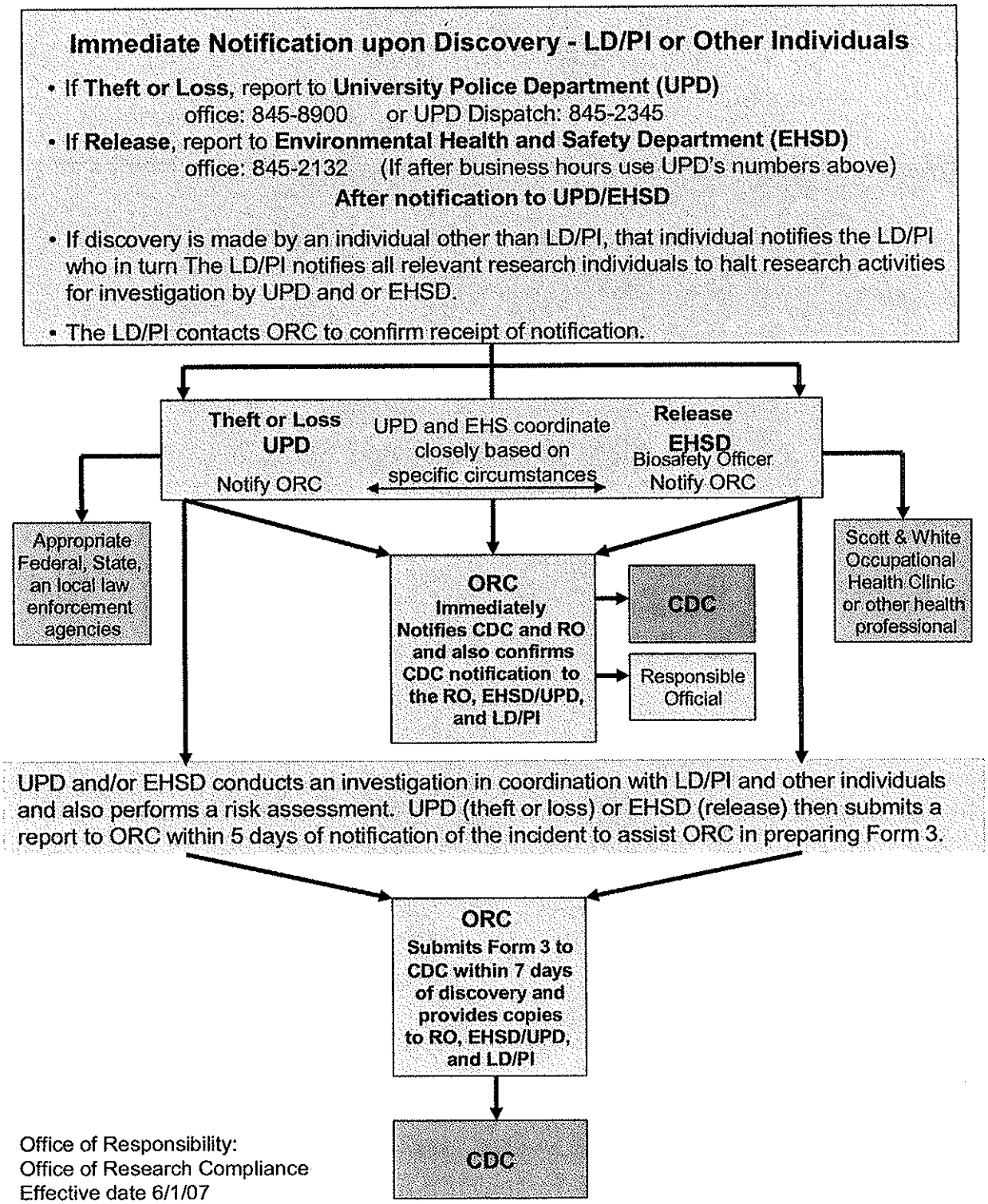
Revised 9/14/06

Amendment Process for Research Involving Select Agents



(Revised 7/20/07)

Theft, Loss, or Release of Select Agents and Toxins (SBATs) Notification and Reporting Procedures



Office of Responsibility:
Office of Research Compliance
Effective date 6/1/07