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July 30, 2007

Mr. Edward Hammond  
The Sunshine Project  
1920 Stuart St.  
Berkeley, CA 94703

Re: Public Information Request 07-108

Dear Mr. Hammond:

The Office of the Vice President for Research provided the enclosed information in response to your request number 07-108. The records have been redacted in accordance with Attorney General letter ruling OR2007-08298.

Responsive information regarding Dr. Ficht's correspondence will be forwarded to you under separate cover by the System Office of General Counsel.

Sincerely,

A handwritten signature in cursive script that reads "Suzy Yeager".

Suzy Yeager  
Director, Open Records

cc: Mr. Scott Kelly



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

FORM APPROVED  
OMB NO. 0578-0213  
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](mailto:Agricultural.Select.Agent.Program@aphis.usda.gov)) or CDC (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: [lrsat@cdc.gov](mailto: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/qa\\_selectagent/index.html](http://www.aphis.usda.gov/programs/qa_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.



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

FORM APPROVED  
OMB NO. 0578-0213  
OMB NO. 0620-0578  
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	
7. Responsible Official (RO) or facility director First: Richard MI: _____ Last: Ewing		8. Telephone: 979 8458585	
11. RO or facility director address (NOT a post office address): same as above		12. City: _____	
15. Type of incident: <input type="checkbox"/> Theft <input checked="" type="checkbox"/> Loss <input type="checkbox"/> Release		16. Immediate notification provided to: <input type="checkbox"/> APHIS <input checked="" type="checkbox"/> CDC	
17. Date of immediate notification: 12/22/2008		18. Type of immediate notification: <input type="checkbox"/> E-mail <input type="checkbox"/> Fax <input checked="" type="checkbox"/> 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: <input type="checkbox"/> No <input checked="" type="checkbox"/> 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: 12/21/2008		28. Date of last inventory: 12/20/2008	
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	
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	
32. Biosafety level of laboratory where incident occurred: ABSL3		35. Agent was recovered (theft/loss): <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
36. Provide a summary of actions taken: <input type="checkbox"/> Called ambulance <input type="checkbox"/> Called fire department <input checked="" type="checkbox"/> Closed laboratory doors <input type="checkbox"/> Closed building <input type="checkbox"/> Consulted MSDS or chemical database <input checked="" type="checkbox"/> Called police department (case #) 12-06-5068 <input checked="" type="checkbox"/> 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 performed on 12/22/06 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):						
	<b>SENDER INFORMATION</b>		<b>RECIPIENT INFORMATION</b>			
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: <input type="checkbox"/> No <input type="checkbox"/> Yes			51. Package with select agents and toxins appears to have been opened: <input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, explain)			
52. Sender was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes			53. Carrier/courier was contacted regarding incident: <input type="checkbox"/> No <input type="checkbox"/> Yes			

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

54. Hazards posed by release: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (if Yes, explain. Use an attachment if necessary.) Low dose of <i>coxiella burnetii</i> in a pre-vaccinated mouse should result in minimal hazards if any.
55. Exposures: <input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, provide number of persons, animals, and plants exposed. Attach additional sheets if necessary.)
56. Area was decontaminated: <input type="checkbox"/> No <input checked="" type="checkbox"/> 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: <input checked="" type="checkbox"/> No <input type="checkbox"/> 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/slan)	24. Vol or Wt per Vial (e.g., ml, mg, ng)	25. Total Quantity	26. Concentration/Vial (e.g., 10 <sup>6</sup> 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: Angelia Raines

Title: ARO (Director - VPR Office of Research Com) 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 (8920-0576).

APHIS/CDC FORM 3 (12/31/2003)  
 (CDC Adobe Acrobat 5.0 Electronic Version, 1/2006)



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

1/11/2007

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 release)

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:

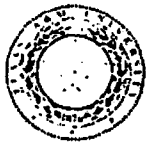
The missing mouse was most likely included in the autoclaved bedding material and disposed. It had been used to produce cultures and was scheduled to be sacrificed on the day of the incident. The day before, the cages had been changed. The animals were counted prior to the cage change and none were missing.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

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  
1186 TAMU  
500 Research Parkway  
Suite B150  
College Station, Texas  
77843-1186  
979-458-1467  
FAX 979-862-0176

**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?

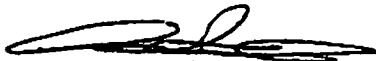
**Response:** There have been no inventory discrepancies in the past.

**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.