Yeager, Susan

From: Clark, Charley
Sent: Monday, July 09, 2007 2:40 PM
To: Yeager, Susan
Subject: FW: Re: Lab accident

-----Original Message-----
From: Meyer, Chris
Sent: Thursday, July 05, 2007 4:51 PM
To: Kelly, Scott
Cc: Clark, Charley
Subject: FW: Re: Lab accident

Scott,

I found the following e-mail which appears to be responsive to the Open Records Request 07-176. I did search my e-mails in response to previous open records requests though I'm not sure that I was tasked to do so. I apparently wasn't thorough enough in my search to find this e-mail. I will continue the search tomorrow for any other records associated with this incident.

Chris

-----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 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

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 09, 2007 2:47 PM
To: Yeager, Susan
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection

Importance: High

-----Original Message-----
From: Clark, Charley
Sent: Monday, July 02, 2007 1:25 PM
To: Yeager, Susan
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

-----Original Message-----
From: Meyer, Chris
Sent: Thursday, April 12, 2007 3:03 PM
To: Clark, Charley
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

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From: Mattox, Brent S
Sent: Thursday, April 12, 2007 2:30 PM
To: Meyer, Chris; Salsman, John M
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

This just appeared on the listserve.

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From: ABSA biosafety forum [mailto:Biosafety@BIOSAFETY.ABSA.ORG] On Behalf Of Edward Hammond
Sent: Thursday, April 12, 2007 1:29 PM
To: Biosafety@BIOSAFETY.ABSA.ORG
Subject: Texas A&M Violates Law in Biodefense Lab Infection

The Sunshine Project
News Release - 12 April 2007
http://www.sunshine-project.org

Texas A&M University Violates Federal
Law in Biodefense Lab Infection

- Student climbs into dirty bioaerosol chamber and contracts brucellosis
- A&M failed to report the incident to federal authorities
- May lose federal funding and owe $750,000 or more in fines.

- Urgent need for mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps to provide missing lab public accountability.

12 April 2007 - An aerosol chamber mishap at Texas A&M University in February 2006 caused a researcher to be infected with the bioweapons agent brucella. Texas A&M University then violated federal law by not reporting the brucellosis case to the Centers for Disease Control (CDC) and now faces severe penalties. This information has only come to light as a result of persistent Texas Public Information Act requests by the Sunshine Project.

Overdue records obtained by the Sunshine Project in the last two days confirm that A&M officials discussed the fact that the federal Select Agent Rule required reporting the brucella infection; but they chose not to do so. A&M is still holding back additional documentation of crime. The scandal points to the urgent need for a mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps and creates public accountability for biodefense lab accidents.

For federal violations, Texas A&M may be fined $500,000, plus up to $250,000 for individual(s) that failed to report the incident. In refusing to produce information about the infection, A&M officials also flouted the Texas Public Information Act. The Sunshine Project is filing a complaint with Texas Attorney General Greg Abbott that may result in other fines and/or jail sentences if A&M officials are found guilty of hiding documents.

What Happened: The infection incident occurred on 9 February 2006. Several A&M researchers, including Principal Investigator Thomas Ficht, were in a BSL-3 lab training in the use of the Madison Aerosol Chamber. Supervising was David McMurray, an A&M professor and self-described inventor of the chamber, who has characterized it as "foolproof".

Following a "hot" run that blew aerosolized brucella into the chamber to expose mice, researchers began clean up procedures. Using what Texas A&M now admits were inappropriate protocols, a researcher "cleaned the unit by climbing partially into the chamber to disinfect it." A&M officials later concluded that the brucella bacteria likely entered her body via eyes as a result of this improper procedure. (This is the third instance of lab-acquired infections related to the Madison chamber that the Sunshine Project has uncovered. The others were in Seattle and New York City.)

By April 2006, the researcher had "been home sick for several weeks." Nobody apparently suspected brucellosis, despite the occupational exposure and, presumably, familiarity with its symptoms. Eventually, the researcher's personal physician ordered blood tests and made the diagnosis on about April 10. On 15 April, the infected researcher began a heavy treatment course reflecting the severity of the situation. received a week of intravenous antibiotics followed by a 45-day course of two additional antibiotic drugs. Just over a month later, new blood tests indicated that the infection had passed.

Failure to Report: E-mails that Texas A&M finally released to the Sunshine Project late on Tuesday night reveal that the University broke federal law by not reporting the infection. The Select Agent Rule required A&M to report the infection immediately upon its discovery and for the school to file a formal report, called APHIS/CDC Form 3, within 7 days.

According to A&M records, the sick researcher told Thomas Ficht of the diagnosis on Monday or Tuesday, April 10 or 11, 2006. Based on the records A&M has released, Ficht does not appear to have told A&M administrators until ten days later. On 21 April, a Friday afternoon, Ficht informed other A&M officials, including Angela Raines, the Responsible Official under the Select Agent Rule and Brent Maddox, the A&M biosafety director, in an e-mail titled "Workmen's Compensation".

Texas A&M has also released a partial e-mail sequence involving discussions during the following week between Ficht, the sick researcher, and Maddox (the safety director). On Tuesday April 25, Ficht noted "according to the select agent guidelines [sic] we are required to report any laboratory exposures to the CDC." Yet no report was filed.

Ficht is the Research Standards Officer of Texas A&M University, a member of the NIH bacterial biodefense and bacterial pathogenesis study groups, and is funded to study bioweapons agents by the Department of Homeland Security and National Institutes of Health. Notably, Ficht is one of only a few US researchers who were studying Brucella before the post-9/11 biodefense boom.

A&M has yet to release any of Maddox or Raines' records about the incident, despite having been obligated to do so by Texas law for almost six months. These undoubtedly would shed more light on A&M's violation of the Select Agent Rule.

A Year Too Late: There is no reason to suspect that A&M would have admitted the truth without pressure. It has taken six months for the Sunshine Project to convince A&M to reveal this incident to the limited extent known today. This week, as the Project was closing in on details in a series of tense e-mails with the Texas A&M General Counsel (including a threat to take the matter to law enforcement), A&M officials apparently decided that they could no longer stonewall.

While A&M was refusing to answer Sunshine Project requests, on Tuesday (10 April), A&M e-mailed CDC to inform it of the incident - a full year after the infection should have been reported. Yesterday (11 April), A&M's Angela Raines filed the required APHIS/CDC Form 3 document, 51 weeks after A&M was required to submit it.

Penalties: The Sunshine Project is calling for maximum penalties to be levied. Says Sunshine Project Director Edward Hammond, "The evidence released to us indicates that Texas A&M officials discussed the federal requirement to report the incident, yet they did not do so. They chose to ignore the law, and that irresponsible decision to endanger public health and security should be swiftly and severely punished with maximum fines and loss of federal research funding."

An Ongoing Problem: For years, watchdogs have pointed to the lack of effective regulation of BSL-3 and BSL-4 labs in the United States, and particularly the need for improved (and transparent) accident reporting. Those calls have grown louder after a series of accidents in recent years that labs tried to hide from the public, including tularemia infections at Boston University, a plague problem in Newark, New Jersey, and a genetically-engineered bird flu incident in Austin, Texas.

The Sunshine Project has gathered data (in press) documenting nearly a score more BSL-3 and BSL-4 accidents, including select agent incidents, almost none of which have been reported to the public. Due to the absence of effective federal regulation, there are, undoubtedly, many more accidents that have been successfully buried, like the Texas A&M brucella incident almost was.

"It is common knowledge in the biodefense business that lab accidents with bioweapons agents are routinely buried in order to avoid negative publicity and endangering funding," says Hammond, "It is only through the power of the Texas Public Information Act that Texas A&M's criminal failures have been revealed."

The Sunshine Project is calling for a mandatory national accident and near-miss reporting system to be established. "When accidents are buried, nobody learns from past mistakes, and communities are kept in the dark about accidents and sloppy labs in their midst." says Hammond, "It's time for biodefense labs to stop talking down to the public with false safety claims and to start being transparent. All BSL-3 and BSL-4 labs should be required to report all significant accidents and near-accidents, and that information should be published by the federal government, with details of every incident, including the name of the lab and the agent involved."

- END -

Note: Look for original A&M documents to be posted online with this news release at the Sunshine Project website.

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 09, 2007 2:49 PM
To: Yeager, Susan
Subject: FW: Centers for Disease Control and Prevention (CDC) Review

-----Original Message-----
From: President [mailto:s-carroll@tamu.edu]
Sent: Monday, July 02, 2007 4:07 PM
To: undisclosed-recipients
Subject: Centers for Disease Control and Prevention (CDC) Review

2 July 2007

MEMORANDUM

TO: Texas A&M Faculty & Staff

SUBJECT: Centers for Disease Control and Prevention (CDC) Review

As you may already be aware, the Centers for Disease Control and Prevention (CDC) notified us over the weekend that we must suspend our homeland security-related research with selected agents and toxins pending the outcome of another site visit by CDC representatives. That next visit is scheduled later this month—in the July 9-23 timeframe.

The CDC notification stems from safety and reporting considerations.
First, let me make the point that the cited incidents at Texas A&M University did not pose a continuing threat to anyone on or off our campus. The first incident, an exposure to Brucella, was the University's error in not reporting the exposure in a timely manner. The more recently reported exposure was simply due to the fact that we have initiated more stringent testing and reporting criteria than in prior periods and than is the norm at other similar research facilities. In fact, none of the individuals with the latest reported elevated blood tests (a reading known as a titer) became ill from that exposure. This is generally the standard at other select agent research facilities used in determining whether to report an exposure to the CDC. In our case, we are exceeding that standard. Safety is always of paramount importance when anyone on campus—be they faculty, staff or students— who handles or otherwise deals with materials that are hazardous or even potentially hazardous. Nothing—absolutely nothing—is more important than safeguarding the health of our personnel.

We are unequivocally committed to taking all appropriate steps to ensure we are in full compliance with all CDC and any other relevant policies and regulations. In fact, we have already strengthened our safety, training and reporting procedures. In addition, we are retaining the services of an independent expert and the environmental health and safety group from the UT Health Science Center in Houston to provide their views on how we can most expeditiously redeploy a fully compliant select agent research program. This action, in coordination with further discussion with CDC, will form the basis for our action plan going forward.

In summary, we plan to cooperate fully with the CDC and look forward to resolving this matter in an appropriate manner as quickly as possible so that we can move forward in our work supporting the nation's homeland security initiatives. Texas A&M is among the world's leading research institutions with a long history of producing solid results that help mankind in many different ways. This is apparent day in and day out in disciplines all across this campus and state. Our goal is to ensure that our select agent research

continues to be recognized at that same high standard.

Eddie J. Davis
Interim President

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 09, 2007 2:49 PM
To: Yeager, Susan
Subject: FW: The Battalion - A&M under investigation after disease transmission

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From: Clark, Charley
Sent: Monday, July 02, 2007 1:29 PM
To: Yeager, Susan
Subject: FW: The Battalion - A&M under investigation after disease transmission

---

From: Moore, Steve
Sent: Thursday, April 26, 2007 6:09 PM
To: Prior, David; Clark, Charley
Subject: RE: The Battalion - A&M under investigation after disease transmission

David, I asked the Batt not to publish this article because it would only point out the views of the Sunshine Project, but in their infinite wisdom....

The answers are that the CDC response could take another week or so. At that point, we will issue the complete details of the exposure, our reaction to it and any changes to our program going forward.

Thanks.

Steven B. Moore
Chief Marketing Officer & VP Communications
Texas A&M University
1180 TAMU
College Station, TX 77843-1180
979.458.1729 (office) / 979.204.7185 (cell)
steve.moore@tamu.edu

From: Prior, David
Sent: Thursday, April 26, 2007 3:45 PM
To: Moore, Steve; Clark, Charley
Subject: FW: The Battalion - A&M under investigation after disease transmission

FYI - is asking very reasonable questions. The Batt simply perpetuates a version of the event. Do we have answers to her questions? ?

From:
Sent: Thursday, April 26, 2007 3:00 PM
To: Prior, David
Subject: The Battalion - A&M under investigation after disease transmission

thebatt.com
The Battalion
The Independent Student Voice of Texas A&M Since 1893

Thursday, April 26, 2007

ARTICLE EMAILED FROM A FRIEND

Dr. Prior,

This article appeared in The Battalion on 4/24/07. I just learned about it yesterday. I am particularly concerned about this statement, which appears on the second page: "The incident occurred when the researcher was cleaning a chamber that contained aerosolized brucella by climbing partially into it, which A&M officials said was inappropriate lab protocol."

This prompts me to ask when University officials expect to hear from the CDC regarding their findings? And when do you think the University will issue a response to correct these damaging and inaccurate statements appearing in the press? Thank you for your assistance.

- Christine McFarland*

A&M under investigation after disease transmission

Texas A&M is being investigated after failing to timely report to the Center for Disease Control and Prevention (CDC) that a student researcher was infected with brucellosis in 2006.

Read Full Article

* The sender's identity has not been verified.

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Importance: High

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Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

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Sent: Thursday, April 12, 2007 2:30 PM
To: Meyer, Chris; Salsman, John M
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
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Subject: Texas A&M Violates Law in Biodefense Lab Infection

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News Release - 12 April 2007
http://www.sunshine-project.org

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- END -

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Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:31 PM
To: Yeager, Susan
Subject: FW: CDC Response Documents

From: Meyer, Chris
Sent: Friday, May 11, 2007 3:13 PM
To: Raines, Angelia
Cc: Clark, Charley; Wallis, Annette; Salsman, John M; Mattox, Brent S
Subject: FW: CDC Response Documents

Angelia,

When will we meet to review the collective responses before they are submitted to CDC? Speaking for myself, I will bend my schedule as necessary to find a meeting time next week.

Chris

From: Salsman, John M
Sent: Friday, May 11, 2007 10:56 AM
To: Meyer, Chris
Subject: FW: CDC Response Documents

From: Mattox, Brent S
Sent: Friday, May 11, 2007 10:53 AM
To: Raines, Angelia
Cc: Salsman, John M
Subject: CDC Response Documents

Please see the attached. We have submitted scanned copies, but files are available.

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:31 PM
To: Yeager, Susan
Subject: FW: CDC Notification

From: Wallis, Annette
Sent: Friday, May 11, 2007 4:35 PM
To: Clark, Charley
Cc: Wallis, Annette
Subject: CDC Notification

Charley,

I talked to Chris, and he did receive an e-mail from Angelia Raines stating she had notified CDC and Dr. Ewing. Also, neither Chris nor I have received a copy of the report that incorporates everyone's responses.

Enjoy your weekend,
Annette

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:31 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Draft - Incident Response Reporting

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Mattox, Brent S
Sent: Wednesday, May 30, 2007 11:07 AM
To: Raines, Angelia; Kretzschmar, Bert
Cc: Vernon Tesh; Thomas Ficht; Wallis, Annette; Meyer, Chris; Salsman, John M; Tiffany Agnew; Fuller Bazer
Subject: RE: Draft - Incident Response Reporting

Looks fine to me. Do we have a definition on what constitutes an occupational exposure? I am sure it will come up.

Brent

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, May 30, 2007 10:59 AM
To: Kretzschmar, Bert; Mattox, Brent S
Cc: Vernon Tesh; Thomas Ficht; Wallis, Annette; Meyer, Chris; Salsman, John M; Tiffany Agnew; Fuller Bazer
Subject: Draft - Incident Response Reporting

Hi Bert and Brent,

I tried to create a presentation for you to use in Friday's training and I updated the SOP as well.

Everyone,

Please review the draft of the updated SOP as well as the presentation and let me know if changes are needed. I know this is a rush, but I would like to start making copies of the materials this afternoon so a quick response would be appreciated.

Thanks! Angie

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 2:36 PM
To: Yeager, Susan
Subject: FW: Report

Follow Up Flag: Follow up
Flag Status: Red

Attachments: Q-Fever.pdf

From: Salsman, John M
Sent: Friday, June 29, 2007 11:55 AM
To: Kelly, Scott
Cc: Clark, Charley; Meyer, Chris
Subject: FW: Report

Scott,

Per your request I have attached a copy of the report. As noted below, Brent had the report hand-carried to ORC, so that it could be distributed appropriately.

Q-Fever.pdf (7 MB)

Thanks, John

From: Mattox, Brent S
Sent: Friday, June 29, 2007 11:17 AM
To: Salsman, John M
Subject: RE: Report

It was sent May 15, with a May 18 addendum added, hand carried.

Brent

From: Salsman, John M
Sent: Friday, June 29, 2007 11:15 AM
To: Mattox, Brent S
Subject: Report

Brent,

Please send me a copy of the report concerning your investigation of the high titer in Dr. Samuel's lab (discussed at the IBC meeting this week). Also, when did you provide the report to ORC and how was it provided (e-mail, hand-carried, other)?

Thanks, John

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 at their Laboratory in Reynolds and obtained additional information on the potential exposures. Although had not entered the BL3 laboratory in , 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 Facility on four (4) occasions prior to the baseline. Laboratory Special Practices does call for baselines prior to exposure. The Facility Access was for 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. indicated 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)
				In / Out				Number		By
8/18/06	Britt Lack	Britt Lack	CMP	8:55	BL					
8/19	Gracie Draper		CMP	1023 1100						
8/20	Gracie Draper		CMP	1020 1109						
8-21	Kasi Russell-Lodrigue		MMP	8:55 10:00	KR					
8/21	Gracie Draper		CMP	221 439						
11-6-06	John Delaney		CMP	9:40	JD					
11-6-06	Kasi Russell-Lodrigue		MMP	10:05 11:55	KR					
11-6-06			MMP	10-05 11:55			R	Adm ID 21600486	KR	KR
11/6										
11/7	Gracie Draper		CMP	154 307						
11/7/06	Kasi Russell-Lodrigue		MMP	2:15 3:30	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 In / Out	Status (Initial One)		[1] Purpose of Access (Use Legend Below)	[2] ID Verification (Use Legend Below)	Verified/ Escorted By (Initial)	Received Hazard Training (Initial) / By
11-14-06	EDWARD SHAW		MMPA	1:45 / 2:30		✓	R	DL 08230694	KR	KR
11/15/06	Kasi Russell-Lodrigue		MMP	8:55 / 10:50	KR					
11/8/06			MMP	8:55 / 10:00			R	VIN 21600686	KR	KR
11/16/06	Gracia Draper		CMP	213 / 331						
11/16/06	Gracia Draper		CMP	250 / 350						
11/16/06	Sean Knox		CMP	8:40 / 11:15	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 / 11:25			R	VIN 21600686	KR	KR
11/22/06	Kasi Russell-Lodrigue		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 #** 1-1 **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	Visitor	Staff		Number		By
12/1/06	Sean Knox		CMP	10:21 / 1:00	SK					
12/3	Gordon Draper		CMP	1154 / 102						
12/4	Gordon Draper		CMP	846 / 1223						
12/5	Gordon Draper		CMP	854 / 1118						
12/6	Amy Henson		CMP	9:43 / 12:10	AH					
12/6			MMPA	10:00 / 10:40			R	21604686	KR	KR
12/6	Kasi Russell		MMPA	10:00 / 10:40	KR					
12/6	Kasi Russell-Logan		MMPA	11:11 / 3:30	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)

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 #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 4/23/2007 Test Reas: DIAGNOSIS
Spec Type: SERUM

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:	S07SM001915	
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 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.

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COMMISSIONER

(continued)

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Tel #: (512)458-7578

Patient

Patient Address:

This test was developed and its performance characteristics determined by the Laboratory Services Section at DSHS. The test has not been approved c 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

Yeager, Susan

From: Kelly, Scott
Sent: Tuesday, June 26, 2007 6:05 PM
To: Raines, Angelia
Cc: Yeager, Susan; Callcott, Diane
Subject: FW: Response to Public Information Request 07-172
Importance: High
Attachments: RE: Response to Public Information Request 07-172

Angie,

Please send me a copy of the Form 3 that was filed related to this elevated titer matter.

Scott Kelly

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:22 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Dr. Samuel

From: Meyer, Chris
Sent: Wednesday, April 05, 2006 11:36 AM
To: Clark, Charley
Subject: Dr. Samuel

Charley,

Regarding the high titers amongst researchers in Dr. Samuel's lab...

One of the groups that I had John and Brent contact was Kevin McGinnis at System Risk Management because of the WCI issues. Apparently, Kevin told his boss (Greg Anderson, I presume). His boss is requiring Kevin to brief Mr. Hooton on the issue. I don't know if that has happened or when, but I thought you should know.

Chris

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:23 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Dr. Samuel
Importance: High

From: Clark, Charley
Sent: Wednesday, April 05, 2006 1:29 PM
To: Prior, David
Subject: FW: Dr. Samuel
Importance: High

David,

This is an update on the Q-Fever (Coxiella Burnetii) issue in Dr. Samuel's lab.

Charley

From: Meyer, Chris
Sent: Wednesday, April 05, 2006 11:36 AM
To: Clark, Charley
Subject: Dr. Samuel

Charley,

Regarding the high titers amongst researchers in Dr. Samuel's lab...

One of the groups that I had John and Brent contact was Kevin McGinnis at System Risk Management because of the WCI issues. Apparently, Kevin told his boss (Greg Anderson, I presume). His boss is requiring Kevin to brief Mr. Hooton on the issue. I don't know if that has happened or when, but I thought you should know.

Chris

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:23 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

From: Mattox, Brent S
Sent: Thursday, April 06, 2006 5:02 PM
To: Clark, Charley
Cc: Salsman, John M
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

This is the correspondence I originally sent out through the Office of Compliance. I just corresponded with with Dr. Wilson, who hopefully will have me an email by tomorrow morning verifying step 3. If I get it, I will forward it to you prior to 9 AM.

Hope this helps,

Brent

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
Subject: Elevated Titers for Q-Fever (Coxiella Burnetii)

At approximately 2:30 PM, the Occupational Health Program received a call from Scott & White reporting high titers for Q-Fever had been received on three individuals from Dr. Samuel's Laboratory. Scott & White had already spoken with Dr. Samuel and had requested follow-up visits with the three individuals. Based on this information, your office (Office of Compliance) was informed. Since you were out of the Office, I also informed Dr. Van Wilson and Dr. Tom Ficht, co-chairs of the Institutional Biosafety Committee at around 3:30 PM.

As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism Coxiella burnetii, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.

2. Follow-up with Scott & White is recommended.

3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:23 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

Attachments: Elevated Titers for Q-Fever (Coxiella Burnetii); Angelia Raines.vcf


Elevated Titers for Q-Fever (C... Angelia Raines.vcf (609 B)

-----Original Message-----
From: Mattox, Brent S
Sent: Friday, April 07, 2006 11:36 AM
To: Clark, Charley; Salsman, John M
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

Latest on the titer issue.

Brent

-----Original Message-----
From: Angelia Raines [mailto:ARaines@vprmail.tamu.edu]
Sent: Friday, April 07, 2006 11:33 AM
To: jsamuel@medicine.tamhsc.edu
Cc: Van Wilson; Mattox, Brent S; ibc@tamu.edu; Thomas Ficht
Subject: Fwd: Elevated Titers for Q-Fever (Coxiella Burnetii)

Dr. Samuel:

Per our conversation, below are two recommendations from Brent Mattox, the Institutional Biosafety Officer (BSO), in regards to the elevated titers for the organism Coxiella burnetii associated with your lab.

1. Follow-up with Scott & White for all lab personnel, including yourself, with elevated titers.

During our conversation , you discussed your SOP for elevated titers and indicated the steps you have taken to ensure the safety of your staff. Please send a complete copy of your lab SOP, including the safety procedures, to my office along with documentation of the steps you have already taken. This information will be reviewed and if changes are needed, you will be notified.

2. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

You also indicated that you would have your lab cleaned but wished to avoid using an aerosol decontaminant at this time. Please note what steps you will take to clean your lab.

I will need a response as soon possible but no later than 4/11/06.

Thank you in advance for your assistance.

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

Yeager, Susan

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
Subject: Elevated Titers for Q-Fever (Coxiella Burnetii)

At approximately 2:30 PM, the Occupational Health Program received a call from Scott & White reporting high titers for Q-Fever had been received on three individuals from Dr. Samuel's Laboratory. Scott & White had already spoken with Dr. Samuel and had requested follow-up visits with the three individuals. Based on this information, your office (Office of Compliance) was informed. Since you were out of the Office, I also informed Dr. Van Wilson and Dr. Tom Ficht, co-chairs of the Institutional Biosafety Committee at around 3:30 PM.

As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism Coxiella burnetii, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.

2. Follow-up with Scott & White is recommended.

3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 11:03 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titer for Q Fever
Attachments: DOC023.PDF

From: Meyer, Chris
Sent: Friday, May 11, 2007 9:32 AM
To: Clark, Charley
Cc: Wallis, Annette; Kretzschmar, Bert; Schneider, Elmer
Subject: FW: Elevated Titer for Q Fever

Charley, FYI...I wanted to keep you in the loop, however, I think that this is for Dr. Ewing to address with management (university and HSC).

From: Mattox, Brent S
Sent: Friday, May 11, 2007 9:00 AM
To: Raines, Angelia; 'jsamuel@medicine.tamhsc.edu'
Cc: Meyer, Chris; Salsman, John M
Subject: Elevated Titer for Q Fever

Angelia/Dr. Samuel:

Scott and White informed me that a high titer (Phase II 1:1024) was received 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.

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 ** * Page 1 of 2*
Date: 5/2/2007

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

Spec #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

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:	S07SM001915
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

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and convalescent serum. Reactions to both phase I and phase II antibodies often develop, but 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
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COMMISSIONER
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TDD: 512-458-7708

(continued)

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 ** * Page 2 of 2*
Date: 5/2/2007

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

Spec #: S07SM001915
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

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

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 11:04 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titer for Q Fever

-----Original Message-----
From: Meyer, Chris
Sent: Friday, May 11, 2007 10:01 AM
To: Clark, Charley
Subject: RE: Elevated Titer for Q Fever

No, not yet.

-----Original Message-----
From: Clark, Charley
Sent: Friday, May 11, 2007 9:55 AM
To: Meyer, Chris
Subject: Re: Elevated Titer for Q Fever

Are we asking for confirmation that it was reported to CDC?

----- Original Message -----
From: Meyer, Chris
To: Clark, Charley
Cc: Wallis, Annette; Kretzschmar, Bert; Schneider, Elmer
Sent: Fri May 11 09:32:21 2007
Subject: FW: Elevated Titer for Q Fever

Charley, FYI…I wanted to keep you in the loop, however, I think that this is for Dr. Ewing to address with management (university and HSC).

From: Mattox, Brent S
Sent: Friday, May 11, 2007 9:00 AM
To: Raines, Angelia; 'jsamuel@medicine.tamhsc.edu'
Cc: Meyer, Chris; Salsman, John M
Subject: Elevated Titer for Q Fever

Angelia/Dr. Samuel:

Scott and White informed me that a high titer (Phase II 1:1024) was received 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.

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:21 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

From: Meyer, Chris
Sent: Monday, April 03, 2006 5:13 PM
To: Clark, Charley
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

From: Salsman, John M
Sent: Monday, April 03, 2006 5:09 PM
To: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

FYI

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
Subject: Elevated Titers for Q-Fever (Coxiella Burnetii)

At approximately 2:30 PM, the Occupational Health Program received a call from Scott & White reporting high titers for Q-Fever had been received on three individuals from Dr. Samuel's Laboratory. Scott & White had already spoken with Dr. Samuel and had requested follow-up visits with the three individuals. Based on this information, your office (Office of Compliance) was informed. Since you were out of the Office, I also informed Dr. Van Wilson and Dr. Tom Ficht, co-chairs of the Institutional Biosafety Committee at around 3:30 PM.

As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism Coxiella burnetii, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.

2. Follow-up with Scott & White is recommended.

3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 9:22 AM
To: Yeager, Susan
Cc: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

From: Clark, Charley
Sent: Monday, April 03, 2006 5:16 PM
To: Prior, David
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

This just came in from Chris and Environmental Health & Safety. I will let you know of developments.

From: Meyer, Chris
Sent: Monday, April 03, 2006 5:13 PM
To: Clark, Charley
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

From: Salsman, John M
Sent: Monday, April 03, 2006 5:09 PM
To: Meyer, Chris
Subject: FW: Elevated Titers for Q-Fever (Coxiella Burnetii)

FYI

From: Mattox, Brent S
Sent: Monday, April 03, 2006 5:07 PM
To: Raines, Angelia
Cc: Salsman, John M
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As Institutional Biosafety Officer, the following are observations and recommendations.

1. Elevated titer indicates direct exposure to the organism Coxiella burnetii, indicating that laboratory precautions failed to isolate the organism from laboratory personnel. At present, we have no indication of any signs of illness among staff. Q-fever is rarely, if ever (Control of Communicable Diseases Manual, 18th ed., American Public Health Association, pg. 436). The disease is easily treatable with antibiotics. Therefore, there should be little or any risk to other individuals. Isolation or confinement of patients is unnecessary.

2. Follow-up with Scott & White is recommended.

3. The Laboratory should be carefully decontaminated and safety procedures reviewed, including the use of personal protective equipment.

In summary, follow-up with Scott & White or a personal Physician should be documented, laboratory procedures evaluated, and thorough decontamination of surfaces and any reusable protective equipment (lab coats or scrubs). EHSD will follow up with the IBC and the Principal Investigator to determine if any additional steps are necessary. Again, there is no evidence the organism has breached the BL3 Laboratory containment.

If you have any questions, I can be reached at 845-2132.

Sincerely,

Brent S. Mattox, CIH
Biological Safety Officer

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:25 PM
To: Yeager, Susan
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection

Importance: High

-----Original Message-----
From: Meyer, Chris
Sent: Thursday, April 12, 2007 3:03 PM
To: Clark, Charley
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

-----Original Message-----
From: Mattox, Brent S
Sent: Thursday, April 12, 2007 2:30 PM
To: Meyer, Chris; Salsman, John M
Subject: FW: Texas A&M Violates Law in Biodefense Lab Infection
Importance: High

This just appeared on the listserve.

-----Original Message-----
From: ABSA biosafety forum [mailto:Biosafety@BIOSAFETY.ABSA.ORG] On Behalf Of Edward Hammond
Sent: Thursday, April 12, 2007 1:29 PM
To: Biosafety@BIOSAFETY.ABSA.ORG
Subject: Texas A&M Violates Law in Biodefense Lab Infection

The Sunshine Project
News Release - 12 April 2007
http://www.sunshine-project.org

Texas A&M University Violates Federal
Law in Biodefense Lab Infection

- Student climbs into dirty bioaerosol chamber and contracts brucellosis
- A&M failed to report the incident to federal authorities
- May lose federal funding and owe $750,000 or more in fines.

- Urgent need for mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps to provide missing lab public accountability.

12 April 2007 - An aerosol chamber mishap at Texas A&M University in February 2006 caused a researcher to be infected with the bioweapons agent brucella. Texas A&M University then violated federal law by not reporting the brucellosis case to the Centers for Disease Control (CDC) and now faces severe penalties. This information has only come to light as a result of persistent Texas Public Information Act requests by the Sunshine Project.

Overdue records obtained by the Sunshine Project in the last two days confirm that A&M officials discussed the fact that the federal Select Agent Rule required reporting the brucella infection; but they chose not to do so. A&M is still holding back additional

documentation of crime. The scandal points to the urgent need for a mandatory federal accident and near-miss reporting system that publishes institution-level data on mishaps and creates public accountability for biodefense lab accidents.

For federal violations, Texas A&M may be fined $500,000, plus up to $250,000 for individual(s) that failed to report the incident. In refusing to produce information about the infection, A&M officials also flouted the Texas Public Information Act. The Sunshine Project is filing a complaint with Texas Attorney General Greg Abbott that may result in other fines and/or jail sentences if A&M officials are found guilty of hiding documents.

What Happened: The infection incident occurred on 9 February 2006. Several A&M researchers, including Principal Investigator Thomas Ficht, were in a BSL-3 lab training in the use of the Madison Aerosol Chamber. Supervising was David McMurray, an A&M professor and self-described inventor of the chamber, who has characterized it as "foolproof".

Following a "hot" run that blew aerosolized brucella into the chamber to expose mice, researchers began clean up procedures. Using what Texas A&M now admits were inappropriate protocols, a researcher "cleaned the unit by climbing partially into the chamber to disinfect it." A&M officials later concluded that the brucella bacteria likely entered her body via eyes as a result of this improper procedure. (This is the third instance of lab-acquired infections related to the Madison chamber that the Sunshine Project has uncovered. The others were in Seattle and New York City.)

By April 2006, the researcher had "been home sick for several weeks." Nobody apparently suspected brucellosis, despite the occupational exposure and, presumably, familiarity with its symptoms. Eventually, the researcher's personal physician ordered blood tests and made the diagnosis on about April 10. On 15 April, the infected researcher began a heavy treatment course reflecting the severity of the situation. received a week of intravenous antibiotics followed by a 45-day course of two additional antibiotic drugs. Just over a month later, new blood tests indicated that the infection had passed.

Failure to Report: E-mails that Texas A&M finally released to the Sunshine Project late on Tuesday night reveal that the University broke federal law by not reporting the infection. The Select Agent Rule required A&M to report the infection immediately upon its discovery and for the school to file a formal report, called APHIS/CDC Form 3, within 7 days.

According to A&M records, the sick researcher told Thomas Ficht of the diagnosis on Monday or Tuesday, April 10 or 11, 2006. Based on the records A&M has released, Ficht does not appear to have told A&M administrators until ten days later. On 21 April, a Friday afternoon, Ficht informed other A&M officials, including Angela Raines, the Responsible Official under the Select Agent Rule and Brent Maddox, the A&M biosafety director, in an e-mail titled "Workmen's Compensation".

Texas A&M has also released a partial e-mail sequence involving discussions during the following week between Ficht, the sick researcher, and Maddox (the safety director). On Tuesday April 25, Ficht noted "according to the select agent guidelines [sic] we are required to report any laboratory exposures to the CDC." Yet no report was filed.

Ficht is the Research Standards Officer of Texas A&M University, a member of the NIH bacterial biodefense and bacterial pathogenesis study groups, and is funded to study bioweapons agents by the Department of Homeland Security and National Institutes of Health. Notably, Ficht is one of only a few US researchers who were studying Brucella before the post-9/11 biodefense boom.

A&M has yet to release any of Maddox or Raines' records about the incident, despite having been obligated to do so by Texas law for almost six months. These undoubtedly would shed more light on A&M's violation of the Select Agent Rule.

A Year Too Late: There is no reason to suspect that A&M would have admitted the truth without pressure. It has taken six months for the Sunshine Project to convince A&M to reveal this incident to the limited extent known today. This week, as the Project was closing in on details in a series of tense e-mails with the Texas A&M General Counsel (including a threat to take the matter to law enforcement), A&M officials apparently decided that they could no longer stonewall.

While A&M was refusing to answer Sunshine Project requests, on Tuesday (10 April), A&M e-

mailed CDC to inform it of the incident - a full year after the infection should have been reported. Yesterday (11 April), A&M's Angela Raines filed the required APHIS/CDC Form 3 document, 51 weeks after A&M was required to submit it.

Penalties: The Sunshine Project is calling for maximum penalties to be levied. Says Sunshine Project Director Edward Hammond, "The evidence released to us indicates that Texas A&M officials discussed the federal requirement to report the incident, yet they did not do so. They chose to ignore the law, and that irresponsible decision to endanger public health and security should be swiftly and severely punished with maximum fines and loss of federal research funding."

An Ongoing Problem: For years, watchdogs have pointed to the lack of effective regulation of BSL-3 and BSL-4 labs in the United States, and particularly the need for improved (and transparent) accident reporting. Those calls have grown louder after a series of accidents in recent years that labs tried to hide from the public, including tularemia infections at Boston University, a plague problem in Newark, New Jersey, and a genetically-engineered bird flu incident in Austin, Texas.

The Sunshine Project has gathered data (in press) documenting nearly a score more BSL-3 and BSL-4 accidents, including select agent incidents, almost none of which have been reported to the public. Due to the absence of effective federal regulation, there are, undoubtedly, many more accidents that have been successfully buried, like the Texas A&M brucella incident almost was.

"It is common knowledge in the biodefense business that lab accidents with bioweapons agents are routinely buried in order to avoid negative publicity and endangering funding," says Hammond, "It is only through the power of the Texas Public Information Act that Texas A&M's criminal failures have been revealed."

The Sunshine Project is calling for a mandatory national accident and near-miss reporting system to be established. "When accidents are buried, nobody learns from past mistakes, and communities are kept in the dark about accidents and sloppy labs in their midst." says Hammond, "It's time for biodefense labs to stop talking down to the public with false safety claims and to start being transparent. All BSL-3 and BSL-4 labs should be required to report all significant accidents and near-accidents, and that information should be published by the federal government, with details of every incident, including the name of the lab and the agent involved."

- END -

Note: Look for original A&M documents to be posted online with this news release at the Sunshine Project website.

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:26 PM
To: Yeager, Susan
Subject: FW: CDC Visit- No Update

From: Tiffany Agnew [mailto:tmagnew@tamu.edu]
Sent: Sunday, April 15, 2007 7:43 PM
To: ddavis@cvm.tamu.edu; gadams@cvm.tamu.edu; Tom Ficht; TESH@medicine.tamhsc.edu; Van Wilson; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Meyer, Chris; Clark, Charley; Callcott, Diane; Faber, Jan; Salsman, John M; jsamuel@tamu.edu; Ihrig, Melanie; Ewing, Richard; McClendon, Rodney P; Kelly, Scott; Moore, Steve; Fuller Bazer; Betsy Browder
Cc: Shannon Davis; Raines, Angelia
Subject: CDC Visit- No Update

Greetings All!

Angelia has asked that I inform you all that as of 7:30 pm, our office has not received any new information in regards to the arrival time of the CDC inspection team. The only information that has been confirmed is that the inspection is scheduled to take place on **Monday, April 16, 2007**. At this time, our office is unable to provide any times or locations; however, we will inform you as soon as information becomes available.

In addition, our office has begun compiling information based upon the questions submitted by the CDC on Friday. Dr. Ficht has been very instrumental in providing extremely detailed answers to all 13 questions.

Thank you!

Regards,

Tiffany

Tiffany M. Agnew
Program Coordinator (Office of Research Compliance)
Texas A&M
1500 Research Parkway
Suite 150 B (Centeq Building)
College Station, Texas 77843-1186
(979) 458-3624
(979) 862-3176 - fax
tagnew@vprmail.tamu.edu

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:26 PM
To: Yeager, Susan
Subject: FW: CDC Visit- No Update

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Monday, April 16, 2007 6:49 AM
To: ddavis@cvm.tamu.edu; gadams@cvm.tamu.edu; tficht@cvm.tamu.edu; TESH@medicine.tamhsc.edu; wilson@medicine.tamhsc.edu; Wallis, Annette; Kretzschmar, Bert; Mattox, Brent S; Meyer, Chris; Clark, Charley; Callcott, Diane; Faber, Jan; Salsman, John M; jsamuel@tamu.edu; Ihrig, Melanie; Ewing, Richard; McClendon, Rodney P; Kelly, Scott; Moore, Steve; Tiffany Agnew; Fuller Bazer; Betsy Browder
Cc: Shannon Davis
Subject: Re: CDC Visit- No Update

Good Morning,

I just spoke with Diane Martin, one of the inspectors from the CDC. They will arrive this morning at 9:00 a.m. Per Diane, they wish to focus solely on the exposure incident and are not inspecting our entire registration, therefore they DO NOT want to have an entrance briefing.
They do want everyone involved to be available but have not yet decided how they are going to approach the inspection. Per Diane, they will most likely want to start off by meeting with Dr. Ewing and myself.
Following that meeting, they will let us know how they want to proceed.

My office will contact you as quickly as possible to provide additional updates.

Thank you,
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

>>> Tiffany Agnew 04/15/07 7:43 PM >>>
Greetings All!

Angelia has asked that I inform you all that as of 7:30 pm, our office has not received any new information in regards to the arrival time of the CDC inspection team. The only information that has been confirmed is that the inspection is scheduled to take place on Monday, April 16, 2007. At this time, our office is unable to provide any times or locations; however, we will inform you as soon as information becomes available.

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Thank you!

Regards,

Tiffany

Tiffany M. Agnew
Program Coordinator (Office of Research Compliance) Texas A&M 1500 Research Parkway Suite 150 B (Centeq Building) College Station, Texas 77843-1186
(979) 458-3624
(979) 862-3176 - fax
tagnew@vprmail.tamu.edu

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:26 PM
To: Yeager, Susan
Subject: FW: Statement issued to local news media organizations

---

From: Choudhury, Tamim
Sent: Monday, April 16, 2007 11:48 AM
To: 'barry@bcscvb.org'; 'brian.blake@nara.gov'; 'eddie.carmon@txdps.state.tx.us'; Carroll, Sherylon; Clark, Charley; 'bcolwel@dot.state.tx.us'; 'mdonoho@bryantx.gov'; 'slfarris@bryanisd.org'; 'cfrazier@co.brazos.tx.us'; 'candy@co.brazos.tx.us'; 'aganter@csisd.org'; 'garzaj@bryan.tx.gov'; Gay, Cynthia A; Happ, John; Hickman, Royce H; 'mhosking@co.brazos.tx.us'; 'bhumphreys@cstx.gov'; 'rjackson@bryantx.gov'; 'pjett@cstx.gov'; 'mlangwell@cstx.gov'; 'rmcgrego@bryantx.gov'; 'smendez@co.brazos.tx.us'; Meyer, Chris; 'bnugent@cstx.gov'; 'tottinger@st-joseph.org'; Parker, Terri; 'gparsons@blinn.edu'; 'heather@bcscvb.org'; Schneider, Elmer; 'Pattie@bcscvb.org'; 'rseaton@cstx.gov'; 'jsocol@ci.bryan.tx.us'; 'pthornton@gbplc.tamu.edu'; 'raven@bryanisd.org'; 'gadams@cvm.tamu.edu'; 'rsilvia@cstx.gov'; 'therev@cbcbryan.org'; 'rsims@co.brazos.tx.us'; ' 'gbrown@cstx.org'; 'dwatkins@bryantx.org'; lillel@tamuhillel.org'; Carroll, Sherylon; Stephenson, Lane B; 'gadams@cvm.tamu.edu'; Clark, Neville; Inbody, Tiffany; Happ, John; ; O'Quinn, Michael
Subject: Statement issued to local news media organizations

All,

Below is a copy of a statement issued to local news media organizations today. At this time, it is unknown what impact, if any, this will have on our plans to host the National Bio and Agro-Defense Facility. We will keep you posted regarding further developments.

Garry Adams
Professor and Associate Dean of Research
Phone: (979) 845-5092
Email: gadams@cvm.tamu.edu

The following is a statement issued by Texas A&M's Executive Vice President and Provost David B. Prior:

"An internal investigation has confirmed that an occupational exposure to the bacterium that causes brucellosis occurred on our campus and that the individual was successfully treated. We have since strengthened our safety, training and reporting procedures following the human error involved in not reporting this incident.

An independent review of our processes and procedures will be conducted by representatives of the Center for Disease Control (CDC), who are on campus today (Monday, April 16). We will be fully cooperative and our goal is to comply with all current biosafety standards.

No university officials will make further comments regarding this incident until our final internal report is

issued following the CDC review."

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:26 PM
To: Yeager, Susan
Subject: FW: misinformation

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:48 AM
To:
Subject: RE: misinformation

- thank you for your e-mail. I am presently in Malaysia at an international meeting. You are quite correct that factual information is essential. Please be assured that I will pass this on to those directly involved in my absence.
David Prior

-----Original Message-----
From:
Sent: 4/18/07 8:58:16 AM
To: "dprior@tamu.edu"<dprior@tamu.edu>
Subject: misinformation

** High Priority **

Dear Dr. Prior,

I am the researcher involved in The Eagle's headline story today. I am very concerned and unhappy about the misinformation that appears in this article and I am asking your help to issue a retraction. I want it made very clear that I DID NOT CLIMB into the aerosol chamber. I REACHED inside, after the last challenge was completed, to wipe down the chamber AS IS OUR STANDARD PROTOCOL. Furthermore, the (exposure) event did not take place as part of a training session on the use of the Madison Chamber, nor were Drs. McMurray or Ficht present at the time of my exposure. These are serious inconsistences which demand a response.
I am asking you and your office for help with this matter. These inaccuracies MUST be corrected. (It is one thing for these statements to appear on the Sunshine Project's website, which surely is read by precious few. But now, these inaccuracies have made their way to the front page of our newspaper and must be addressed.) I ask for your help in this matter.

Sincerely,

Research Associate
Department of Microbial and Molecular Pathogenesis College of Medicine-MS 1114 Texas A&M Health Science Center College Station, TX 77843-1114
(979)845-3679 (lab)
(979)845-3479 (fax)

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:27 PM
To: Yeager, Susan
Subject: FW: misinformation

Attachments: misinformation

misinformation

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:53 AM
To: Davis, Eddie J; Moore, Steve; Perry, Bill L; Clark, Charley
Subject: FW: misinformation

All - you will have received a copy of my reply to This account differs from earlier reports. Clearly there needs to be further clarification -internally and maybe externally.
Bill - you know my time zone and schedule - if apprpriate please call.
David

Yeager, Susan

From:
Sent: Wednesday, April 18, 2007 8:58 AM
To: Prior, David
Subject: misinformation

Importance: High

** High Priority **

Dear Dr. Prior,

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Sincerely,

Research Associate
Department of Microbial and Molecular Pathogenesis College of Medicine-MS 1114 Texas A&M Health Science Center College Station, TX 77843-1114
(979)845-3679 (lab)
(979)845-3479 (fax)

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:27 PM
To: Yeager, Susan
Subject: FW: misinformation

-----Original Message-----
From: Davis, Eddie J
Sent: Wednesday, April 18, 2007 10:08 AM
To: Perry, Bill L; Clark, Charley; 'Richard Ewing'; Moore, Steve
Subject: FW: misinformation

Suggest one of you get back with Despite concerns about misinformation, I think we need to get the CDC visit behind us before we begin to debate this issue further in the newspaper. EJD.

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:48 AM
To:
Subject: RE: misinformation

· thank you for your e-mail. I am presently in Malaysia at an international meeting. You are quite correct that factual information is essential. Please be assured that I will pass this on to those directly involved in my absence.
David Prior

-----Original Message-----
From:
Sent: 4/18/07 8:58:16 AM
To: "dprior@tamu.edu"<dprior@tamu.edu>
Subject: misinformation

** High Priority **

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Sincerely,

Research Associate
Department of Microbial and Molecular Pathogenesis College of Medicine-MS 1114 Texas A&M

Health Science Center College Station, TX 77843-1114
(979)845-3679 (lab)
(979)845-3479 (fax)

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:27 PM
To: Yeager, Susan
Subject: FW: Confidential

Importance: High

-----Original Message-----
From: Moore, Steve
Sent: Wednesday, April 18, 2007 10:12 AM
To: Prior, David; Davis, Eddie J; Perry, Bill L; Clark, Charley
Cc: Kelly, Scott
Subject: RE: Confidential
Importance: High

I certainly understand the issue, but I have asked Angelia to discuss this with Scott Kelly before we issue a request for retraction. I think we need to make sure that we have provided the correct information via the public information request from the Sunshine Project (which is the source for the story). If not and we ask for a retraction, it might appear that we did not properly comply with the original request.

Clearly, we need to correct the error, I just want to make sure we are doing it in a fashion which will not create another question. I am waiting to hear back from either Scott or Angelia before we proceed.

Thanks.

Steven B. Moore
Chief Marketing Officer & VP Communications Texas A&M University 1180 TAMU College Station, TX 77843-1180
979.458.1729 (office) / 979.204.7185 (cell) steve.moore@tamu.edu

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:53 AM
To: Davis, Eddie J; Moore, Steve; Perry, Bill L; Clark, Charley
Subject: FW: misinformation

All - you will have received a copy of my reply to This account differs from earlier reports. Clearly there needs to be further clarification -internally and maybe externally.
Bill - you know my time zone and schedule - if apprpriate please call.
David

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:28 PM
To: Yeager, Susan
Subject: FW: misinformation

-----Original Message-----
From: Perry, Bill L
Sent: Wednesday, April 18, 2007 11:34 AM
To: Davis, Eddie J; Clark, Charley; 'Richard Ewing'; Moore, Steve
Cc: Perry, Bill L; Prior, David
Subject: RE: misinformation

All,
I called Rod McCallum of HSC first, so he would know I would be calling I have called her and said I would work on this. I have a phone message in to Steve Moore. Charley Clark was here so he knows this.
Will update.
Bill

-----Original Message-----
From: Davis, Eddie J
Sent: Wednesday, April 18, 2007 10:08 AM
To: Perry, Bill L; Clark, Charley; 'Richard Ewing'; Moore, Steve
Subject: FW: misinformation

Suggest one of you get back with Despite concerns about misinformation, I think we need to get the CDC visit behind us before we begin to debate this issue further in the newspaper. EJD.

-----Original Message-----
From: Prior, David
Sent: Wednesday, April 18, 2007 9:48 AM
To:
Subject: RE: misinformation

- thank you for your e-mail. I am presently in Malaysia at an international meeting. You are quite correct that factual information is essential. Please be assured that I will pass this on to those directly involved in my absence.
David Prior

-----Original Message-----
From:
Sent: 4/18/07 8:58:16 AM
To: "dprior@tamu.edu"<dprior@tamu.edu>
Subject: misinformation

** High Priority **

Dear Dr. Prior,

I am the researcher involved in The Eagle's headline story today. I am very concerned and unhappy about the misinformation that appears in this article and I am asking your help to issue a retraction. I want it made very clear that I DID NOT CLIMB into the aerosol chamber. I REACHED inside, after the last challenge was completed, to wipe down the chamber AS IS OUR STANDARD PROTOCOL. Furthermore, the (exposure) event did not take place as part of a training session on the use of the Madison Chamber, nor were Drs. McMurray or Ficht present at the time of my exposure. These are serious inconsistences which demand a response.
I am asking you and your office for help with this matter. These inaccuracies MUST be corrected. (It is one thing for these statements to appear on the Sunshine Project's

website, which surely is read by precious few. But now, these inaccuracies have made their way to the front page of our newspaper and must be addressed.) I ask for your help in this matter.

Sincerely,

Research Associate
Department of Microbial and Molecular Pathogenesis College of Medicine-MS 1114 Texas A&M Health Science Center College Station, TX 77843-1114
(979)845-3679 (lab)
(979)845-3479 (fax)

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:28 PM
To: Yeager, Susan
Subject: FW: misinformation

-----Original Message-----
From: Davis, Eddie J
Sent: Wednesday, April 18, 2007 1:50 PM
To: Perry, Bill L; Clark, Charley; 'Richard Ewing'; Moore, Steve
Cc: Prior, David
Subject: RE: misinformation

Thanks,EJD.

-----Original Message-----
From: Perry, Bill L
Sent: Wednesday, April 18, 2007 11:34 AM
To: Davis, Eddie J; Clark, Charley; 'Richard Ewing'; Moore, Steve
Cc: Perry, Bill L; Prior, David
Subject: RE: misinformation

All,
I called Rod McCallum of HSC first, so he would know I would be calling I have called and said I would work on this. I have a phone message in to Steve Moore.
Charley Clark was here so he knows this.
Will update.
Bill

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From: Davis, Eddie J
Sent: Wednesday, April 18, 2007 10:08 AM
To: Perry, Bill L; Clark, Charley; 'Richard Ewing'; Moore, Steve
Subject: FW: misinformation

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Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:28 PM
To: Yeager, Susan
Subject: FW: Review of Reportable Events for Select Agents and Toxins

---

From: Clark, Charley
Sent: Wednesday, April 18, 2007 1:59 PM
To: Ewing, Richard
Cc: Prior, David; Wallis, Annette
Subject: Review of Reportable Events for Select Agents and Toxins

Dick,

University Risk and Compliance has been asked to review the University's current procedures regarding notification of reportable events for select agents and toxins. Our review will focus on procedures, including redundancies, to ensure that CDC and other entities receive timely notification of reportable events as required by applicable regulations.

We would like to discuss the project with you. Please e-mail or call me at 845-0977 if you have questions, etc.

Thanks,
Charley

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:28 PM
To: Yeager, Susan
Subject: FW: The Battalion - A&M under investigation after disease transmission

---

From: Prior, David
Sent: Thursday, April 26, 2007 3:45 PM
To: Moore, Steve; Clark, Charley
Subject: FW: The Battalion - A&M under investigation after disease transmission

FYI - is asking very reasonable questions. The Batt simply perpetuates a version of the event. Do we have answers to questions? ?

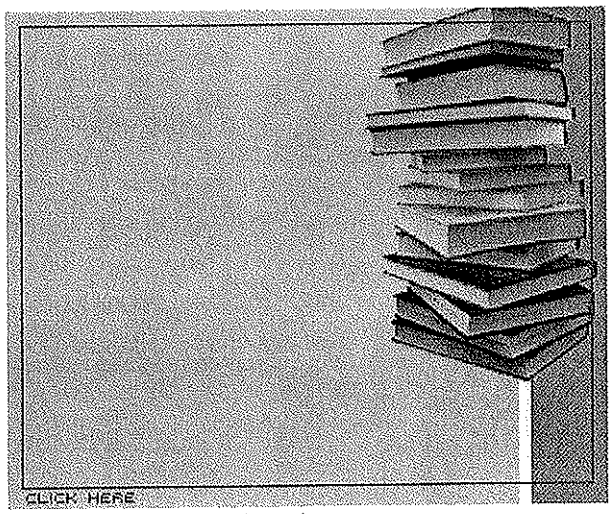
From:
Sent: Thursday, April 26, 2007 3:00 PM
To: Prior, David
Subject: The Battalion - A&M under investigation after disease transmission

thebatt.com

The Battalion
The Independent Student Voice of Texas A&M Since 1893

Thursday, April 26, 2007

ARTICLE EMAILED FROM A FRIEND



Dr. Prior,

This article appeared in The Battalion on 4/24/07. I just learned about it yesterday. I am particularly concerned about this statement, which appears on the second page: "The incident occurred when the researcher was cleaning a

chamber that contained aerosolized brucella by climbing partially into it, which A&M officials said was inappropriate lab protocol."

This prompts me to ask when University officials expect to hear from the CDC regarding their findings? And when do you think the University will issue a response to correct these damaging and inaccurate statements appearing in the press? Thank you for your assistance.

A&M under investigation after disease transmission

Texas A&M is being investigated after failing to timely report to the Center for Disease Control and Prevention (CDC) that a student researcher was infected with brucellosis in 2006.

Read Full Article

* The sender's identity has not been verified.

View our Privacy Policy.

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:29 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: Draft - Incident Response Reporting

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Tuesday, June 05, 2007 5:44 PM
To: Kretzschmar, Bert; Mattox, Brent S
Cc: Vernon Tesh; Thomas Ficht; Wallis, Annette; Meyer, Chris; Salsman, John M; Tiffany Agnew; Fuller Bazer
Subject: RE: Draft - Incident Response Reporting

Hi Brent,

The following is per Scott Kelly. Please share as broadly as needed. I am also asking Tiffany to make sure this is added to the current SOP and shared with the PIs, IBC, etc.

Thanks,
Angelia

Our working definition that can be used for Occupational Exposure is "If an individual has or is observed to have, a disease, abnormal health condition, or laboratory finding that is caused by or related to exposures in the workplace (including an elevated titer), that shall constitute an occupational exposure for reporting purposes."

>>> "Mattox, Brent S" <bsmattox@tamu.edu> 5/30/2007 11:07 AM >>>
Looks fine to me. Do we have a definition on what constitutes an occupational exposure? I am sure it will come up.

Brent

-----Original Message-----
From: Angelia Raines [mailto:araines@vprmail.tamu.edu]
Sent: Wednesday, May 30, 2007 10:59 AM
To: Kretzschmar, Bert; Mattox, Brent S
Cc: Vernon Tesh; Thomas Ficht; Wallis, Annette; Meyer, Chris; Salsman, John M; Tiffany Agnew; Fuller Bazer
Subject: Draft - Incident Response Reporting

Hi Bert and Brent,

I tried to create a presentation for you to use in Friday's training and I updated the SOP as well.

Everyone,

Please review the draft of the updated SOP as well as the presentation and let me know if changes are needed. I know this is a rush, but I would like to start making copies of the materials this afternoon so a quick response would be appreciated.

Thanks! Angie

Yeager, Susan

From: Clark, Charley
Sent: Monday, July 02, 2007 1:29 PM
To: Yeager, Susan
Subject: FW: The Battalion - A&M under investigation after disease transmission

---

From: Moore, Steve
Sent: Thursday, April 26, 2007 6:09 PM
To: Prior, David; Clark, Charley
Subject: RE: The Battalion - A&M under investigation after disease transmission

David, I asked the Batt not to publish this article because it would only point out the views of the Sunshine Project, but in their infinite wisdom....

The answers are that the CDC response could take another week or so. At that point, we will issue the complete details of the exposure, our reaction to it and any changes to our program going forward.

Thanks.

Steven B. Moore
Chief Marketing Officer & VP Communications
Texas A&M University
1180 TAMU
College Station, TX 77843-1180
979.458.1729 (office) / 979.204.7185 (cell)
steve.moore@tamu.edu

From: Prior, David
Sent: Thursday, April 26, 2007 3:45 PM
To: Moore, Steve; Clark, Charley
Subject: FW: The Battalion - A&M under investigation after disease transmission

FYI - is asking very reasonable questions. The Batt simply perpetuates a version of the event. Do we have answers to questions? ?

From:
Sent: Thursday, April 26, 2007 3:00 PM
To: Prior, David
Subject: The Battalion - A&M under investigation after disease transmission

thebatt.com

The Battalion
The Independent Student Voice of Texas A&M Since 1893

Thursday, April 26, 2007

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A&M under investigation after disease transmission

Texas A&M is being investigated after failing to timely report to the Center for Disease Control and Prevention (CDC) that a student researcher was infected with brucellosis in 2006.

Read Full Article

* The sender's identity has not been verified.

Yeager, Susan

From: Wallis, Annette
Sent: Monday, July 02, 2007 1:30 PM
To: Yeager, Susan
Cc: Wallis, Annette
Subject: FW: ACW edits SBAT Incident Response Policy 6-1-07.doc
Attachments: Incident Reporting Flowchart ver 5-31-07.ppt; ACW edits SBAT Incident Response Policy 6-1-07.doc

Suzy,

This file is sent to you in response to Public Information request 01-176.

Thank you,
Annette Wallis

From: Wallis, Annette
Sent: Wednesday, May 30, 2007 1:58 PM
To: Angelia Raines
Subject: ACW edits SBAT Incident Response Policy 6-1-07.doc

Angelia,

I have attached a Word file with the following edits (my edits are highlighted in blue) base on my review of the file I received from you this morning.

I have inserted a Flowchart that has the PI contact ORC to confirm receipt of notification. It is the last sentence in the first big blue box. This was added at Charley's request to provide an additional control check point to ensure ORC received timely notification from either EHSD or UPD. This flowchart also has the UPD number for dispatch that Chris Meyer requested in the event Bert could not be reached.

The flowchart inserted on the Word file you sent had a distorted formatting. I inserted the new PowerPoint into the edited attached Word file by using "paste special as a Picture Enhanced Metafile". I then drug it to a larger size. I have also attached a separate PowerPoint file as well as the edited Word file.

Edits to Word file (highlighted Blue) I noticed the yellow highlights but I did not make them and do not know why they are highlighted.

- Page one: deleted space in title box before Notifications
- 1.1 change to include UPD Dispatch number and delete Bert's cell and home number

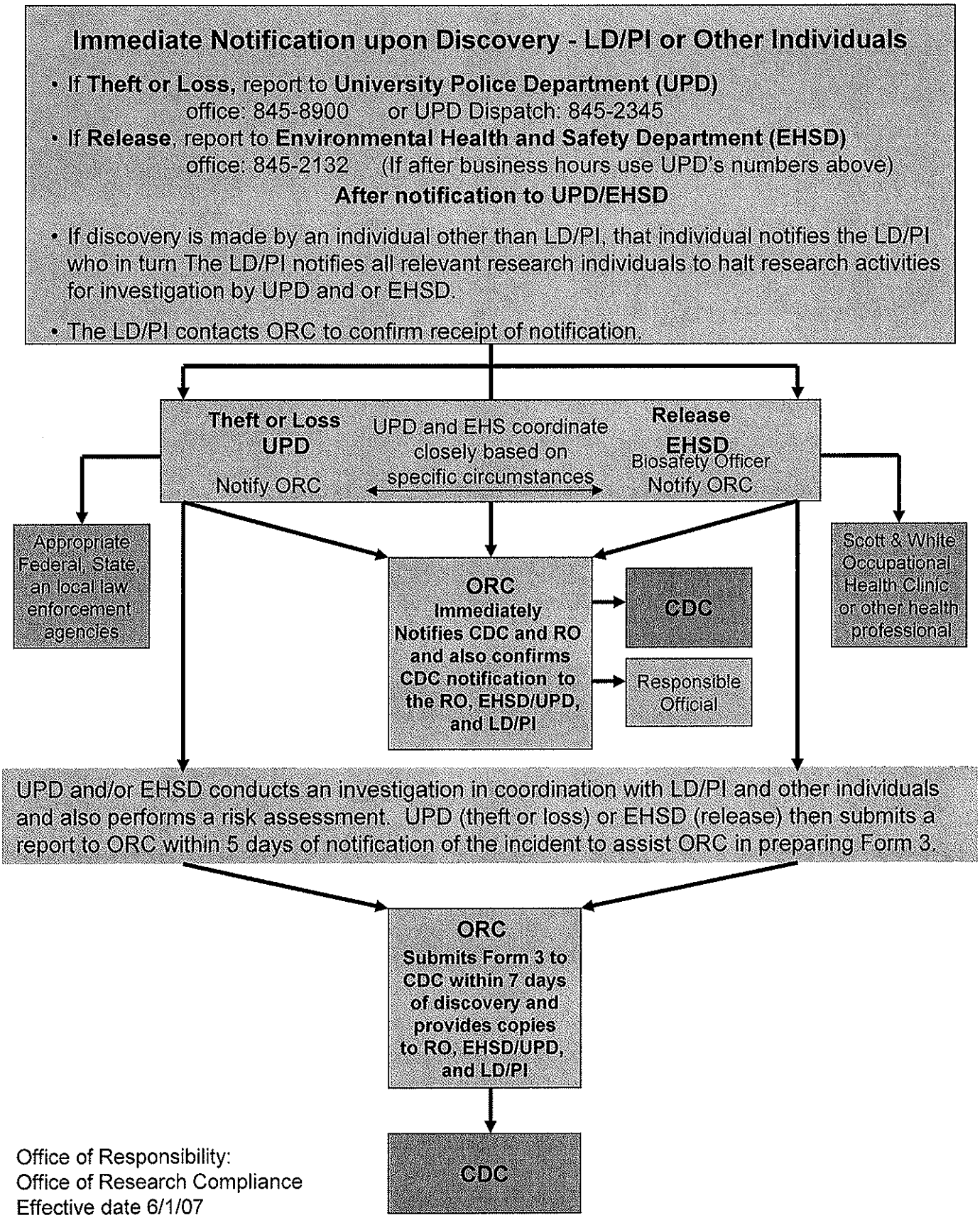
  Added sentence that LD/PI also contacts ORC
- 1.2.1 deleted comma after (BSO))

- 1.2.5 Added ORC will also update the RO to be consistent with the write-up on theft/loss
- Added 1.5 for training on release which was listed under theft/loss
- 2.1 change to include UPD Dispatch number and delete Bert's cell and home number
  Also added the LD/PI will also contact ORC.
- 2.2.4 and 2.2.5: reversed order to be consistent with write-up on release
- 2.4 Deleted training on release
- Under #12 for ORC: deleted also ...For rDNA, NIH must also be notified ~~also~~.
- Insertion of new flowchart. Note: I took off version date and put effective date to correspond with policy header box.

I hope this is helpful. If you use the file, you wil probably want to take off all the highlights, both blue an yellow.

Annette

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

600 – IBC COMMUNICATIONS, NOTIFICATIONS and REPORTS	
601. Report of Theft, Loss, or Release from SBAT Facilities	
Policy: IBC 601 **Effective Date: 5/10/07**	**Revised Date: 5/29/07** **Revised By: Angelia Raines** **Revision Effective Date: 6/1/07**

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** – Occupational exposure 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.

3 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

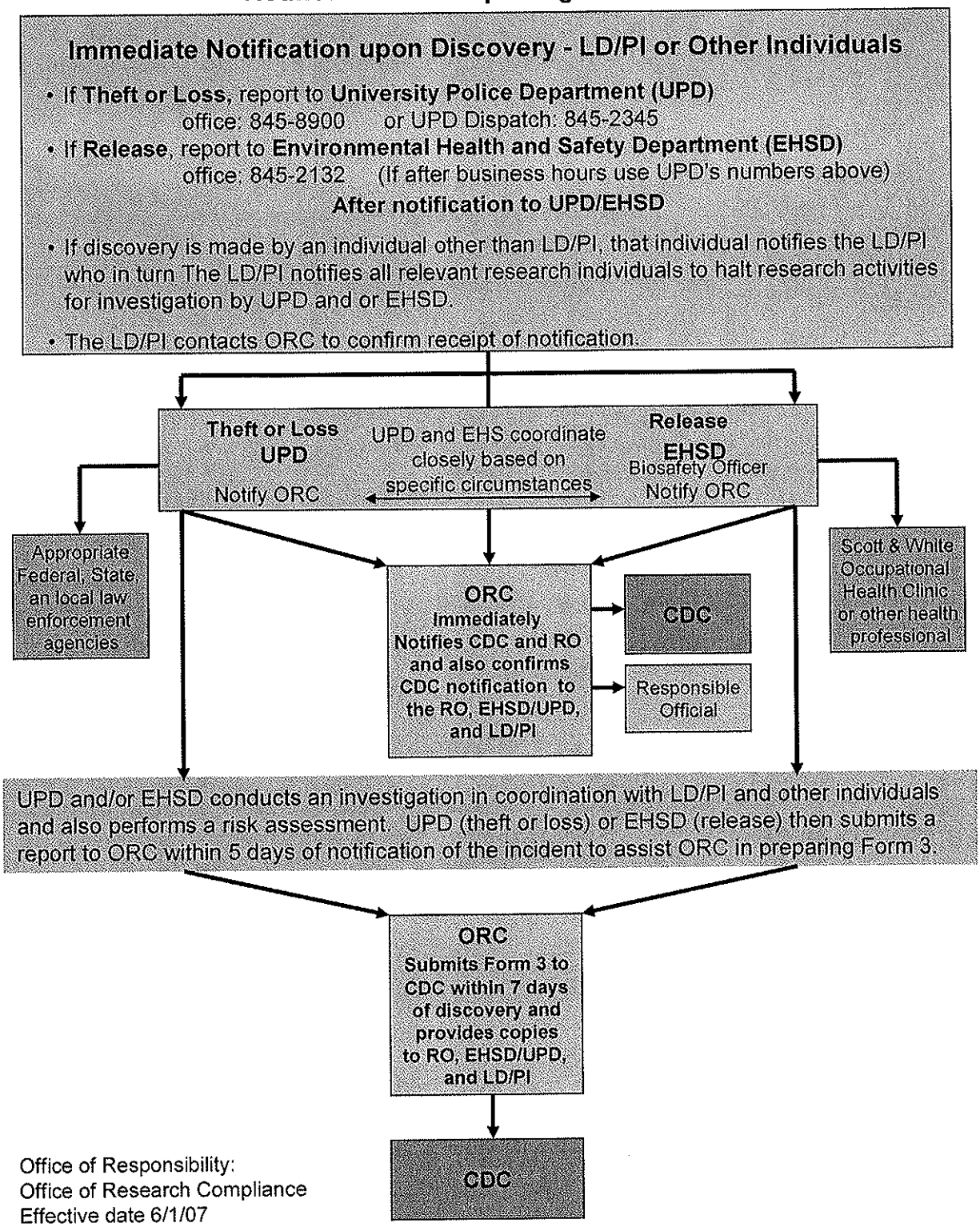
A flow chart has been added to document the process.

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	**PI Davis** Office – 979 862-4113
PI Ficht Office – 979 845-4118	**PI Samuel** Office – 979 862-1684
PI Tesh Office – 979 862-4113	

Incidents involving Theft or Loss
University Police Department (UPD) contact

Bert Kretzschmar
Office – 979 845-8900

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

After hours 5:00 pm
Contact the University Police Department contact
Lt. Bert Kretzschmar
Office – 979 845-8900

Other Contact information		
Vice President for Research/Responsible Official (RO)	Richard Ewing (RO)	979 845-8585 (Office) or
	Fuller Bazer (ARO)	979 693-2876 (Office) or
	Angelia Raines (ARO)	979 847-9362 (Office) or
Comparative Medicine Program	Melanie Ihrig	979 845-7433 (Office) or
	Elizabeth Browder	979 845-7433 (Office) or
	Frank Stein	979 845-6488 (Office) or
Institutional Biosafety Committee (IBC)	Thomas Ficht	979 845-4118 (Office) or
	Vernon Tesh	979 862-4113 (Office) or
	Tiffany Agnew	979 458-3624 (Office) or
Other Emergency Numbers	College Station Police	979 764-3600 or 9-911
	Medical Emergency	
	College Station Fire	979 764-3700 or 9-911
	Radiological Emergency	979 832-1111
	University Maintenance	979 845-4311

TEXAS VETERINARY MEDICAL CENTER
COLLEGE OF VETERINARY MEDICINE
TEXAS A&M UNIVERSITY
COLLEGE STATION, TEXAS 77843-4467

Department of
VETERINARY PATHOBIOLOGY

Tel.: 979-862-4402
Fax: 979-862-1088

April 6, 2006

MEMORANDUM

TO: All TB/Brucellosis Project Personnel

Dr. Ficht's Lab	**Dr. Adams' Lab**	**Others Con't:**
Thomas Ficht	Garry Adams	Cheryl Chamblee
Jianwu Pei	Jario Nunes	John Edwards
Qingmin Wu	Doris Hunter	Dawn Currin
Melissa Kahl-McDonagh	Roberta Pugh	Eric Hansen
Han Shuo	Sara Lawhorn	Brad Weeks
Navina Bhatkar	Sangeeta Khare	Ralph Storts
Brian O'Shea	Fred Appleton	Rosemary Vollmer
Alfredo Wong-Gonzales	Allan Patranella	Allison Ficht
Qingmin Qin	Quynh Tran	Angela Arenas
Paul deFiguereido	Carlos Rosetti	Stan Weingart
Xicheng Ding	Josely Figueiredo	Hong Liu
		Kenneth Carson
Dr. Templeton's Lab		
Joe Templeton	**Dr. Davis' Lab**	
Chris Schutta	Donald Davis	

FROM: Dr. Thomas Ficht

SUBJECT: Routine TB/Brucellosis Testing

The quarterly blood samples will be collected from personnel who are at risk for TB/Brucellosis on Tuesday, May 16, and readings on Thursday, May 18, 2006. Please report to Room 108 VMR, for sampling between 10 a.m. and 12 p.m. If for some reason you are not able to make this time you will be required to go to the Scott & White clinic to be tested. If there were any personnel left off this memo, please distribute a copy to them.

Whether or not you plan to be tested, please return this form by Wednesday, May 10, signed and checked in the appropriate space, to Mary Ronsonet, Room 110 VMR building. Thanks.

_____Yes, I will be present for test

_____No I will not be present for test

_____(Signature)

_____(Printed Name)

From: Mary Ronsonet <mronsonet@cvm.tamu.edu>
To: <jwcrouch@swmail.sw.org>
Date: 3/29/2006 2:38:32 PM
Subject: Test Results

Good afternoon Mr. Crouch,

Per our conversation-
Please send a copy of the blood test results taken October 4, 2005 for the following persons to the address below:

Thomas Ficht ✓
Jianwu Pei ✓
Melissa Kahl ✓
Qingmin Wu ✓
Carol Turse ✓
Joshua Turse ✓
Jenni Weeks ✓
Navina Bhatkar ✓
Alfredo Wong-Gonzalez ✓
Shu Han ✓
Allison Ficht ✓
Angela Arenas ✓
Kristen Nielson ✓
Hong Liu 12/12/05

Thank you,
MPR

Mary Ronsonet
Lead Office Assistant
TAMU Veterinary Pathobiology
College Station, TX 77843-4467
Phone: (979) 862-4402
FAX: (979) 862-1088

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: 10/13/2005

Submitter copy to:

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

Spec #: S05SM005037
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 10/6/2005
Spec Type: SERUM

Test Reas: DIAGNOSIS

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:	S05SM005037
Date Collected:	10/4/2005
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.

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

TEXAS Department of State Health Services

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1100 WEST 49TH STREET
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LABORATORY SERVICES SECTION
CLIA #45D0660644

CONFIDENTIAL LABORATORY REPORT

Submitter copy to:

Date: 10/13/2005

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

Spec #: S05SM005030
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 10/6/2005
Spec Type: SERUM

Test Reas: DIAGNOSIS

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:	S05SM005030
Date Collected:	10/4/2005
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.

Susan U. Neill, Ph.D., M.B.A.
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CONFIDENTIAL LABORATORY REPORT

Date: 10/13/2005

Submitter copy to:

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

Spec #: S05SM005029
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 10/6/2005
Spec Type: SERUM

Test Reas: DIAGNOSIS

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:	S05SM005029
Date Collected:	10/4/2005
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.

Susan U. Neill, Ph.D., M.B.A.
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Date: 10/13/2005

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

Spec #: S05SM005028
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 10/6/2005
Spec Type: SERUM

Test Reas: DIAGNOSIS

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:	S05SM005028
Date Collected:	10/4/2005
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.

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CONFIDENTIAL LABORATORY REPORT

Date: 10/13/2005

Submitter copy to:

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

Spec #: S05SM005027
Subm #:
Lab: MEDICAL SEROLOGY
Tel #: (512)458-7578

Patient

Patient Address:

Date Rcvd: 10/6/2005
Spec Type: SERUM

Test Reas: DIAGNOSIS

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:	S05SM005027
Date Collected:	10/4/2005
BRUCELLA AGGLUTINATION	<1:40

An agglutination titer of <1:40 is considered to be negative.

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