OSU

Office of University Research Compliance
415 Whitehurst
Stillwater, Oklahoma 74078-1020
405-744-1676
Fax: 405-744-4335

April 25, 2006

Edward H. Hammond
The Sunshine Project
P.O. Box 41987
Austin, TX 78704

Dear Mr. Hammond:

In response to your request under the Freedom of Information Act, copies of the minutes of all meetings of the Oklahoma State University Institutional Biosafety Committee since May 1, 2003 are enclosed. Some information was redacted since disclosure could compromise institutional or national security. Please contact me if I can assist further or if you need additional information.

Sincerely,

Steven O'Geary

Steven O'Geary, Ph.D.
Director

cc: Stanley Gilliland, Ph.D., Biosafety Officer
Stephen McKeever, Ph.D., Vice President for research and Technology Transfer
Jada Bruner Gailey, IBC Administrator

Minutes
Biosafety Committee Meeting
July 16, 2003

Present: Olson, Bale, Barrow, Fathepure, Fox, Fulton, Marlow, Matts, Miller, Strange, Tauer

Other: Gailey

Absent: Ackerson, Anderson, Essenberg, Gilliland, Millikin, Murray, Saliki, Van Den Bussche, Verchot-Lubicz

The meeting was called to order by Carol Olson, Director of Research Compliance

The agenda was accepted as distributed.

Miller moved and Marlow seconded acceptance of the March 13, 2003, minutes. Motion carried.

Old Business:

a) [redacted] #KDC110702, Comparative Genomics of Francisella tularensis... Olson reported that the investigator had met the conditions for acceptance. Later in the meeting Barrow noted that [redacted] had submitted other protocols:
   - KDC052203A Polymer-Based Yersinia Pestis Point of Case Diagnostic
   - KDC052203B Development of aptamer beacons to lipopolysaccharide for real-time sensing of biological warfare agents
   - KDC052203C Biological Warfare Agent Water Monitor

   These were reviewed by a subcommittee, and the labs were inspected 5-30-03 by Barrow, Fox, and Bale. While there were deficiencies, they were such that the subcommittee approved provisional approval of [redacted] until August 15. The inspection team will reinspect to ensure these corrective actions have been taken

b) The agenda reflected administrative action that had been taken with Morton's #RJM021703 (revised). She had met the requirements set forth in the March 13 meeting, and an approval letter has been sent to her.

c) Morton #RJM021103 (revised). Barrow, Marlow, and Fox re-inspected [redacted] for non-select agents (recombinant DNA, bacterial, viral at BSL-2). The lab was approved with very minor recommended corrections for work at a BSL-2 safety level by this subcommittee. Marlow moved and Miller seconded a motion for the IBC to approve the revised protocol. Motion carried. An approval letter will be sent to Morton (sent 7-22-03).

[redacted]

The group did not move from the table the protocol which had been tabled at the March, 2003 IBC meeting. The discussion involved the issues surrounding [redacted]. Barrow, Miller, Bale, Fox, and Marlow had been assigned an action item in March to follow up on the issues with that lab, and report back at the next meeting.

Miller noted that he had received an electronic communication from [redacted] (attached to minutes) in which he stated he had not followed up on the structural issues. He stated that his lab did not grow large amounts of liquid culture (the circumstance in which he described as the potential biggest risk with the exhaust system), and when they did, volumes tended to be less than 25 ml.

Marlow stated that the group had conversed with Neal Hickerson, the engineer in the physical plant who accompanied the inspection team during the March inspections of BSL-3 labs. It seems to be a general consensus that whether or not to insist on a correction of this deficiency with the exhaust system, which will be very expensive, is a risk assessment decision. The CDC regulations state the criteria for filtration for BSL-3 labs. HEPA filtration is rarely necessary and is to be determined on a case by case basis. It is to be based on a hazard assessment and how the lab is used.

Discussion ensued about an agent specific assessment. Marlow stated his belief that given what [redacted] has stated in his communication back to Miller, it is probably appropriate for the lab not to be HEPA filtered. Miller and Barrow tended to agree. Strange questioned what would occur if there were a failure of the autoclave. General discussion followed, which included more talk about the structural design of that room and building.

Marlow then moved to accept the current autoclave exhaust for the specific work [redacted] states he is doing in that room, and not to require that room to be HEPA filtered before he could continue that work. Bale seconded that motion.

In the discussion, it was pointed out that this motion dealt only with the deficiency cited in the March inspection about the exhaust system. Fox, Marlow, and/or Barrow will contact the engineer at the Centers for Disease Control to discuss this further. If that discussion reveals issues that would impact this decision, it will be brought back to the committee. With that, the motion carried.

Marlow stated that a reinspection of [redacted] lab on 7-15 revealed that several deficiencies remain. On that date, there was still no inventory of the agent. The freezer had been delivered, but was not in service. The lab was still cluttered and dirty. The lab is idle at this time. Strange moved and Bale seconded a motion to send an updated statement to [redacted] identifying what still has to be done to put the lab back up. These issues include:

- Inventory updated
- Thoroughly clean lab

- Install freezer
- Secure a self closure on the ante room door
- Advisement of status of HEPA filter requirements.

The compliance office was directed to send the letter. Motion carried with no further discussion

e) [redacted] #RE022803 Multiple Projects Involving Herpesvirus Work The IBC approved the action taken by the subcommittee. A clarification of the room numbers was indicated, and an approval letter was sent to [redacted] on 7-14-03.

f) [redacted] #JHW030303 Bacterial Sugars to Potentiate Macophage Immunity.

After serious discussion about the lack of attention to correcting the outstanding deficiencies with his laboratory and submitting revisions to his protocol, the IBC accepted the Office of University Research Compliance' s recommendation and voted to send him written notice that if these deficiencies were not corrected by August 1, 2003, he could not conduct work with select agents or work associated with the above referenced protocol. Barrow offered to visit with him about this. The letter will come from the Compliance office. The motion for this action was made by Miller and seconded by Barrow, and carried.

A copy of the letter is attached as part of the minutes. The committee also suggested that a subcommittee should look at the engineering of the room, and call CDC's facility engineer with any questions. A report will be made at the next meeting.

g) [redacted] Francisella Diagnostics JRM030503 (revised): Francisella Diagnostics and JRM050203 Yersinia Diagnostics. This is the same protocol, but for a different agent. He requests BSL-2 work for [redacted], and BSL-1 work for [redacted]. He asks for current inspections.

He has clarified that no BSL-3 work is going to be conducted in these rooms. All select agent work will be done in [redacted]

The inspection team did not approve [redacted] for BSL work at this time. Barrow believed that it would be prudent for him, Fox, and Marlow to visit with him and point out their concerns. They did not submit an inspection report to the compliance office at this time.

The compliance office will send [redacted] a letter outlining the status.

h) [redacted] ([redacted])

Olson reported that Dr. [redacted] has asked to be taken off the application to the CDC for the select agent program. They reviewed a letter sent to [redacted] outlining the requirements he still must comply with (attached). Substantial discussion ensured regarding monitoring of Dr. [redacted] and other investigators who choose not to register because they plan to stay below the ceiling

(toxin possession). The compliance office staff had recommended to the IBC that a subcommittee be appointed to monitor these labs for compliance.

Fox mentioned the procedure used to monitor radiation purchase and use. In that process, no purchase can be made without the concurrence of the radiation safety office. Likewise, no delivery of purchases can be made without that approval. Miller moved and Strange seconded a motion directing the IBC to develop a protocol that is patterned from the radiation protocol. Motion carried. The compliance office director will appoint a subcommittee to develop a draft policy for review by the IBC. At a minimum, the subcommittee will include the biosafety officer and the chair of the IBC.

New Business:

a) [redacted] #CKL040203 Surveillance for Avian Influenza Virus. A new protocol and lab inspection report were enclosed with the agenda for this meeting. The compliance director reported that [redacted] had not made the corrective actions required by the IBC at the March 13, 2003 meeting. Miller moved to table action on the protocol until the lab deficiencies are corrected, and the lab is approved. Barrow seconded the motion. Miller asked that the IBC send a letter to this effect to [redacted], and note that he (Miller) made the motion. Motion carried. The compliance office staff will send the letter.

b) [redacted] #WM061602 Murine and Baboon Model for Monkeypox Virus Infection. Olson stated she had not included the protocol to be reviewed because there were approximately 15 items that Dr. [redacted] had to complete before he could be registered with the CDC. [redacted] and [redacted] are aware of this, and know he cannot work with select agents until all the approvals are granted. The funding is not here for his research, and his lab is not finished. Olson asked for a motion to table until these issues are resolved. Barrow moved and Strange seconded a motion to table. Motion carried.

c) [redacted] #AS061103 Analysis of Type III Secretion in Pseudomones Acruginosa. The funding agency required review by the IBC before funding would be distributed, even though this research requires only a BSL-1 lab. In these cases, it is the tradition of the IBC to allow an administrative review and approval. Marlow provided this review, and a letter of approval was sent to the investigator. Olson asked that the IBC still approve this action. Miller moved and Barrow seconded a motion to accept the action of the vice chair. Motion carried. A letter will be sent to the investigator advising him that the IBC had issued this full approval.

d) [redacted] #CM052203 Phase IV Efficacy Study for the Equine Influenza Fraction of Ft. Dodge Animal Health' s Fluvac Innovator Double EFT Killed Virus Vaccine. A subcommittee composed of Fatherpure, Miller, and Barrow reviewed and granted approval of this research, which is not harmful to humans. The IACUC has primary oversight of this research. The IACUC prefers to see evidence that the IBC has reviewed and approved the particular biologic agent or toxin in these cases. This message was conveyed to the investigator, and that letter is attached to these minutes.

Strange moved and Miller seconded approval of that subcommittee' s actions. Motion carried.

e) Cyril Clarke #CC041503 Polymeric Amplification for Rapid L. Monocytogenes Detection. This was another protocol that could be handled with an administrative review. Barrow, Fox, and Marlow had looked at this protocol and approved it as meeting the safety and security requirements of an BSL-2 lab which did not use select agents. Miller moved and Strange seconded approving the subcommittees actions. Motion carried.

f) [redacted] #SMD052903 Shigella Flexneric Adhesins This protocol involves recombinant DNA, pathogenic microorganisms, and vertebrate animals. The lab is in [redacted]. Dabo required approval for the funding agency. A subcommittee granted approval of the lab and the protocol. Marlow moved and Barrow seconded motion to accept this action, and the motion carried.

g) [redacted]: [redacted] lab was approved during the March inspection cycle, but he has not submitted a protocol to the IBC. The compliance office has requested the IBC to give a time deadline for this, as his name is submitted for registration with the select agent program. Miler moved and Fox seconded granting him until August 15, 2003, to submit a protocol to the compliance office. Motion carried.

Miscellaneous Business:

Olson reported on the following outstanding issues:

a) Application to CDC and USDA for Select Agent Registration
The CDC has provided us an accession number to use when communicating. The CDC staff has requested corrections and additions to the application. These corrections required that the list of personnel match exactly the name the individuals submitted with their Form 961 to the FBI. Minor revisions to the lab plans of some investigators were required for clarification. These have been resubmitted.

b) Security Risk Assessment
[redacted]

c) Security Plans: University and Lab Specific
The June 11, 2003 deadline to have these developed was met, and VP Alexander accepted the plans for the University and specific labs. Olson noted that she had made a series of recommendations to him, to include conducting mock exercises, assessment of other assess control technology for lab doors, identification tags, and college and departmental plans to

coincide with the university and departmental plans. Olson stated the necessity of the new VPR being brought up to speed almost immediately to facilitate the full implementation by the November deadline.

d) Access Control to Labs with Select Agents
Don Pierce has identified affordable technology to control assess to the labs. The information about this technology has been provided to the associate dean for research in [redacted]. The labs meet minimum security requirements now, but the goal is to enhance this.

e) Records Management
G. Lyle demonstrated the lab specific database to the faculty using select agents, and is altering the database based on that feedback. He has also had discussions with persons in Information Technology [redacted]

f) Next steps
Institutions are being inspected by the CDC. It is critical that all outstanding issues be corrected as soon as possible, as OSU could be notified soon of a CDC visit. Olson is updating VP Alexander, legal counsel, and internal audits regularly. She will prepare a status report for the new VPR as soon as the position has been filled.

g) Biosafety Officer search
There were not many applications. Currently three are viable candidates. The search committee has interviewed one candidate, and will interview a second this week. The search was extended and significant effort was made to post the listing in as many places as possible. The IBC noted that every university is looking for persons to fill this position.

h) Discussion on development of procedures for submission of protocols, inspection procedures and web page enhancement
Olson stated she would be working with a subcommittee to develop written procedures for submitting protocols and having inspections conducted that can be posted on the biosafety web page. Also, she noted that the web page needs extensive revision, and that this subcommittee would be critical to providing suggestions for this. Olson is going to see if there are standardized services for web page enhancement through the new VP for Information Technology' s unit.

Barrow noted that completion of this activity would really help confusion that exists in the scientific community. While they understand that the IBC is undergoing significant reorganization, and this has reorganization has coincided with the new requirements of the Bioterrorism Act of 2002, they still recommend early action in providing this service on the web for them.

The meeting adjourned at 12:10 p.m.

OSU

Office of University Research Compliance
415 Whitehurst
Stillwater, Oklahoma 74078-1020
405-744-1676
Fax: 405-744-4335

July 18, 2003

[redacted]
CAMPUS

Dear Dr. [redacted]

The Institutional Biosafety Committee (IBC) reviewed outstanding protocols and lab inspection reports at their July 16, 2003 meeting. Your protocol #JHW030303 entitled "Bacterial Sugars to Potentiate Macrophage Immunity" had been tabled at the March 13 meeting, and you were provided a list of corrective actions in a memo sent to you on March 27.

The IBC voted to give you until August 1, 2003, to provide the information necessary for them to review your protocol and to correct the lab deficiencies. If that information is not forthcoming, the IBC will take steps necessary to ensure that research without an approved protocol is not continued.

On July 18, 2003, I received a second Laboratory Inspection Report from a re-inspection of [redacted] conducted by Barrow, Marlow, and Fox. Based on that report and from conversation between you and the inspection team, the following information will be required by August 1:

a. Written justification for why you believe your research using select agents :Brucella abortus (S), Brucella melitensis (S), Yersinia pestis (S), and Francisella tularensis (S) is low risk. The revised protocol should include appropriate Standard Operating Procedures;

b. Written justification for why HEPA filtration is not necessary for [redacted] exhaust for work with these organisms.

The laboratory upon reinspection has been approved provisionally for BSL 2 and BSL 3 work. Specifics relative to that are written in the attached lab inspection report.

After these requirements are met, the IBC will review your protocol, and your laboratory will be re-inspected. When these issues are addressed to their satisfaction, protocol approval and an

approved lab inspection report will be issued.

The IBC is denying your request to use Bacillus anthracis and Mycobacterium sp. in [redacted] or [redacted]. Your revised protocol should NOT include these organisms for those rooms.

If you plan to do research with these select agents, you must submit a new protocol addressing that research. The lab in which you would propose to conduct that research would have to be inspected for that purpose.

Please direct your revisions to the Office of University Research Compliance, attention: Dr. Carol Olson or Jada Bruner.

Sincerely,

Carol Olson

Carol Olson
Director, University Research Compliance

cc: Bill Barrow
Denver Marlow
Gregory Fox
Robert Miller
[redacted]

Enclosure: Lab Inspection Report: July 17, 2003

OKLAHOMA STATE UNIVERSITY

OSU

Office of University Research Compliance
415 Whitehurst
Stillwater, Oklahoma 74078-1020
405-744-1676
Fax: 405-744-4335

May 14 , 2003

RECEIVED
MAY 21 2003
University Research Compliance

[redacted]
Oklahoma State University
[redacted]
CAMPUS

Dear Dr. [redacted]

Following our lengthy conversation this morning regarding your desire to have your registration to use select agents and/or their toxins withdrawn from OSU's application to the Center for Disease Control and the USDA/APHIS, I have received written confirmation of this request by electronic mail.

The Office of University Research Compliance will initiate the request to the CDC and USDA to terminate your request to conduct research using select agents and toxins under regulations outlined in 42 CFR 73 and related Codes of Federal Regulation. These regulations provide thresholds of amounts of toxins on the select agent and toxin list that investigators may possess and be exempt from registration.

You have repeatedly stated that your research will never require amounts of toxin on the select agent list over this threshold, and the decision agreed by all of us to include you on the original application to CDC was because some vendors or other entities may require an EA 101 as their tracking mechanism. When the EA 101 is used, prior approval from CDC must be obtained before any biologic agent or toxin can be shipped.

We discussed the fact that withdrawing your name for consideration by the CDC does not absolve you of certain compliance responsibilities, to include:

- Research using biologic agents or toxins must be done under an approved protocol, with approval granted by the Institutional Biosafety Committee;
- Research using biologic agents or toxins must be done in a laboratory approved by the committee;
- Inventory control will be maintained by you in the same manner as researchers using select agents or toxins over the threshold amount, and will be monitored by the tracking and monitoring system maintained by the staff in the Office of Research Compliance;
- Purchases of toxins, of any amount, on the select agent list will have to have prior approval from the biosafety officer for the university;
- Shipping restrictions as outlined in 42 CFR 73 or any related Code of Federal Regulation may be imposed on toxins, regardless of the amount ordered;
- Lab specific safety Standard Operating Procedures must be developed and approved as part of your protocol and posted in the laboratory;

A lab specific security plan must be developed, although certain requirements of that plan may not be applicable to your research, as the amount of the toxin you possess is under the threshold. The plan will be submitted for review and approval to the Responsible Official through the Office of University Research Compliance

If you determine that vendors require tracking through an EA 101 to ship toxins of any amount, by electing to be removed from the registration in the Select Agent Program, you forfeit the opportunity to purchase from that vendor.

You understand the adverse impact of this decision to be removed from the registration program may have on any future funding opportunity where the amount of toxin required to conduct the research would put you over the threshold allowed in the exemption category of 42 CFR 73.

Based on your written communication to me and our conversation by telephone today, I will rescind the request to have your lab re-keyed and keys restricted. However, as part of your safety plan, as well as your security plan, you will be expected to demonstrate how you will manage distribution and receipt of keys to that laboratory.

You will also still be required, as part of your protocol to use any biologic agent or toxin, to ensure that your staff and/or students comply with the U. S. Patriot Act. This requirement is in addition to any requirements of the Bioterrorism Preparedness act of 2002. Any changes to staff from what you initially turned in with your protocol must be reported immediately to the Office of University Research Compliance, and demonstrated compliance with the terms of the Patriot Act must be included. This documentation for compliance is included as Appendix F in the Biosafety Protocol Form.

If you plan to order any toxin, please notify my office prior to placing that order. We currently have not created the form to be used for prior approval by the biosafety officer, so we will have to improvise if you order in the next couple of weeks.

Please confirm your acceptance and understanding of the impact of your decision by signing below and returning an original to my office in 415 Whitehurst Hall.

Sincerely,

Carol Olson

Dr. Carol Olson
Director of University Research Compliance

Confirmed [redacted]

cc: Bill Barrow
Denver Marlow
Greg Fox
Robert Miller

[redacted]

Biosafety Committee Meeting
October 16, 2003
002 Life Sciences East

Present: Olson, Barrow, Ackerson, Anderson, Bale, Essenberg, Fathepure, Fox, Gilliland, Matts, Miller, Saliki, Strange, Van Den Bussche

Absent: Marlow, Fulton, Millikin, Verchot-Lubicz

The meeting was called to order by the Director of Research Compliance.

Barrow moved and Fox seconded motion to accept the agenda as distributed. Motion carried.

Miller moved and Fox seconded acceptance of minutes from the July 16, 2003 meeting as distributed. Motion carried with no discussion.

Old Business

A. The record shows that approval letter was sent to [redacted] for KDC 110702 on 6-13-03.

B. The record shows that lab deficiencies in [redacted] and [redacted] were corrected. After reinspection, the lab was approved and approved lab report was sent to [redacted] on 9-18-03. Approval for protocols KDC052203A, KDC052203B, and KDC052203C were pending approval based on satisfactory approval of [redacted] and [redacted]. Thus approval for these three protocols were sent October 8, 2003.

C. Protocol #RCE030603 for [redacted] remains tabled. [redacted] has deficiencies that prohibit approval as a BSL-3 facility. Vice President S. McKeever has sent written notification to [redacted] that he is not approved by Oklahoma State University to conduct select agent work in that laboratory, and that he must have met all the required university and federal requirements to conduct that research in another BSL-3 facility. The Centers for Disease Control will inspect the facility to provide recommendations for correcting the deficiencies during their inspection of the select biological agent and toxin program. This is scheduled for October 29 and 30, 2003.

D. [redacted] met the requirements imposed by the IBC at its July meeting, and was reinspected on 9-18-03. It was approved for use as a BSL-3 facility.

E. Protocols JRM030503(Revised) and FJM052003 : [redacted] were discussed. The agenda stated that these protocols had been previously reviewed and were ready for approval following approval of [redacted] as a BSL-2 lab. B. Barrow had gotten additional clarification from [redacted]. [redacted] will not work with infectious agents in [redacted] at this time. He may seek approval for that room as a BSL-2 at a later time. The current plan is that the DNA will be extracted in another approved lab and brought to him. He will work with purified DNA in [redacted].

With this clarification, Gilliland moved and Barrow seconded a motion to approve these two protocols under the following condition: extraction of non-infectious nucleic acid will be done in an approved BSL-3 facility. At such time that [redacted] wishes to conduct research requiring BSL-2 containment, he will submit a new protocol for review and approval by the IBC. Motion carried with no opposition or abstentions. The Office of University Research Compliance will send the approval letter with those conditions outlined.

F. The record notes that Dr. [redacted] has been taken off the application to the CDC and USDA for approval to use select toxins. He has submitted written notification to the Office of University Research Compliance that he intends to use non-toxic L-chair of B. toxin in accordance with the conditions outlined in an approved protocol #LL090203.

G. The procedures being finalized to monitor select agent toxins is patterned after the procedure used in the radiation compliance program. Essentially the investigator Seeks approval from the Biological Safety Officer to purchase the toxin. After confirming that the investigator's inventory is below the exempt limit (if the person is not registered with the CDC), the request to purchase will be approved. When it arrives at the Hazardous Materials Division of the Mailing Services, personnel there will confirm with the Biological Safety Officer that approval has been obtained. Once confirmed, the delivery will be made. The Biological Safety Officer has responsibility to ensure investigators'compliance with the inventory levels.

H. Dr. Pamala Coker accepted the position of Biological Safety Officer, effective 10-1-03.

New Business:

A. Protocol LL909203 (exempt). [redacted]. Barrow moved and Miller seconded motion to accept approval of subcommittee members, Murray, Tauer, and Verchot-Lubicz. Title: "Molecular Mechanisms of Lung Surfactant Secretion." Lab approval current as of 4-23-03. Motion carried.

B. Protocol#100803WB [redacted] "Narrow-Spectrum Drug Targets for *Bacillus Anthracis*/In Vitro Screens for Antimicrobial Activity." Approved lab inspection

reports dated March, 2003 for [redacted]. [redacted] described the NIH funding mechanisms surrounding this protocol. The project initially uses [redacted], but the research will evolve toward use of [redacted]. They will be developing and validating [redacted]. Miller moved and Strange seconded approval of the protocol as submitted. As the work evolves and other personnel are added, modifications and/or new protocols will be submitted for review and approval by the IBC. Motion carried with no opposition or abstentions. The approval letter will be sent by the Office of University Research Compliance.

C. Protocol KDC072403, [redacted] "Development of Aptamer Beacons for Antemortem Diagnosis of Chronic Wasting Disease." Olson put this item on the agenda, although there are still signatures needed on the protocol. The Office of University Research Compliance has requested this information more than once. Gilliland moved and Miller seconded motion not to act on this protocol (which had not been previously distributed) until the original protocol has all the appropriate signatures and information. The Office of University Research Compliance was tasked to notify [redacted] that his protocol will not be reviewed until this information is provided, and that he is not authorized to perform the research until such time as approval is granted. Motion carried without opposition.

D. Protocol SMM072803 [redacted] "Functional Genomes of Plant Pathogenic Fungi." Exempt protocol reviewed by Murray, Van den Bussche, Saliki and approved. Miller moved and Matts seconded motion to approve subcommittee approval. Motion carried.

E. Protocol JHW030303(Revised) [redacted]. "Bacterial Sugars to Potentiate Macrophage Immunity." The IBC determined that [redacted] had met the conditions stated for approval with the revisions submitted. Barrow moved and Miller seconded a motion to approve the protocol. Motion carried without opposition. The Office of University Research Compliance will issue the approval letter.

F. Protocol #091503RM [redacted] "Oxidative Stress Response in Plants." This protocol (exempt) was reviewed by Murray, Matts, Tauer and approved. Research is done in [redacted]. It is a BSL-1 lab. It is close to a BSL-2 lab. Discussion centered around ensuring appropriate training has been provided for persons doing BSL-1 work in a BSL-2 area. The consensus was that these two lab areas ([redacted]) should be reinspected (last inspection was in 1998) by Dr. Coker, and that this inspection should ensure appropriate training has taken place. Matts moved and Gilliland moved to accept the approval of the subcommittee, and the motion carried. The record notes from 355B belong to [redacted].

Select Agent Registration Update

Olson noted that significant progress has been made towards complying with the new federal laws governing select biological agents and their toxins. The Information Technology Security Office will be responsible for the cybersecurity of the program. The inventory records and protocol tracking databases are completed and have undergone successful penetration testing by IT people. Final versions of the safety, biosecurity, and emergency response are near completion. The inspection date is Oct 29 and 30.

The meeting adjourned in regular form at 4:30 p.m.

Biosafety Committee Meeting
February 4, 2004

Present: Olson, Bale, Barrow, Essenberg, Fathepure, Fulton, Gilliland, Marlow, Matts, Miller, Strange, Tauer, Verchot-Lubicz, Anderson, Millikin, Van Den Bussche

Absent: Fox, Ackerson, Saliki

Carol Olson called the meeting to order. Strange moved and Fox seconded a motion to accept the agenda as printed. Motion carried.

Fox moved and Bale seconded a motion to accept the minutes of the October 16, 2003 meeting with the correction that Tauer was present. Motion carried.

Old Business

A. **Outstanding Protocols**

1. [redacted]: #KDC072403. "Development of Aptamer Beacons for Antemortem Diagnosis of Chronic Wasting Disease."

The discussion centered on a lack of clear and detailed explanation of the research proposed. Matts is on one of [redacted] student's graduate committee and believed that he was using scrapie-infected brains from the diagnostic lab to prepare the prions. Prions are extremely resistant to breakdown. Appendix G is not consistent with responses in other parts of the application. For example, the investigator responded that this prion was not harmful to persons. Appendix G as written is not consistent with this statement. Other outstanding issues include: Verify where are the prions coming from? Are there partners, and if yes, who? Describe the proposed animal work. There is no record of an approved animal protocol, but this is not unusual. The investigators normally obtain other approvals before seeking IACUC approval. Investigator needs to consult the BMBL for decontamination procedures and prion inactivation procedures and revise protocol accordingly. Strange moved and Matts seconded a motion requesting answers to these issues. Miller, Barrow, and Marlow will review the responses. If found satisfactory, their concurrence will be sufficient to issue an approval letter. Motion carried.

2. [redacted]: #RCE030603 and [redacted] update.

The protocol was tabled at a previous IBC meeting because the laboratory, [redacted], had not received a satisfactory inspection. The Centers for Disease Control inspection team determined that this lab was not certifiable in its present condition as a BSL-3 facility. S. McKeever has communicated to [redacted], [redacted], and [redacted] the terms and conditions necessary for [redacted] to conduct research with select agents. His select agents remain in another approved BSL-3 facility. This protocol remains tabled. No IBC action is required at this time. [redacted] stated that

he had some work he would like approval for that can be performed in a BSL-2 laboratory. He will submit a new protocol for that component.

3. [redacted]: #091503RM, "Oxidative Stress Response in Plants."

   This protocol is for research to be performed in [redacted]. This protocol was reviewed by a subcommittee composed of Murray, Matts, and Tauer, who approved it. No lab inspection is necessary for the work to be conducted, but these rooms will be placed on the list of BSL-1 labs with active protocols, and baseline inspections will be performed as scheduling permits. Miller moved and Gilliland seconded a motion to accept the action of the subcommittee. Motion carried. The researcher will be informed that his protocol received full approval from the IBC. His initial letter allowed him to begin work, pending full approval of the IBC.

4. [redacted]: #CKL040203 "Surveillance for Avian Influenza Virus."

   Fox and Barrow approved the laboratory on October 16, 2004. [redacted] lab was not included in the CDC inspection, as his select agent is only on the USDA/APHIS list. His protocol was tabled at a previous meeting as his lab had outstanding deficiencies.

   Olson addressed the last item on the agenda along with the issues surrounding this protocol. A revised protocol from [redacted] was distributed. This revised protocol noted that the lab inspection report was satisfactory. She stated that the University had received a query from USDA/APHIS regarding [redacted] research and his lab, based on the material that had been originally submitted with the application to USDA. To address USDA's issues, the following actions were taken:

- A revised application to USDA was submitted which deleted all reference to animal work. At the time of submission, [redacted] had anticipated funding to conduct animal work. The funding did not materialize. Likewise, the original above referenced protocol included animal work. A revised protocol in review Feb. 4, 2004 deleted reference to animal work. His lab in [redacted] is only a BSL-2 lab. The non-animal work is appropriate in a BSL-2. Any identified pathogenic strain must be conducted in an approved BSL-3 facility. Miller moved and Barrow seconded a motion to approve [redacted] research for non-animal work as written in the revised application. Motion carried. A letter will be sent to him from the University Research Compliance office.

B. <u>Toxin Use Below CDC Threshold:</u>

The CDC approved the proposed process for monitoring toxin purchases as distributed at the previous meeting. Olson stated the problems with implementing this procedure, because of the ease faculty have in ordering directly from the

companies. The IBC members will assist the Compliance Office in developing implementation procedures and getting the information out to faculty.

C. Biological Safety Officer

Olson stated that Dr. Coker is no longer the biosafety officer. Bob Miller is currently serving as interim biosafety officer.

D. CDC Inspection

Olson updated the IBC on the CDC inspection in October. OSU received a positive inspection. Deficiencies cited were the lack of a formalized program to verify design and operational parameters at the time of commissioning a biological laboratory, and in follow-up annual re-verifications. The [redacted] was not approved for BSL-3 research. The [redacted] is not formally eliminated from our registration. Physical Plant and Environmental Health Services are taking the lead in developing procedures for the verification program. McKeever has asked for verification that the required work is done within the 60 days we stated it would be up to date. If CDC accepts our corrective actions, we will be approved to use select agents and provided a registration number. Until that occurs, select agents may not be received nor shipped.

II. New Business

A. Protocols

1. Protocol MD0110904, [redacted],"Pathophysiology and Biomarkers of Sustained Exertion Disease Syndrome."

   Provisional approval was given by Coker, Marlow, and Barrow to conduct a two-week experiment using a toxin under the approved limit for federal regulations to call it a select agent. This experiment was an extension of approved animal work. Olson noted that there had been several issues surrounding this protocol that underscore the need for the IBC to adopt policies and procedures for handling requests for approvals at the last minute, and to make these policies widely known. The executive committee will work with the Research Compliance office and review other institutions' policies prior to making recommendations to the entire IBC. No action was requested at this time from the IBC.

2. Protocol KS 121503, [redacted], "Suppression of RN Silencing in Maize."

   This protocol was reviewed by a subcommittee composed of Coker, Verchot, and Van Den Bussche and approved. A letter was sent to the investigator authorizing the research to start, pending full IBC approval. Matts moved and Gilliland seconded a motion to accept the action of the subcommittee. Motion carried. She will be notified of the full approval status. This research can be conducted in a BSL-1.

3. Protocol KS010204, [redacted], "Virus-Based Gene Expression and Silencing Vectors for Maize."

   A subcommittee composed of Van Den Bussche, Matts, and Anderson reviewd and approved this protocol. The work is in a BSL-1 lab. Approval was given to the investigator, pending full IBC approval. Miller moved and Bale seconded a motion to accept the action of the subcommittee. Motion carried. This full approval status will be conveyed to her.

4. Protocol #KB12804, [redacted], "Preliminary Studies on the Effect of the Conjugative Transponon, Tn 5252, on the Virulence of S. Pneumonieae in the Respiratory Tract of Mice."

   Olson had done a preliminary review and advised [redacted] of deficiencies to the protocol. Marlow had assisted him with issues dealing with use of the Lab Animal Resource facility. [redacted] had submitted changes. Marlow had submitted a general inspection report for rooms in the [redacted] also signed by Barrow and K. Olson (IACUC chair). With this information, Miller moved and Gilliland seconded a motion to accept. Motion carried. A letter to that effect will be sent to him.

B. <u>IBC/IACUC Coordination</u>

An informal process exists to coordinate approvals across compliance areas through the committee cross representation. A second method is the review by Research Compliance staff on the routing sheets for funded and/or proposed projects. The IACUC is revising its application protocol form to include more information about biosafety issues pertinent to a specific protocol. A Memorandum of Understanding is being considered as a way of formalizing this cooperation. It is necessary to include certain information, but equally necessary not to include excessive information on what is considered sensitive information. The IBC will approve any final form the IACUC proposes. Marlow will have an inspection of the new ABSL-3 facility that will be available for any investigator wanting to use that facility to include with his/her protocol.

The meeting closed in regular form.

Biosafety Committee Meeting
April 23, 2004

Present: Olson, Barrow, Marlow, Ackerson, Bale, Fathepure, Fox, Gilliland, Matts, Strange, Mullikin, Miller, Essenberg, Verchot-Lubicz

Absent: Anderson, Tauer, Saliki, Van Den Bussche

The meeting was called to order by Olson.

Barrow moved and Fox seconded a motion to approve the agenda. Motion carried. Miller moved and Strange seconded a motion to accept the minutes of the February 4, 2004, meeting. Motion carried.

Old Business

A. Toxin purchase update: Olson stated that no further action had been taken on formalizing these procedures.

B. CDC Inspection: The CDC has approved Oklahoma State University's application to be registered with that agency to conduct research using select biological agents and toxins.

Olson stated that the USDA has not inspected the facility yet. The only non-overlap agent used currently is Dr. [redacted]. Faculty on the overlap list are required to have USDA export/import permits. They are obtaining these.

New Business

A. **Protocol KDC033044A: [redacted] "Development of Aptamer Beacons for Antemortem Diagnosis of Chronic Wasting Disease."**

Barrow led discussion. The investigator was present to answer questions. Barrow moved and Strange seconded a motion to accept. Motion carried. Olson will send an approval letter.

B. **Protocol KDC033004 [redacted] "Cattle E coli 0157 Colonization Model."**

Barrow led discussion. [redacted] will not be using purified toxin. He is just using the culture. He will get a permit if required from the USDA. Bale moved and Strange seconded a motion to accept. Motion carried. Olson will send an approval letter.

C. **Protocol KDC033004 [redacted] "W. Persica Species Research"**

Barrow led the discussion. The investigator had checked that a BSL-1 was required. Because little is known about this organism, the Committee elected to require BSL-2 containment, as the room is already approved at that level. Strange moved and Miller seconded a motion to accept with this condition. Motion carried, and Olson will send the letter.

D. **Protocol WWB 033104 [redacted] "Novel Method to Augment Existing Brucellosis Vaccine."**

[redacted] discussed his protocol. This proposal is to use a specific technique to reduce brucellosis in a bison herd. This is to develop baseline data and to test a the efficaciousness in a mouse model. A BSL-3 containment is required. [redacted] lab is approved at a BSL-3. The animal biosafety-level three is not certified yet. Strange moved and Miller seconded a motion to approve Phase I in [redacted] lab, and approve phase 2 conditionally, pending certification and approval of the new ABSL-3. Motion carried. Olson will send a letter.

E. **Protocol RCE031604 [redacted] "Interactions of Bacterial Pathogens and their Animal Hosts."**

Fox said the approval had been held up pending satisfactory approval of the laboratory in [redacted]. The eyewash has now been upgraded. The other deficiency was the absence of on site laundry facilities.

Fox moved and Marlow seconded a motion to approve this protocol, stating that the investigator should use disposable lab coats until a washer and dryer were provided in the building. Motion carried, and Olson will send a letter of approval.

F. **Protocol PRD032504 [redacted] "Expression of Wheat Gluten Protein in E-Coli."**

Matts moved and Miller seconded a motion to accept. Motion carried. Olson will send a letter.

G. **Protocol AG012604 [redacted] "Drought-Tolerance of Mannitol-Accumulating Wheat."** The lab has had a successful inspection on 3-17-04. A subcommittee has given initial approval. Miller moved and Matts seconded a motion to grant full approval. Motion carried. Olson will notify the investigator.

H. **Protocol SEG021304 [redacted] "Food Safety: Farm to Table"**

This has been approved by a subcommittee, and the lab inspection is favorable and current. Miller moved and Strange seconded a motion to accept by full committee. Motion carried, and Olson will send notification of this action to the investigator.

Miscellaneous Business

A. **Web Page Revisions Update:** Olson stated that her staff are reviewing other institutions' web pages and are updating the content and appearance of the biosafety web page. The policy has been updated to reflect the current select agent regulations.

B. [redacted] **and related issues:** Several buildings do not offer laundry facilities, and investigators are violating safety policy by taking lab coats home to launder. After considerable discussion a motion was made by Gilliland and seconded by Strange to recommend to the vice-president for research that the administration provide laundry facilities in these buildings or provide funds for a laundry service. The motion also states that lthe practice of taking lab coats home should cease immediately. Motion carried. Olson will write the letter on behalf of the Biosafety Committee.

Bale stated that there used to be some disposable lab coats in surplus. He and/or Fox will check and get these to faculty who will need to move to disposable lab coats if they are still available.

C. **Protocols Needing Review:**

The university policy states that research and teaching involving biohazardous materials (regulated human, animal, and plant pathogens, biologically derived toxins, recombinant DNA molecules and infectious agents must be approved by the biosafety committee. However, the current version is under revision following the new biosecurity regulations. Thus, many faculty may not understand the requirements. The application is consistent with these terms, and the committee agreed that if the research/teaching fell into that category, some level of oversight by the IBC was warranted.

[redacted] discussed the research in entomology and plant pathology. Much of this research is not being reviewed by this committee. Olson asked for time to review other universities' position on this and to visit with that faculty before a formal action or sanction was made by the IBC. She will work with [redacted] on this. Clearly, much education still remains in order for all investigators to understand and comply with the regulations. Also discussions within the IBC are needed to determine processes to utilize to achieve the needed levels of review and oversight.

During the round robin, Larry Mullikin said a lot of the protocols for emergency management he has been seeing is not accurate regarding the appropriate procedures the fire first responders will utilize. Bale is the liaison to the university's emergency management team, and will work with Fox and Mullikin to ensure accuracy in the University's plan and procedures. Mullikin and Ackerson agreed to present a fall seminar on issues related to emergency management.

The meeting adjourned at 11:30 a.m.

Minutes Biosafety Meeting
June 8, 2004
204 Whitehurst Hall

Present: Olson, Barrow, Marlow, Bale, Essenberg, Fox, Gilliland, Miller, Mullikin, Tauer, Van Den Bussche, Verchot-Lubicz

Absent: Anderson, Ackerson, Fatherpure, Matts, Saliki, Strange

The meeting opened in regular form. Marlow moved and Fox seconded acceptance of a Revised Agenda as distributed. Motion carried.

Barrow moved and Gilliland seconded acceptance of the April 23, 2004 minutes as distributed. Motion carried with no discussion.

Old Business:
Protocol:

A. **GZ012003, [redacted], "Production of Recombinant Porcine Antimicrobial Peptides as Antibiotic Alternatives."** There were two elements of review: a modification to the December 2003 approved protocol and the lab inspection of [redacted].

Dr. [redacted] has increased the list of organisms in section 3.1. None are on the select agent list. Gilliland, Fox, Marlow, Bale, and Barrow inspected the new lab. The following deficiencies were noted:

a. Post-it notes need to be replaced with appropriate signage.
b. Obtain and use luer-lock syringes for use with all infectious agents.
c. Use disposable lab coats until Agriculture has their facilities completed.
d. Obtain and post appropriate PPE signage (Fox has).
e. Replace fabric chairs or cover with appropriate vinyl. Plastic bags, or the equivalent are not acceptable.
f. Obtain an appropriate device to secure gas cylinder to the wall.
g. Add an emergency phone list by the lab phone.
h. Do not use fume hood by the door. One suggestion is to switch the functions of the two existing fume hoods, where the one by the door is used for storage, and the other fume hood is used for the experiments.
i. Clean up boxes and other trash.

The protocol listed personnel changes. The new personnel must initial Section 1.9 of the protocol. Other relative minor corrections that Dr. Coker had suggested were incorporated into the revision.

Gilliland moved that this lab be provisionally approved for work for 30 days effective on the date the letter is sent to Dr. [redacted]. He incorporated approval of the modification, after the corrections are made. Barrow seconded. Motion carried. Gilliland requested

that a copy of the requirements be sent to the investigator and his department head. This will be done.

New Business:

A. Protocols:

1. **Protocol WWB 050304, [redacted]: "Single Drug Therapy for HIV and Tuberculosis."**

[redacted] described the protocol, the research of which will take place in an approved BSL 2 and 3 lab [redacted] and the under-construction animal BSL-3 facilities.

This study is not funded yet. An anti-HIV natural product (+)-calonolide A, is active against drug resistant strains of Mycobacterium (M) tuberculosis. Part of the research will use the M. tuberculosis infected macrophages. For these, they will use murine and human macrophage cell lines to understand how the compound is handled in infected macrophages. Calanolide A is in Phase II clinical trials for treatment of HIV. As part of this study, the investigators will use recombinant HIV-RT to develop crystallographic models to understand how (+) calanolide A interacts with the viral agent. They will do this by cloning, expressing and purifying sufficient quantities of HIV-RT for crystallography. It will not involve use of HIV. The project requires use of the virulent strain of M. tuberculosis H37Rv to determine the target in M. tuberculosis. The investigator will cultivate small quantities of M. tuberculosis from time to time. Mouse models will be used, and IACUC approval will be obtained.

Essenberg moved approval, subject to approval of the BSL-3 animal facility when animals are used. Gilliland seconded. There was no further discussion, and motion carried.

B. **Protocol MD051204, [redacted]: "Markers of Recovery From Sustained Strenuous Exercise."** This research is conducted using racing sled dogs for evaluation of the immune system. Staphylococcus enterotoxin B will be used to stimulate immune cells. A volume of 100 micro liters solution will be added to whole blood for a final SEB concentration of 1 microgram/ml for incubation experiments. The blood will be incubated. Thereafter mononuclear cells will be harvested, homogenized, and cellular RNA will be isolated and stored for future analysis of specific cytokine expression patterns.

Olson discussed issues that the IBC should address, to include: purchasing procedures, shipping procedures, inventory logs, and training.

Barrow, Marlow, Bale, and Fox had discussed the protocol with [redacted], and had inspected the Mobile Lab. Considerable discussion ensued regarding the procedures to ensure that

the investigator does not go over the limit of the enterotoxin to move the project under the select agent requirements, although OSU requires procedures to be equivalent.

Barrow moved and Fox seconded a motion to approve this protocol following satisfactory correction of the following deficiencies in the protocol and the lab inspection (which will be discussed below):

1. The investigator must ship the enterotoxin through the OSU Hazardous Materials unit, under the direction of [redacted], who will ensure that the appropriate Dept. of Transportation safeguards are followed at OSU and in Alaska. The OSU Office of Research Compliance will advise [redacted] that this shipment will be forthcoming and advise Davis that he must contact [redacted].

2. Require that the OSU Biosafety Officer (Robert Miller) sign off on the purchase order for the enterotoxin, following his assurance that his inventory logs denote that he has ordered no more than 5 mg of the toxin, total.

3. Revise his protocol to include:
    a. Inventory logs showing current inventory. Section 4.4 on the revised version indicates the investigator asks for less than 10 mg in two locations, and on the original it asks for less than 5 mg in two locations. This section (4.4) must be clarified on both versions.
    b. List [redacted] as the storage area for the enterotoxin, and denote the containment level of the room. (1.4)
    c. On section 4.7, note where the autoclave is, and where exactly the investigator is going to dispose of the container.
    d. 4.10: Submit the required training records to the Office of University Research Compliance, as they were not available to the inspectors of the mobile lab.
    e. As investigator told inspectors the glove box was not going to be used, revise the sections of the protocol that address this, and revise with what they are going to do. The biosafety hood will have to be certified by EHS.

4. The protocol will not be approved until the following deficiencies on the mobile lab are corrected:
    a. Prepare and have available for inspectors a chemical hygiene plan, a biosafety manual and Standard Operating Procedures.
    b. Training records with notice that personnel have read and understand procedures.
    c. Develop refresher training and document.
    d. Obtain locked container for the toxin.
    e. Install appropriate biosafety hood for toxin work, and have it certified by EHS.
    f. Paint sides and install appropriate flooring that is impervious to spills.
    g. Repair the end of the cabinet so that the exposed particleboard is not present.

h. Install an appropriate eyewash station.

With these conditions, the motion carried. Olson was directed to send a letter outlining these deficiencies to Dr. [redacted], with a note that the lab should be re-inspected by August 10. Fox asked that [redacted] be recommended to get a carbon monoxide monitor in the trailer. That requirement is not under the auspices of IBC, so it was excluded from the required conditions.

B. Plant Pathogens Research Update:

Olson stated that she had met with Verchot-Lubicz, Gilliland, Wright, and Westerman about research in agriculture that uses plant pathogens. Wright stated that faculty would begin submitting research protocols. Discussion about the USDA-funded plant pathogen network activity ensued, and a protocol is being developed to cover those activities. Olson complimented the group for their cooperation with this requirement.

C. Emergency Procedures for BSL Labs

Larry Mullikin developed draft emergency response procedures based on the actual procedures the fire department emergency responders use. Mullikin noted that many of the procedures he had reviewed bore little resemblance to what the first responders actually do. Two drafts have been previously circulated. A few suggestions were made that Mullikin will want to incorporate. He will send around a final draft. After the IBC accepts these, Mullikin wants to provide these to his counterparts in the Big XII. Other units at OSU should see them, and the Office of University Research Compliance will put them on the biosafety web site. Mullikin will offer training in the fall, sponsored by the compliance office. The IBC thanked Mullikin for his efforts in this important arena.

Miscellaneous Business

A. Incomplete Protocol Submissions: Olson asked for guidance on whether to send protocols that are not complete out for IBC review. The guidance from the IBC was not to send them until they are completed.
B. Biosecurity Training Report: Olson reported that the university had satisfied the requirement for annual training in biosecurity through the on-line training module just completed by all persons with a DOJ clearance.
C. Sunshine Project: The Sunshine Project has requested copies of minutes. The University legal counsel is providing guidance on complying with this request.
D. Webcast: Olson distributed material regarding another training module on BSL-3 laboratories which will be launched on June 17.

Meeting adjourned in regular form at 4:45 p.m.

Biosafety Committee Meeting Minutes
August 19, 2004
004 Life Sciences East

Present: Olson, Barrow, Marlow, Anderson, Bale, Essenberg, Fathepure, Fox, Gilliland, Matts, Miller, Mullikin, Veenstra.

Absent: Ackerson, Saliki, Strange, Tauer, Van Den Bussche, Verchot-Lubicz

The meeting was called to order at 3:00 by Carol Olson.

Olson introduced the guests: [redacted], [redacted], and [redacted]. Veenstra was also introduced as a new member representing the College of Engineering.

Barrow moved and Gilliland seconded a motion to accept the agenda as printed. Motion carried.

Fox moved and Barrow seconded a motion to accept the June 8, 2004 minutes as distributed. Motion carried.

Old Business

A. Protocol GZ012003—[redacted]. Dr. [redacted] had his lab inspected. Deficiencies were corrected, and he has received a protocol approval.

B. Protocol MD051204—[redacted] "Markers of Recovery from Sustained Strenuous Exercise."

Barrow led discussion about this outstanding protocol. Members were asked to follow the June 16, 2004, memorandum to [redacted] outlining the requirements needed for obtaining approval for his mobile lab and for his protocol.

Protocol Status:

- Appendix H still says 10 mg of toxin, although he clarified the amount was no more than 5 mg in Section 4.4 and 4.5. He needs to make this change to Appendix H.
- Experts using this toxin recommend autoclaving 3 hours and 30 minutes at 120 degrees C. He will be advised of this requirement and be asked to change his protocol application to reflect this. This action will be taken to dispose of any remaining toxin after the experiments are completed. This will be noted in his logbook and inventory logs.
- The toxin will not be ordered until the December time frame. It will be stored, unopened, in [redacted]. The inspection team approved this. [redacted]

will be advised that he must follow all shipping regulations and time frames required by OSU.

- Obtain written approval of order of toxin from the biosafety officer or the chair of the biosafety committee, Bill Barrow.

Mobile Lab Status

All the deficiencies have been corrected, according to Barrow and Marlow who did the reinspection on August 18. An approval will be sent to him.

An approval for the protocol will be sent when the final deficiencies are corrected. Miller moved and Barrow seconded approving the protocol when the Office of Research Compliance has received the revised protocol with the final deficiencies corrected. Motion carried.

C. Emergency Procedures: Update by L. Mullikin

Mullikin was complimented for this task. Miller moved and Fox seconded accepting these procedures. Motion carried. Olson will interact with EHS to be sure these are well publicized on their home page, and they will be added to the Research Compliance web pages.

New Business

A. Protocol BO052704, [redacted], "Plant Disease and Insect Diagnostic Lab." Primary Reviewer: Stan Gilliland. Gilliland stated inspecting [redacted] was premature for a number of reasons: The lab has not been assigned to Entomology and Plant Pathology at this point. It appears the space belongs to Forestry. A diagnostic lab requires a set of Standard Operating Procedures (SOPs) addressing such issues as how samples are received, where, how the containers are opened and where, what is done with the sample, how is it processed and disposed, plus general laboratory safety and security procedures. SOPs describing the protocol for handling a select agent or other serious agent from the diagnosis must be developed, to include all the appropriate reporting requirements. Issues about the lab's air pressure and circulation must be addressed. There are other deficiencies such as a lack of wash facilities, signage, training materials and records of training, sharps containers, biosafety cabinet working and certified, and pervious materials.

[redacted] was present for the discussion. Fox moved and Gilliland seconded the following motion, which carried:

1. On behalf of the Biosafety Committee, C. Olson to send letter to appropriate administrators in Agriculture advising them that the Biosafety Committee has conducted a preliminary inspection of [redacted], and that until the space is assigned to Entomology and Plant Pathology, that unit does not have the authority to require the work to be done to correct and/or identify structural deficiencies.

The Biosafety Committee further recommends that this space be assigned to Entomology and Plant Pathology so that these corrective actions can be made. This is recommended as a short-run remedy.

2. The Biosafety Committee further recommends that administrators in Agriculture give serious consideration to including the entire plant diagnostic laboratory in the proposed new BSL-3 plant facility.

Fox moved and Gilliland moved tabling the protocol until these issues are addressed at the agricultural administrative level and until the deficiencies in the protocol (e.g., provision of complete SOPs) are corrected. Motion carried.

B. [redacted] Protocols:

1. Protocol KDC061804B "Ruminant B-Lymphocyte Green Fluorescent Protein Aggregation Bioassay for Elk Chronic Wasting Disease."

2. Protocol KDC061804A "Development of Aptamer Beacons for Ante mortem Diagnosis of Chronic Wasting Disease #2" Barrow was the primary reviewer for both of these.

Integral to review of these protocols and lab is the work of a subcommittee who had been established to develop procedures for working with prions. That committee consisted of Bill Barrow (chair), Denver Marlow, Robert Miller, Stanley Gilliland, Greg Fox, and ex officio member [redacted] (post doctoral scientist and co-PI of protocols above) Thus, these issues were discussed together.

This subcommittee had attended the prion conference sponsored by the Oklahoma Food and Agricultural Product Center and Barrow had consulted other nationally-known experts in prion research as the committee worked on these guidelines. As a result of this process, [redacted] had been advised that an earlier approved protocol might be subject to revised restrictions.

A number of issues surfaced relating to Clinkenbeard's funded prion research, to include:

- Incineration as a component of decontamination and inactivation. The BMBL, 4th ed., p. 139 states inactivation procedures are the use of denaturing organic solvents (stated strength) and steam autoclaving. It is recommended that dry waste be autoclaved at 132 degrees C for 4.5 hours or incinerated. The [redacted] incinerator is really not designed for dry waste, and there are possible plans to replace that incinerator with another technology for getting rid of animal carcasses and related waste.
- The inspection reports on rooms in [redacted] that have been inspected for prion research must so state, and [redacted] and his co-investigators must provide written documentation regarding the rooms which have thus far had prion research done in them. The IBC must review these reports in light of the proposed prion guidelines. The rooms in question to date include [redacted].
- [redacted] states he has USDA approval based on their inspection of [redacted] to conduct prion research. The IBC has not seen this inspection, and a copy will be requested.

- The IBC needs to discuss and vote on whether they want to require both autoclaving, sterilization, and incineration and ensure that the new prion guidelines are consistent with the IBC determination and that they are clearly understandable. For example, if the IBC proposes standards greater than the BMBL, those standards should be so stated and communicated clearly to investigators. The IBC also has the right and obligation to base these types of decisions on specific projects, as appropriate.
- Issues exist on what safety actions should be taken, if any, that are out of the norm for labs where prion research has been conducted, but is no longer being conducted before other projects and/or investigators are approved to conduct research in them
- New SOPs conforming to the new prion guidelines will have to be developed by [redacted] and reviewed by the IBC.
- If [redacted] dedicates one lab for prion research, any protocols previously approved for those rooms will have to be modified.

After lengthy discussion, the IBC took the following actions:

Matts moved and Mullikin seconded a motion to accept the subcommittee's recommended procedures for prion research at OSU, with very minor changes, which Barrow will make before forwarding to Research Compliance Office. Motion carried. The Compliance Office will notify associate deans for research of these procedures, and disseminate to other relevant constituencies, as well as post on the biosafety web site.

Barrow moved and Marlow seconded a motion to table action on the two protocols of [redacted] until all these issues can be worked through. Motion carried, and Olson is to notify [redacted] of this action and request any additional information needed for the review and for the files on behalf of the IBC.

Olson thanked the subcommittee for their diligence and effort in developing these guidelines.

The IBC also recommended that C. Olson notify the vice president for research and technology transfer about the incineration facility, noting that if prion research were going to be supported and funded at OSU, the appropriate inactivation facilities should be provided.

C. New Biosafety Web Pages Demonstration:

Olson and Kevin Worley, Research Compliance information technology specialist, demonstrated the new biosafety pages. Olson asked for a motion to accept these as replacements for the existing web page content. Mullikin moved and Miller seconded a motion, which carried. These pages should be deployed within the first week of the fall semester.

D. [redacted] Select Agent and CDC Oversight:

CDC has advised that [redacted] should be notified that his current lab, where no select agent work is being done, should be a storage area only. Miller will contact CDC to determine if this action is to close the loop on our registration whereby the IBC and Responsible Official have advised [redacted] that until his lab is successfully inspected for select agents by USDA, he cannot perform that work there, or if the CDC position on avian flu virus is that all strains are highly pathogenic until diagnosed otherwise. [redacted] research is diagnostic on field fecal samples. At present, no work on that virus is being conducted in that lab. No IBC action is required.

Miscellaneous Business

A. Emergency Response Training: Larry Mullikin will present a seminar on Emergency Response Procedures to the general university community. All are encouraged to come and to distribute flyers in their departments. This training will count for the OSHA quarterly training, according to Fox.
B. Alabama Department of Public Health Training: Olson stated that the Research Compliance Office will arrange for webcasts and copies of these training sessions. Material will be distributed to the IBC regarding these training opportunities.

Meeting closed at 5:15 p.m.

Institutional Biosafety Meeting
October 21, 2004
Life Sciences East 004

Present: Olson, Barrow, Anderson, Essenberg, Fox, Matts, Mullikin, Tauer, Van Den Bussche, Veenstra

Not Present: Strange, Verchot, Ackerson, Bale, Gilliland, Marlow, Saliki, Fathepure

The meeting opened in regular form by Olson. Tauer moved and Fox seconded motion to accept the revised agenda as distributed. Motion carried.

The minutes of August 19 were discussed. A correction was made. Last bullet on page 3 should read: "[redacted] states he has USDA approval based on their inspection of [redacted] to conduct prion research." Barrow moved and Fox seconded a motion to approve with this correction. Motion carried.

Old Business

A. Protocol MD051204, [redacted], "Markers of Recovery from Sustained Strenuous Exercise." The subcommittee approved the revised protocol which addressed the deficiencies outlined at the last IBC meeting, and the investigator received an approval letter. No further action is required.

B. Protocol BO52704, [redacted], "Plant Disease and Insect Diagnostic Lab." Olson reported that she had had a long visit with [redacted] regarding the requirements of the IBC. The forestry department has relinquished ownership of the space where the diagnostic lab is. The recommendation of the IBC that this lab be part of the proposed BSL-3 lab was turned down due to a lack of space in the new proposed BSL-3. Instead, the decision of the administration was to upgrade this space to BSL-2 containment. Dr. [redacted] had also worked with Gilliland and the Agricultural Division's building manager to finalize the specifications for this. These have been submitted to Physical Plant for a bid. She is aware that the protocol's approval is contingent on the lab meeting BSL-2 containment requirements. She submitted a revised set of Standard Operating Procedures. Gilliland had submitted his recommendation in writing, as he was absent from the meeting. He asked for further clarification on:
   - #8: Indicate time and temperature for autoclaving
   - What procedures will be followed if a select agent or other high risk pathogen is diagnosed?

   Barrow moved and Tauer seconded a motion to ask for revisions as stated by Gilliland. Motion carried.

C. [redacted] Protocol(s) update: On Sept. 7 Olson, Barrow, Marlow, and Gilliland reviewed four prion-related protocols of [redacted]. Two appear to e the same protocol submitted at different dates. After a lengthy review, a memo was sent to [redacted] on Sept. 9 outlining requirements and requesting a revised protocol covering all his prion research be submitted no later than Oct. 1. The revised protocol was not submitted. [redacted] requested a meeting now scheduled for Nov. 10 with Olson, Gilliland, and Barrow to discuss this memo to determine what he needed to do. The IBC discussed [redacted] behavioral pattern and determined that a directive to him should be sent from the Institutional Official, Steve McKeever, advising him that he is not permitted to conduct any prion research, funded or unfunded, that has not been specifically approved and approved for a certain lab. He should also advise [redacted] that he should bring a revised protocol to the Nov. 10 meeting that addresses the issues in the Sept. 9 memo. The Sept. 9 memo is attached as part of these minutes. Van Den Bussche moved and Anderson seconded that this be done. Motion carried with no dissentions or abstentions. Olson is charged with sending the recommendation forward to McKeever.

D. Update to Emergency Response Training of Sept. 9, 2004: Olson stated that the office had received a lot of positive feedback from participants at the training, and thanked Chief Mullikin for providing it. Discussion ensued about holding a table top exercise in spring of 2005 which would address a catastrophic event. As natural disasters, such as fire and tornadoes, have been identified as the highest threats at OSU, it was decided to concentrate on a scenario such as a tornado hitting [redacted]. Fox and Mullikin will construct the scenario and take the lead in organizing the event.

E. Laundry Facilities Update: A&S will be installing laundry facilities in one of the microbiology rooms. Agriculture will use a combination of disposable lab coats and a laundry service. The associate deans for research conveyed this information to Olson.

New Business

A. Protocol BM101504, [redacted], "Activin Validation for Detachment of E. coli 0157:H7 from Beef Carcass Plates." Gilliland was the primary reviewer. His written comments were to approve the research as proposed, and to advise the investigators that the protocol will receive approval following a satisfactory inspection of [redacted]. Currently equipment is on order. Fox moved and Matts seconded the motion to this effect. The motion carried with no further discussion.

B. Protocol GZ012003: [redacted], "Use of Infectious Agents in [redacted]." This is a modification to this protocol. [redacted] has requested approval to use influenza virus strains that are not on the select agent list. Gilliland was the primary reviewer, and interacted with him to obtain Standard Operating

Procedures for handling these organisms. These were provided with the protocol request. Gilliland's written recommendation was to ask for further clarification in his SOP:

- #6 All lab coats should be autoclaved prior to laundering. Laundering should be done on site or disposable coats used.
- Indicate the time and temperature of autoclaving.
- #4: Clarify if you are sure the flu shot will be available to your staff, and revise accordingly, if the answer is no.

Barrow moved and Ban Den Bussche seconded a motion to this effect. Motion carried after a short discussion to ensure that the strains were not on the select agent list.

C. Protocol LJS101804, [redacted], "Role of Insulin-like Growth Factor—II and Growth Differentiation Factor-9 in Regulating Ovarian Cell Function and Gene Expression in Cattle." This is an exempt proposal. It requires BSL-1. Matts moved and Tauer seconded a motion to accept. Motion carried.

D. Update on Dr. Bob Ellis: Olson stated OSU had hired Bob Ellis, biosafety officer at Colorado State University to inspect the working BSL-3 labs as part of the requirement that the Responsible Official review the program annually. He also reviewed the new BSL-3 labs coming on line. A report will be sent before the end of October, thus satisfying the CDC requirement for annual inspection. He gave two seminars while he was here. Barrow stated the faculty had been pleased with their interaction and his assistance. Ellis complimented the program highly.

E. Biosafety Officer Search update: [redacted] turned down the offer. Dr. McKeever had asked for input from the committee on a strategy to cover this important position, as we have been unsuccessful twice in a national search for a Ph.D. level person. The IBC's recommendation was that we evaluate the model used in radiation safety, whereby the biosafety officer would be a faculty member with release time for this position, and would have full time assistance in the field, and administrative support from the compliance staff. Gilliland has agreed to continue the position in the interim.

Miscellaneous Business

A. Olson said the meeting schedule had been revised to allow for a December meeting, as there are a lot of grant deadlines during that period. If there are no protocols to be reviewed, the December meeting will be cancelled. Olson said she was retiring in December and thanked the IBC for their cooperation and assistance.

Meeting adjourned in regular form.

Institutional Biosafety Committee
December 8, 2004
Life Sciences East 204

Present: Barrow, Ackerson, Anderson, Bale, Essenberg, Fathepure, Fox, Gilliland, Marlow, Matts, Miller, Olson, Strange, Veenstra, Verchot,

Absent: Karns, DeWitt, Van Den Bussche, Mullikin, Tauer, Saliki

Not voting: McTernan, Blagden

Miller moved and Strange seconded acceptance of the agenda. Motion carried.

Miller moved and Barrow seconded acceptance of minutes of October 21, 2004 meeting as distributed. Motion carried.

Olson introduced Beth McTernan, Office of University Research Compliance, who is the primary administrative support personnel for the IBC, and Treena Blagden, doctoral student in Food Sciences under the tutelage of Stan Gilliland. Blagden will be assisting Gilliland with his role as Biosafety Officer.

Old Business

A. Protocol BO52704. [redacted], "Plant Disease and Insect Diagnostic Lab." Gilliland stated this item remains as old business. The equipment for this room is not installed.
B. Protocol KDC112904. [redacted], "Development of Aptamer Beacons for Antemorten Diagnosis of Chronic Wasting Disease. Clinkenbeard consolidated three protocols into this one and designated a different site for the prion research: [redacted]. This lab has been reinspected to include prion research. Miller moved and Gilliland seconded a motion to accept this new protocol and to close protocols KDC03304A; KDC072403; and KDC061804A, and to approve [redacted] for the conduct of this research. Motion carried.
C. Protocol BM101504. [redacted]: "Activin Validation for Detachment of E. coli 0157: H7 from Beef Carcass Plates." This protocol was approved previously, pending approval of [redacted]. Gilliland noted this lab had now received approval. Miller moved and Barrow seconded motion to grant full approval for this protocol in this facility. Motion carried.
D. Olson updated the IBC on the independent inspector's visit. Dr. Bob Ellis from Colorado State University inspected the active BSL-3 labs for the annual inspection required by CDC for the select agent program and gave each of these an unqualified approval. He also performed an initial inspection of the new ABSL-3 and BSL-3 labs and sent his comments to the Director of University Research Compliance. His comments about the overall Biosafety program and the laboratories, as well as the oversight provided by the IBC

were extremely positive. Barrow and Marlow gave more detailed information about the security and use of the rooms. Olson stated that she is meeting with Dean [redacted] and Associate Dean [redacted] to discuss the BSL-3 in [redacted] and to recommend an organizational structure similar to [redacted] whereby the College would have its own building facilities manager and liaison to the Physical Plant, and would have dedicated physical plant personnel for that lab.

E. Update on Emergency Response Training. At the October meeting, Mullikin and Fox agreed to develop and take the lead in implementing a live drill, such as a scenario where a tornado would take off the roof of [redacted]. Fox stated they had not started the development of this nor set a date for the spring training. Ackerson, Gilliland and Bale agreed to work on the committee. Olson stated McKeever's interest in having this type training. Others who volunteered to serve on the planning and implementation committee are Mike Bale, Stan Gilliland, and Elaine Ackerson.

New Business

A. Update on Biosafety Officer. Olson stated that VP McKeever had negotiated an agreement with Stanley Gilliland to assume this role for at least one year, with the assistance of Treena Blagden. The IBC expressed its gratitude to Gilliland for his service in this role.
B. Update on the Director of University Research Compliance. McTernan stated the position closed in November. The screening committee meets for the first time 12-9-04.
C. Update on Select Agent Program Review. Olson stated that McKeever had received notice from her that the select agent program had been reviewed and had met all the requirements. She noted that major modifications to safety, biosecurity, and emergency management plans by [redacted] and [redacted] will be required when the new labs are commissioned for select agent work. McKeever has acknowledged his approval of the program for the ensuing year, under the conditions that appropriate modifications will be forthcoming, and charged the IBC to ensure that these conditions are met.
D. Update on Amendment to CDC for Select Agent Research. Olson updated the IBC regarding the progress on adding the new ABSL-3 and BSL-3 labs to the registration. The CDC has been very cooperative in assisting with this amendment procedure, and has advised OSU of its intention to re-inspect the facilities. Update on new Biosafety-level 3 containment labs was given by Marlow and Barrow. The biosecurity technology was discussed thoroughly, as were the procedures for oversight by the colleges and departments. All procedures will be reviewed and approved by the CDC and the IBC at OSU.
E. Protocols:
    a. [redacted] JRM112904. This protocol combines approved existing protocols JRM030503 and JRM052003 and requests approval to move the research site to [redacted], a BSL-2 facility. Gilliland moved and Strange seconded a motion to approve the research protocol, pending a

satisfactory inspection of [redacted]. Motion carried. Gilliland stated he planned to coordinate inspection of that lab week of December 13.

b. [redacted] KDC111604, "Ruminant B-Lymphocyote Green Fluorescent Protein Aggregation Bioassay for Elk Chronic Waste Disease" to be performed in [redacted]. The goal of the proposed research is to develop a [redacted] for detecting CWD. This request is for Phase I of a two-phase project. This phase uses recombinant DNA. Matts moved and Barrow seconded a motion to approve. Motion carried.

c. [redacted] KDC111904, "Development of Aptamer Beacons to Lipopolysaccharide for Real-Time Sensing of Biological Warfare Agents and Polymer-based Yersinia Pestis point-of-case diagnostic." This strain is exempt from select agent regulations, and has been so noted on the CDC amendment. [redacted] proposes to do this research in a new BSL-2 lab in [redacted]. Gilliland moved and Miller seconded a motion to approve this research, which is a consolidation of existing current protocols, pending satisfactory approval of the new lab. Motion carried, and the investigator will be apprised of this action. Until this lab is approved, he must conduct the research in his approved lab.

d. [redacted]. JF111904, "Niche Adaptation of Serratia marcescens." Research site is a BSL-1 lab in [redacted]. Gilliland moved and Miller seconded a motion to approve. Motion carried.

F. Update on [redacted]. [redacted] has left OSU. His lab has been decommissioned and diagnostic specimens of non-pathogenic avian flu virus have been properly transferred to [redacted] for storage until [redacted] can transport them to his new facility. His protocols have been closed, and his keys have been turned in. His lab can be re-keyed for general use, as directed by the Department of [redacted].

G. Discussion of review process for Recombinant DNA protocols at exempt and BSL-1 levels. Olson had developed recommendations to approve exempt level research for 5 years, and then to request the investigator to complete a questionnaire patterned after the IACUC form in which the investigator responds that the work continues as approved; the protocol should be closed; or the protocol should be kept open, but modifications are required, and a modification is enclosed. Miller moved and Strange seconded approval of this change in administrative oversight. Gilliland will review and recommend any needed changes for oversight at BSL-1 levels, and circulate these changes to the IBC, with plan to review at the next regularly scheduled meeting.

Meeting closed at 4:45 p.m.

Minutes
February 16, 2005
Institutional Biosafety Committee
004 Life Sciences East

The meeting was called to order at 3:03pm

Present: Barrow, Ackerson, DeWitt, Essenberg, Fathepure, Fox, Gilliland, Marlow (arrived 3:55pm), Matts, McTernan, Strange, Verchot,

Absent: Anderson, Bale, Karns, Miller, Van Den Bussche, Mullikin, Veenstra

Not voting: McTernan,

Agenda: Strange moved and Fox seconded acceptance of the agenda. Motion carried.

Minutes: Fox moved and Matts seconded acceptance of minutes of December 8, 2004 meeting as distributed. Motion carried.

Old Business

A. The new Director of University Research Compliance will be J. Steven O'Geary. Dr. O'Geary will start March 7th, 2005, pending approval of the appointment by the OSU Board of Regents.

B. The amendment OSU CDC select agent application to include the new BSL-3 and ABSL-3 labs is progressing. Because of the differing schedules for completion of each project, the application will be updated in stages. The information to be submitted to the CDC for the BSL-3 complex in [redacted] is almost complete.

C. JRM112904, "Francisella/Yersina Molecular Diagnostics Based on Non-Viable Material", [redacted], PI. This protocol combined JRM030503 & JRM052003 and moved research to [redacted]. It was approved 12/8/04 pending a satisfactory lab inspection. The Lab was inspected on 12/13/04 and passed. A protocol approval letter was sent to the PI. The protocol expires 12/14/09.

D. KDC 1112904 "Development of Aptamer Beacons to Lipopolysaccharide for Real-Time Sensing of Biological Warfare Agents and Polymer-based Yersinia Pestis point-of case Diagnostic. [redacted], PI. Consolidated existing approved protocols for Clinkenbeard. Approved 12/8/04 pending inspection of new BSL-2 labs [redacted]. Lab inspections to be scheduled during Feb. 2005.

New Business

A. Protocol 05-01, [redacted], Plant and Soil Sciences, "Bacterial Diversity and Community Structure in Chimpanzee Feces". This protocol has been submitted to cover activities involved in a one week training session by the PI of two researchers from other universities.
A motion was made by Fox and seconded by Gilliland that the protocol be approved pending the following items be satisfactorily addressed:
   1. Provide more detail in the application and 1.9 on the training and experience of all three PI's. Each PI will need to initial next to their name as stated in the application.
   2. Confirm the source. If chimpanzee feces will be used, the committee will require that the experiments/training be conducted in an approved BSL-2 laboratory because of concerns that infectious agents may be present in the samples. Documentation of the source of the feces will be required.

   For: 10
   Against: 0
   Motion Approved

B. Protocol 05-02, [redacted], "Identification and Analysis of Secreted Proteins and the Type IV Secretion System of Coxiella burnetii". The proposed research describes a plan to identify C. burnetii proteins [redacted] and develop [redacted].
A motion was made by Essenberg and seconded by Gilliland that the protocol be approved pending the following items be satisfactorily addressed:
   1. The committee requirement that immediately upon receipt of the proposed source (Coxiella burnetii Nine Mile Phase II strain, clone 4) a confirmatory test be performed to define the clone as avirulent. This process should be described in Section 5 of the application
   2. Addition of the title of the research to 1.3 of the application form.
   3. All listed personnel must initial next to their name in section 1.9 as stated in the instructions.
   4. Satisfactory laboratory inspection of [redacted] at the BSL-2 level. PI will contact the Biosafety Officer when labs are ready for inspection.

   For: 10
   Against: 0
   Motion approved

C. Protocols JRM022302-1, JRM022302-2, JRM022302-3: [redacted], PI. Modification requested change in location from [redacted] for all these BSL-2 level studies. [redacted] was successfully inspected

12/13/04. Modification request was reviewed by the Biosafety Officer and the IBC Chair and approved 1/11/05.

D. Modification and Renewal Request for Protocol KDC033004C, [redacted], PI. "W. persica Species Research". Modification requests change in location from [redacted] for this BSL-2 level study. The requested renewal and modification were discussed and a motion made by Gilliland and seconded by Marlow for approval pending satisfactory inspection of [redacted]. The renewal will be for one year from the current date of expiration.
For: 11
Against:0
Motion approved

E. Modification Request for Protocol AS110802, [redacted], PI. "Foodborne Colonization and Virulence Determinants". Modification requests the addition of an infectious agent, *Clostridium difficile*, and a change in location of the research from [redacted]. The requested modification was discussed and a motion made by Gilliland and seconded by Essenberg for approval pending satisfactory inspection of [redacted].
For: 11
Against: 0
Motion approved

F. April Meeting Date Change The meeting date for the next IBC meeting needed to be changed because of a conflict with the Chair's schedule. The board was polled and the date was reset for April 27th, 2005. Beth McTernan will try to schedule the meeting at the [redacted] to allow the IBC to easily tour the new BSL-2/BSL-3 complex. This will be confirmed before the next meeting.

Meeting adjourned at 4:15pm

Minutes
April 27, 2005
Institutional Biosafety Committee
115 McElroy Hall

The meeting was called to order at 3:05 pm

Present: Barrow, Ackerson, Bale, DeWitt, Essenberg, Fox, Gilliland, Marlow, Matts, Strange, Veenstra ,

Absent: Anderson, Fathepure, Karns, Miller, Van Den Bussche, Mullikin, Verchot

Not voting: Trenna Blagden, Steven O'Geary, Beth McTernan,

Agenda: Gilliland moved and Bale seconded acceptance of the agenda. Motion carried.

Minutes: Strange moved and Essenberg seconded acceptance of minutes of February 16, 2005 meeting as distributed. Motion carried.

Introduction of new Director of University Research Compliance, Dr. Steven O'Geary

Old Business

A. An amendment to the OSU CDC select agent application was submitted by the Office of University Research Compliance (URC) to the CDC to add [redacted] as BSL-3 laboratories for research with select agents. The CDC coordinates the review of the amendment. Comments from both the CDC and APHIS have been received by the URC and responses prepared and submitted. We anticipate that CDC will want to inspect these labs before approving the amendment. Discussions with CDC indicate that an inspection visit will include not only the labs currently submitted, but also any labs that will be brought on line within the next 6 months. This would include the 3 new ABSL-3 labs and the new BSL-3 lab in [redacted].

B. **BO052704 –** [redacted], PI. "Plant Disease and Diagnostic Lab"
The revisions to the original protocol requested in the letter of October 26, 2004 have been addressed. The deficiencies noted in the pre-inspection of the laboratory [redacted] have been corrected and the lab re-inspected on 4/13/05 and approved.
A modification to protocol has been submitted to delete personnel that are no longer employed by the lab and add personnel.
A motion was made by Gilliland and seconded by Barrow to approve the revised protocol and the requested modification for a period of five years. The motion was approved unanimously.

C. **KDC111904 -** [redacted], PI. "Development of Aptamer Beacons to Lipopolysaccharide for Real-Time Sensing of Biological Warfare Agents and Polymer-based Yersinia Pestis point-of case Diagnostic. This protocol consolidated existing approved protocols for [redacted]. This protocol was approved at the last meeting pending inspection of the laboratories [redacted]. McTernan reported that the initial laboratory inspection occurred on February 22, 2005. There were several items that required correction. These items were corrected and the [redacted] BSL-2 laboratories were re-inspected 4/6/05 and approved. A protocol approval letter was sent to the PI 4/8/05, approval expires 12/9/07. The approval of this protocol allowed the closure of the following protocols:

- KDC052203A - Polymer-Based Yersina Pestis Point-of-Case Diagnostic
- KDC052203B – Development of Aptamer Beacons to Lipopolysaccharide for Real-Time Sensing of Biological Warfare Agents
- KDC052203C – Biological Warfare Agent Water Monitor
- KDC03004B – "Cattle E coli 0157 Colonization Model"

D. **05-01-** [redacted], Plant and Soil Sciences, PI. "Bacterial Diversity and Community Structure in Agroecosystems". This protocol was approved pending the receipt of and determination that the requested revisions are satisfactorily addressed. The PI submitted a response on 4/15/05. The revisions are summarized below:

- One PI (Dr. [redacted]) was dropped as he will not attend the training. Training information and initials are provided for the remaining PIs.
- Source changed to soil. Chimpanzee feces will not be used.

A correction was made to question 2.1.2 of the protocol. The box should be checked no. It was checked yes previously because of the proposed use of chimpanzee feces as the source of the DNA. It was verified with the PI that this should have been changed to no with the elimination of the feces as the source. A motion was made by Barrow and seconded by DeWitt to approve the protocol as amended for a term of one year, expiring 4/26/06. The motion was approved unanimously.

E. **05-02 -** [redacted], PI. Identification and Analysis of Secreted Proteins and the Type IV Secretion System of Coxiella burnetii". This protocol was approved pending the receipt of and determination that the requested revisions are satisfactorily addressed. The PI submitted a response on 4/6/2005. The revisions are summarized below:

- Section of the application was expanded to include a procedure for confirmation of C. burnetii clone 4 purity;
- The title of the research was added to 1.3 of the application form;
- All personnel have initialed after their name in section 1.9 of the application;

- [redacted] were inspected on 4/15/05 and found satisfactory by the IBC

A motion was made by Gilliland and seconded by Barrow to approve the revised protocol for a term of 5 years. The motion was approved unanimously. Protocol expiration date will be April 26, 2010.

F. **KDC033004C -** [redacted], PI. "Y. persica Species Research". Modification and renewal. A modification requesting a change in location from [redacted] for this BSL-2 level study was reviewed at the last meeting. The modification was approved pending inspection of new BSL-2 labs [redacted], expiration will be one year from date of current expiration. McTernan reported that the initial laboratory inspection occurred on February 22, 2005. There were several items that required correction. These items were corrected and the [redacted] BSL-2 laboratories were re-inspected 4/6/05 and approved. A protocol approval letter was sent to the PI 4/8/05, approval expires 04/24/06.

G. **AS110802 -** [redacted], PI. "Foodborne Colonization and Virulence Determinants" A modification requesting the addition of an infectious agent, *Clostridium difficile*, and a change in location of the research from [redacted] was reviewed at the last meeting. The modification was approved pending satisfactory inspection of [redacted]. McTernan reported that the initial laboratory inspection occurred on February 22, 2005. There were several items that required correction. These items were corrected and the [redacted] BSL-2 laboratories were re-inspected 4/6/05 and approved. A protocol approval letter was sent to the PI 4/8/05, approval expires 01/2008 (unchanged)

New Business

New Protocols

A. **05-03 -** [redacted], PI. "mRNA Stability and Translation in Plants" This is a recombinant DNA study at the BSL-1 level. A mail review was conducted; reviewers were M. Anderson, J. Verchot-Lubicz, S. Gilliland. Protocol was approved 3/11/05 for one year.

B. **05-04 –** [redacted], PI. "Tick Cell Gene Expression and Modulation of Anaplasm phagocytopohilum infection". Protocol was received and the laboratory pre-inspected. Several deficiencies were noted and sent to PI. Awaiting response before protocol is sent to committee for review.

C. **05-05 –** [redacted], PI. "Identification and Analysis of Proteins Secreted by Rickettsia montana during infection of host

cells". The proposed research describes a plan to identify [redacted] and the development of specific [redacted]. A motion was made by Fox and seconded by Bale that the protocol be approved pending the following items be satisfactorily addressed:

1. Address the discrepancy in the responses to questions 1.5, 2.1.2 and 3.2 of the application regarding the pathogenicity of the organism.
2. Please identify the source of the culture.

Motion was approved unanimously.

D. 05-06 - [redacted], PI. "Germplasm Enhancement for Vegetable Crops in the Southern Plains". This is a recombinant DNA study in plants at the BSL-1 level. A mail review was conducted; reviewers were M. Anderson, R. Matts, R. Miller. Protocol was approved by reviewers. Need IBC input on length of approval.

The committee discussed the terms of approval for protocols. Discussion centered on consistency of approval periods between compliance committees and the need for oversight. It was determined that consistency among the committees is not possible due to differences in the governing regulations. Discussion on oversight centered on the development of a procedure to query the PIs about their active protocols on an annual basis. The query would request input on the status, any changes, and ask if the protocol should remain open. For non-exempt protocols, at the end of five years, the PI would be required to officially renew the protocol by resubmitting an application for committee review.

E. Discussion of Approval Terms and Annual Review

A motion was made by Gilliland and seconded by Fox to establish a policy that exempt protocols approved indefinitely and non-exempt protocols are generally approved for a period generally not to exceed five (5) years.
Motion Approved unanimously

Dr. Marlow suggested that a draft policy/procedure be developed to provide for annual review of protocol/investigator status to monitor on-going activities. This draft will be distributed to the committee and discussed at the next meeting.

Modifications

The following modifications were processed by the Compliance office:

A. **CC012803 –** [redacted], PI. In vivo Emergence and Survival of MDR Samonella". Modification. Modifications requested included:

- Change location of research from [redacted] to [redacted] and [redacted].

- Addition of personnel, Dr. [redacted], Postdoctoral Associate and Dr. [redacted], Postdoctoral Associate.
- Modification of research protocol to include in vivo experiments in calves. IACUC approval has been obtained.

Modifications were reviewed by the OSU Biosafety officer and approved.

B. **CRC101700 –** [redacted], PI. "Novel Biosensor for Detecting Antibiotic Resistance" Modification. Modifications requested included:
   - Change location of research from [redacted] to [redacted].
   - Addition of personnel, Dr. [redacted], Postdoctoral Associate and Dr. [redacted], Postdoctoral Associate.

   Modifications were reviewed by the OSU Biosafety officer and approved.

C. **LL082202 –** [redacted], PI "Molecular Mechanims of Lung Surfactant Secretion/Mechanism of Alveolar Epithelial Cell Differentiation" **LL090203 -** [redacted], PI. " Molecular Mechanims of Lung Surfactant Secretion" Modification. Modification requests the addition of [redacted] to both protocols. Sent to BSO for review. Approval is pending successful lab inspection of [redacted].

Beth McTernan announced that Dr. [redacted] will be leaving OSU and has requested to transfer his biological agents to the [redacted], where he will be employed effective July 1, 2005. The situation was turned over to [redacted] in mailing services who has worked with the US and Canadian officials to make sure all transportation requirements are met.

The final rules were published for 7CFR Part 331, 9CFR part 121, and 42 CFR Part 73. A summary of the differences between the interim and final rules was provided to the committee members and is attached to these minutes. The Compliance office will be reviewing the changes to determine if they impact any research or administrative procedures at OSU.

Dr. Gilliland discussed the pre-inspection/inspection process that he has instituted. Any lab requiring inspection is first pre-inspected by Trenna Bladen, using the standard laboratory inspection checklist, and any deficiencies noted and sent to the PI. This gives the PI time to correct any obvious problems prior to official inspection by the committee.

Next IBC meeting is scheduled for June 15, 2005 – Dr. Marlow has offered to conduct a tour of the new ABSL facilities. Beth McTernan will finalize these arrangements and schedule a room at the [redacted] for the meeting.

Meeting adjourned at 4:00 pm for a tour of the [redacted] BSL3 labs

Select Agents and Toxins Final Rule - Q and A's

1. What are the differences between the amended interim final rules and the final rules? Are there any major changes to the rules?

The final rules (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73) are being published in response to public comments received regarding the interim final rules and to harmonize the structure and format of the USDA regulations and the HHS regulations. For the most part, the regulations remain unchanged. The following outlines the most significant revisions:

- Provided clarification on what is meant by the term access as "an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin."
- Revised the genetic element section to include the regulation of nucleic acids that can produce infectious forms of any of the select agent viruses (e.g. genomes of positive strand RNA viruses on the select agent lists such as Eastern Equine Encephalitis virus, Venezuelan Equine Encephalitis virus, and Tick-borne encephalitis complex (flavi) viruses).
- Clarified that both registered and unregistered entities must report the identification of select agents and toxins presented for diagnosis, verification, or proficiency testing.
- Added a new requirement that entities that perform exempt activities of the identification of select agents and toxins presented for diagnosis, verification, or proficiency testing are now required, upon identification of the select agent or toxin, to secure such agent or toxin against theft, loss, or release during the period between identification and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported.
- Added language to clarify who would be deemed to own or control and, as such, would require a security risk assessment.
- Added a new requirement that drills or exercises of security, biosafety, and incident response plans must be conducted at least annually.
- A single form number will be used for each of the identical forms used by USDA and HHS. For example, "Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins," which was previously referenced as APHIS Form 2040 or CDC Form 0.1319, will now be referenced as APHIS/CDC Form 1).

2. Were there any changes made to the list of select agents or toxins in the final rules, compared to the amended interim final rules? (A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.)

- The list of USDA select agents and toxins has been changed to remove Newcastle disease virus (VVND), and add Newcastle disease virus (velogenic) in its place, to make it clear that we are regulating all of the velogenic strains.
- The USDA list of overlap select agents and toxins has been clarified by removing *Clostridium botulinum*, but continuing to list Botulinum neurotoxin producing species of *Clostridium*.

- The list of PPQ select agents and toxins has been changed to remove *Phakopsora pachyrhizi* and plum pox potyvirus from the list.
- The HHS and overlap select agents and toxins list remains unchanged. The list of the HHS and overlap select agents and toxins can be found at http://www.cdc.gov/od/sap.

3. Will my current certificate of registration remain valid once the final rule takes effect?

Yes, all registration certificates issued under the amended interim final rule will remain valid until the expiration date provided on the entity's certificate of registration.

4. I am currently registered under 7 C.F.R. Part 331, 9 C.F.R. Part 121, or 42 C.F.R. Part 73. Do I need to submit a new application or an amendment to my application as a result of updates to the final rule?

No, entities currently registered under 7 C.F.R. Part 331, 9 C.F.R. Part 121, or 42 C.F.R. Part 73 are not required to submit a new application when the Final Rule becomes effective. However, the Responsible Official should review all sections under the Final Rule to determine if any of the changes throughout the regulation dictate a modification to the information submitted to the USDA Secretary. The Responsible Official should immediately apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application to the USDA Secretary.

5. Will individuals have to undergo a new security risk assessment?

No. Security Risk Assessments (SRA) issued under the amended interim final rule will remain valid when the Final Rule becomes effective.

6. When does the Final Rule become effective?

The Final Rules become effective 30 days after publication in the Federal Register. Since it was published in the March 18, 2005 issue of the Federal Register, the Final Rule will become effective on April 17, 2005. An individual or entity must be in compliance with the provisions set forth in the regulation on the effective date as promulgated in the Final Rule.

7. Will my entity require a re-inspection as a result of the recently-published final rule?

No. Publication of the Final Rule does not require a re-inspection. However, without prior notification, program inspectors shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

Institutional Biosafety Committee
Oklahoma State University
Minutes
June 22, 2005
Life Sciences East – Room 004

ATTENDANCE

Members Present:	Members Absent:	Non-Members Present:
W. Barrow, Chair	D. Marlow, Vice Chair	T. Blagden
E. Ackerson	J. Fletcher (ex-officio)	
M. Anderson	G. Fox	
M. Bale	L. Mullikin	
C. DeWitt	R. Van Den Bussche	
R. Essenberg		
B. Fathepure		
S. Gilliland, BSO		
M. Karns		
R. Matts		
R. Miller		
S. O'Geary, Administrative Officer		
M. Strange		
J. Veenstra		
J. Verchot-Lubicz		

Call to Order:
Noting that a quorum was present, O'Geary called the meeting to order at 3:04 P.M. CDT.

Approval of the Agenda:
O'Geary called members' attention to the agenda and stated that the word "mechanisms" was misspelled in Item E. He also explained that "Draft Procedure for annual review of active protocols" (Item C, under New Business) was removed from the agenda.

Action: Barrow moved and Essenberg seconded a motion to approve the agenda with the noted modifications.
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

Approval of the Minutes:
Action: Gilliland moved and Ackerson seconded a motion to accept the minutes of the April 27, 2005 meeting as submitted.
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

Old Business

A. Update on Amendment to CDC and CDC Inspection:

O'Geary clarified the status of the new ABSL-3 and BSL-3 labs. He also reported on the June 8, 2005 inspection of two new BSL-3 laboratories by representatives of the Centers for Disease Control (CDC). He noted that the two site inspectors seemed impressed with the labs and were complimentary of our approach to biosafety. O'Geary informed committee members that a facility inspection report resulting from the CDC inspection was received on this day (6/22/05) and that we would respond within the required 30-day timeframe. Moreover, he explained that a few deficiencies were identified.

B. **05-04 – [redacted], PI. "Tick Cell Gene Expression and Modulation of Anaplasm phagocytopohilum infection."** The protocol was received, the laboratory was pre-inspected, and the noted deficiencies were sent to the PI.
Gilliland and Blagden announced that Dr. [redacted] laboratory was recently inspected and the deficiencies noted in the pre-inspection had been satisfactorily addressed. However, the protocol must be revised.

C. **05-05 – [redacted], PI. "Identification and Analysis of Proteins Secreted by Rickettsia montana during infection of host cells."**
O'Geary announced that this protocol was approved June 1, 2005, after receipt of requested revisions. [redacted] laboratory was inspected June 22, 2005.

D. **05-06 - [redacted], PI. "Germplasm Enhancement for Vegetable Crops in the Southern Plains."**
O'Geary announced that this is a recombinant DNA study in plants (BL-1). He stated that a mail review was conducted by Anderson, Matts, and Miller. The protocol was approved by reviewers as an exempt protocol (no expiration date, annual review). A letter was issued to the PI April 8th.

E. **LL082202 – [redacted], PI "Molecular Mechanisms of Lung Surfactant Secretion/Mechanism of Alveolar Epithelial Cell Differentiation"**
LL090203 - [redacted], PI. "Molecular Mechanisms of Lung Surfactant Secretion"

O'Geary announced that the PI submitted a modification. The modification requested the addition of [redacted] to both protocols. The request was reviewed by Gilliland and approved pending successful lab inspection of [redacted]. The laboratory was inspected and approved on May 2, 2005. Subsequently, the modification was approved.

New Business

A. New Protocols

1. **05-07 – [redacted], PI. "Nuclear Factor-Kappa B (NF-kB) Regulation of Conceptus Development in the Pig"**
O'Geary announced that this protocol was found to qualify for exemption, as it is a recombinant DNA study (BSL-1 level). A mail review was conducted by Essenberg, Gilliland, Matts. An approval letter was issued June 1, 2005 (no expiration date, annual review).

2. **05-08-[redacted], PI. "Anthrax Detection by SPR Using a Sandwich Assay"**
Gilliland led the discussion. Committee members agreed that the Principal Investigator (PI) must address the following:

- Clarify how he will determine that this strain of *Bacillus anthracis* is avirulent by explaining the plan for testing sterility.

- The PI must submit confirmation to the IBC that the *Bacillus anthracis* is not active. In addition, the PI must submit an updated letter from the Centers for Disease Control (CDC), on CDC letterhead stationary, about this particular strain. The letter should explain the dose, the procedures used for testing this particular strain for

sterility, details about the testing (including whether the procedure used is the standard procedure for testing sterility), and how the strain was irradiated. Moreover, the PI's response to Item 3.7 is dependent upon the letter from the CDC. If the PI can not confirm/verify that the strain is not active, this research must be conducted in a BSL-2 facility.

- The PI will be asked to remove the checkmark from "Pathogenic Microorganisms" in Item 1.5 of the IBC application form. The PI's initial response is incorrect.

- On the IBC application form, the PI needs to expound on the response to Item 3.1 so as to define the microorganism more specifically.

- Since the Sterne strain of *Bacillus anthracis* is not categorized as a Select Agent, the PI's response to Item 3.3 must be changed to "no."

- On the IBC application form, all listed personnel must initial next to his/her respective name in Item 1.9.

- If it is determined that this research must be performed at BSL-2 level, the lab ([redacted]) must be inspected and approved at the BSL-2 level. Satisfactory laboratory inspection would be required before work could begin on this project.

At the behest of the committee, the PI will be invited to attend the meeting at which the revised version of this protocol is reviewed.

Action: Gilliland moved and Bale seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which must be reviewed by a convened quorum of the IBC. (Concerns and stipulations are noted above.)
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

3. **05-09 – [redacted], PI. "Environmental Detection of Anatoxin-A using Molecularly Imprinted Polymers and Surface Plasmon Resonance Spectroscopy"**

Gilliland and O'Geary led discussion. Committee members agreed that the PI must address the following:

- This research must be conducted in a BSL-2 facility. As such, the PI's laboratory ([redacted]) must be inspected and approved at the BSL-2 level. A biosafety cabinet must be used for work with Anatoxin-A and the biosafety cabinet must be hard-ducted. The PI must be informed that satisfactory laboratory inspection is required before work can begin on this project.

- The PI must revise the application and protocol for BSL-2 level work.

- Anatoxin-A is not a Select Agent. However, the PI's standard operating procedures (SOPs) indicate that he is working with a select

agent. He will need to submit SOPs that are specific for work with this toxin, especially emergency plans in case of intoxication.

- All personnel must wear a respirator to work with Anatoxin-A. This should be explained in the SOPs.

- Regarding the SOPs pertaining to waste disposal that were reviewed by IBC members, the PI must change the phrase "must be" to "will be."

- The PI will be asked to provide a specific description of how he plans to use Anatoxin-A in the research. He must also clarify how much of the toxin will be used.

- Disposal and deactivation procedures need to be defined and documented. These must be submitted with the revised application materials.

- Via Item 4.3, the PI must cite the animal model used to determine the LD50 value.

- Via the response to Item 4.10, the PI indicates that personnel have not been trained for work with Anatoxin-A. The PI must define the training he will require of laboratory personnel and he must clarify how he will document training for those individuals who will work with Anatoxin-A. The PI will be informed that absorption through the skin is of great concern.

- The PI must have the appropriate Materials Safety Data Sheet (MSDS) readily available in his laboratory. A copy of the appropriate MSDS is to be forwarded to the PI with the requested revisions/clarifications.

At the behest of the committee, the PI will be invited to attend the meeting at which a revised version of this protocol is reviewed.

Action: Barrow moved and Gilliland seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which must be reviewed by a convened quorum of the IBC. (Concerns and stipulations are noted above.)
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

4. **05-10 – [redacted], PI. " Revealing the Attenuating Mutations of F. tularensis LVS"**

Barrow led discussion. Committee members agreed that the PI must address the following:

- On the IBC application form, the PI must complete Item 1.4 by adding the date of the last laboratory inspection and the names of the individuals who performed the inspection.

- On the IBC application form, the PI will be instructed to select "no" in response to Item 3.4.

- The PI must update the chart regarding lines of authority (page 2 of the Safety and Biosecurity Plan for [redacted]) and submit the revised chart with the revised IBC application form. Furthermore, the PI will be asked to forward 2 additional copies of the revised chart to the Office of University Research Compliance, 415 Whitehurst Hall.

- The PI will be asked to review the standard operating procedures (SOPs) and the Safety & Biosecurity Plan for [redacted] to confirm that all information is current and accurate. The PI must revise these documents, as needed, and forward copies to the Office of University Research Compliance.

The PI will be reminded that this research can not begin until the ABSL-3 facility is operational.

Action: Barrow moved and Ackerson seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which must be reviewed by a Pending Revision Committee, a subcommittee of the IBC. (Concerns and stipulations are noted above.)
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

5. **05-11 – [redacted], PIs. "Tick 4D8 Protein Development of Cattle Vaccines Against Tick Infestations"**

O'Geary announced that this protocol was found to qualify for exemption, as it is a recombinant DNA study (BSL-1 level). A mail review was conducted by DeWitt, Matts, and Van den Bussche. An approval letter was issued June 15, 2005 (no expiration date, annual review).

6. **05-12 – [redacted], PI. "Enhancing the Safety of Meat By-Products with Novel Processing Hurdles"**

Gilliland led discussion. [redacted] responded to questions about the research. Committee members agreed that the PI must address the following:

- On the IBC application form, the PI will be asked to change the response to Item 1.4 to [redacted].

- On the IBC application form, the PI will be directed to change the response to Item 1.5 by checking the box for prions or inserting the word "prions," if the IBC application form has not been revised to include prions.

Action: Gilliland moved and Miller seconded a motion to approve the protocol pending submission of a revised IBC application form that satisfactorily addresses the stipulations raised by IBC review (no expiration date, annual review). (Stipulations are noted above.)
Motion Carried: In Favor=14/Opposed=0/Abstained=1). [redacted], the PI for this project, abstained.

B. Laboratory Biosafety Incident Report

Dr. [redacted] explained the incident, which took place in his laboratory. Committee members had copies of the Report of Laboratory Biosafety Incident, which was submitted to the Office of University Research Compliance on May 19, 2005 by Dr. [redacted]. According to Dr. [redacted], no problems resulted from the incident and the individual who was injured continued with the experiment/research. Dr. [redacted] explained that the individual wrote a report of the incident, which he reported to the Biosafety Officer and to his Department Chair. He also explained that no infected material was in the biosafety cabinet at the time of the incident. A member of the committee asked if it is a common practice for his staff to reuse needles, to which Dr. [redacted] responded by explaining how they normally operate.

O'Geary asked committee members if they felt changes should be made to the standard operating procedures (SOPs) for the lab in question. Committee members agreed that no changes were necessary.

MISCELLANEOUS BUSINESS

A. Announcements

O'Geary announced that the next meeting of the Institutional Biosafety Committee is scheduled for August 24, 2005. He also announced that Jada Bruner Gailey will assume the role of IBC Administrator on July 1, 2005.

Action: Miller moved and Barrow seconded a motion to adjourn.
Motion Carried: Unanimously. (In Favor=15/Opposed=0/Abstained=0)

The meeting adjourned at 4:38 P.M. CDT.

Institutional Biosafety Committee
Oklahoma State University
Minutes
August 24, 2005
Life Sciences East – Room 004

Attendance

Members Present:	Members Absent:	Non-Members Present:
W. Barrow, Chair	M. Anderson	T. Blagden
E. Ackerson	B. Fathepure	
M. Bale	J. Fletcher (ex-officio)	
C. DeWitt	S. Gilliland, BSO	
R. Essenberg	R. Miller	
G. Fox	L. Mullikin	
M. Karns	R. Van Den Bussche	
D. Marlow, Vice Chair	J. Veenstra	
R. Matts	J. Verchot-Lubicz	
S. O'Geary, Administrative Officer		
M. Strange		

Call to Order

Noting that a quorum was present, O'Geary called the meeting to order at 3:20 P.M. CDT.

Approval of the Minutes

Action: Strange moved and Bale seconded a motion to accept the minutes of the June 22, 2005 meeting as submitted.
Motion Carried: In Favor = 9/Opposed=0/Abstained=2

Old Business

A. O'Geary provided an update on the status of the new ABSL-3 and BSL-3 facilities. He did not provide a timeframe for submission of an amendment to the Centers for Disease Control (CDC) that will add these facilities to the University's registration. However, he indicated that University personnel continue to work on issues related to the BSL-3 space in [redacted]. In addition, he noted that the contractor recently provided the University with keys to the new ABSL-3 facility. [redacted] mentioned that additional work was needed before the ABSL-3 space would be considered acceptable.

B. O'Geary informed committee members of the University's response to minor deficiencies noted in a letter from the CDC, which resulted from the CDC site inspection of June 8, 2005. Given that the University had not received a response from the CDC to our July 22nd letter that responded to each deficiency, the Office of University Research Compliance forwarded a letter from Dr. Stephen McKeever, Responsible Official (RO), to the CDC's Angela Mosley asking that CDC personnel certify the labs inspected on June 8th prior to September 2nd. **NOTE:** The two labs were added to the University's registration by the CDC prior to September 2, 2005.

New Business

A. Protocols for Review by Committee

1. **Protocol 05-4 – "Tick cell gene expression and modulation of Anaplasma phagocytpohilum infection", PIs:** [redacted]

O'Geary led the discussion. Committee members agreed that the Principal Investigator (PI) must address the following:

- Via the IBC Protocol Review Form, the PI must note that [redacted] will function as a storage facility. The PI must submit the corresponding Standard Operating Procedures (SOPs).
- The PI must modify the SOPs to explicitly specify how spills will be handled.
- The PI must submit SOPs for decontamination of the liquid nitrogen tank, given that spills are possible. In addition, the PI is to be informed that the IBC requires double containment to be used given that microorganisms are to be stored in a non-BSL-2 facility. The PI must revise his IBC Protocol Review Form accordingly.
- The IBC requires that pathogenic cultures and non-pathogenic cultures be stored separately. Thus, the PI must dedicate one discrete tank to storage of pathogenic cultures and another tank to storage of non-pathogenic cultures. The PI will be asked to clarify the type of tanks and the level of containment that will be used for storage of pathogenic cultures and non-pathogenic cultures. Also, the PI will be asked to specify the type of labeling on these tanks.
- The IBC recommended that the PI assess the location of the liquid nitrogen tanks and where these will be filled, given the precautions that must be taken.

General Standard Operating Procedures (SOPs):

- Item 5: last sentence; the PI will be asked to change the word "shapes" to "sharps."
- Item 8: the PI will be asked to be more specific.
- Items 5, 11, 12, and 15: the PI will be asked to specify at what time, frequency, and temperature items will be autoclaved. This information is also needed in the Specific SOPs.

Action: Essenberg moved and Matts seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which are noted above. The revised IBC application form, including the protocol, will be reviewed by a subcommittee of the IBC.
Motion Carried: Unanimously. (In Favor=11/Opposed=0/Abstained=0)

2. **Protocol 05-13 – "Use of cells of Lactobacillus delbrueckii ssp lactis or chitosan to inhibit Escherichia coli 0157:H7 and/or Salmonella enteritidis on surface of beef and/or pork carcasses", PIs:** [redacted]

O'Geary led the discussion. Committee members agreed that the Principal Investigator (PI) must address the following:

- In Item 5.1 and also via the Standard Operating Procedures (SOPs), the PI lists *Listeria monocytogenes* as a microorganism that will be used in this project. However, *Listeria monocytogenes* is not included in response to Item 3.1. The PI must amend the IBC Protocol Review Form as necessary or clarify the information for the IBC.
- IBC members noted that [redacted] is not listed in response to Item 1.4, Item 3.5, or Item 3.6. However, [redacted] is listed in the IBC Protocol

Review Form in other places (e.g., Item 5.1 and SOPs). Members also noted that samples may be analyzed in [redacted] (see SOP #9) but that [redacted] is not listed in response to Item 1.4, Item 3.5, or Item 3.6. Information regarding research location and storage location must be consistent throughout the Protocol Review Form. The PI will be asked to make the appropriate revisions.

- The PI must clarify/explain the use of [redacted].

Action: Barrow moved and Bale seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which are noted above. The revised IBC application form, including the protocol, will be reviewed by a subcommittee of the IBC.
Motion Carried: In Favor=10/Opposed=0/Abstained=1 (DeWitt abstained)

3. **Protocol 05-16 – "Chitosan based scaffolds for periodontal tissue engineering", PI:** [redacted]

   O'Geary led the discussion. Committee members agreed that the Principal Investigator (PI) must address the following:

   - Regarding Item 1 of Appendix H (Protocol Specific Standard Operating Procedures), the PI must change "apron" to "lab coat."
   - Regarding Items 3 and 4 (and others as appropriate) of Appendix H (Protocol Specific Standard Operating Procedures), the PI must indicate the temperatures, frequency, and duration for autoclaving. In addition, the PI must delete the word "discarded" and insert the word "placed."
   - Via Item 6 of Appendix H (Protocol Specific Standard Operating Procedures) the PI indicates that he will add 10% Clorox to the glass container. The PI must specify the quantity of Clorox that will be added to the glass container?
   - Regarding Items 10 and 11 of Appendix H (Protocol Specific Standard Operating Procedures), the PI will be asked if 70% alcohol is sufficient to sterilize the hood and additional areas. He will be asked to explain the rationale for this percentage and provide the relevant source/citation.
   - Regarding Item 11 of Appendix H (Protocol Specific Standard Operating Procedures), the PI must delete the word "hide" and insert the word "hood."
   - In response to Item 3.10, which is found on page 3, the PI will be directed to select "no," given that no vaccine is available if exposed to ATCC 43719: Actinobacillus actinomycetemcomitans (facultative anaerobe).
   - Given that the acronym "BSC" represents biosafety cabinet, the PI will be asked to refrain from using this acronym to refer to "Biohazardous Sharps Container." He must make appropriate changes throughout the IBC Protocol Review Form.
   - This research must be conducted in a BSL-2 facility. As such, the PI's lab(s) must be inspected and approved at the BSL-2 level. Satisfactory laboratory inspection is required before work can begin on this project.
   - Convened members of the IBC recommend that a microbiologist be identified to serve as co-PI on this project and provide assistance to you. This recommendation is not a requirement to secure IBC approval of this protocol.

Action: Barrow moved and DeWitt seconded a motion to require the PI to submit a revised IBC application form that addresses the concerns and stipulations raised by IBC review, which are noted above. The revised IBC application form, including the protocol, will be reviewed by a subcommittee of the IBC.
Motion Carried: Unanimously. (In Favor=11/Opposed=0/Abstained=0)

4. **Protocol 05-17 – "Intestinal colonization of multidrug-resistant bacteria", PIs:** [redacted]

   O'Geary led the discussion. Committee members agreed that the Principal Investigator (PI) must address the following:

   - Given that the PI's lab in [redacted] was never inspected and approved by the University's Biosafety Officer, which is required for it to be designated as a BSL-2 facility, and given the PI's departure for the University of [redacted], the IBC declined to approve the protocol.
   - IBC members expressed concern that the PI conducted research involving microorganisms *Salmonella spp.*, *Listeria monocytogenes*, *Escherichia coli* 0157:H7, and *Klebsiella pneumoniae*, which require BSL-2 level containment, without obtaining prospective IBC review and approval and without obtaining the prerequisite lab approval.
   - IBC members asked that the PI be informed that University policy requires that all research, regardless of funding, conducted by faculty, staff, students, post docs, visiting scientists or other temporary personnel on OSU property or involving the use of OSU-owned equipment, be reviewed and approved by the IBC if the activity involves the use of microorganisms or toxins that have the potential to be harmful to humans, animals, and/or plants. Furthermore, the PI is to be informed that this includes inspection of BSL-2 and/or BSL-3 laboratories where the research is to be conducted.
   - Out of concern for future occupants, the IBC requires that Gilliland, the University's Biosafety Officer, assess and approve the decontamination of [redacted], once [redacted] has vacated the laboratory.
   - Committee members directed O'Geary to contact the Office of Legal Counsel to ascertain the ramifications of the IBC notifying the University of [redacted] biosafety officer of its concerns about [redacted] actions.

   NOTE: O'Geary spoke with Mr. Scott Fern in the Office of Legal Counsel. Fern informed O'Geary that the Oklahoma Attorney General issued a ruling in 1997 that is binding on Oklahoma State University. Under Oklahoma law, state agencies may not give out job performance information to third parties unless the agency has prior written permission from the individual to do so. Fern viewed the information about [redacted] as job performance related and advised that the information not be released to officials at the University of [redacted] without the written permission of Dr. [redacted].

   During discussion of this protocol, IBC members were informed that Gilliland, acting on behalf of the University, did not approve the transfer of the PI's collection of *Salmonella spp.*, *Listeria monocytogenes*, *Escherichia coli* 0157:H7, and *Klebsiella pneumonia* to the University of [redacted]. In addition, members learned that via an August 19, 2005 E-mail message, the PI confirmed that he would destroy these cultures by autoclaving them.

Action: Bale moved and Barrow seconded a motion to approve the actions of the committee, as noted above.
Motion Carried: Unanimously. (In Favor=11/Opposed=0/Abstained=0)

5. **Protocol 05-18 – "Analysis of virulence gene expression", PI:** [redacted]

   Barrow led the discussion.

Action: Barrow moved and Essenberg seconded a motion to approve the protocol as submitted, with the stipulation that the PI be informed that IBC members agreed that this protocol requires BSL-2 level containment. This approval will expire August 28, 2008.

Motion Carried: Unanimously. (In Favor=11/Opposed=0/Abstained=0)

B. The following protocols were reviewed by a subcommittee of the IBC:

- Protocol 05-14 – "Infection and colonization of bermudagrass by Ophiosphaerella herpotricha, the causal agent of spring dead spot of bermudagrass", PIs: [redacted]
  1. Mail reviewed by Anderson, Miller, and Verchot-Lubicz. PI was contacted with questions generated by review. Revised application received and approved.

[redacted]Protocol 05-15 – "The structure of pectins", PI: [redacted]

  1. Mail reviewed by Van Den Bussche, DeWitt, and Matts. PI was contacted with questions generated by review. Revised application received and approved.

- Protocol DWM011700 – "Analysis of Embryo-Defective Mutants of Arabidopisis", PI: [redacted]
  1. PI submitted a one year no cost extension of time via a university routing sheet. Office of University Research Compliance personnel contacted the PI since the initial IBC approval had expired. Based on communication with PI and internal review, the protocol was approved for continued work.

C. Secure webpage for meeting information:
   1. O'Geary announced that Office of University Research Compliance personnel are working to establish a secure web site for IBC meeting information so that committee members can access and review protocols, minutes, and agendas online. This medium will eliminate the need for printed documents to be delivered to committee members via meeting packets. Once established, IBC members will be notified via E-mail that meeting information is available for review. Members will then be able to access the information, including protocols that require full IBC review, via the Web. O'Geary announced that there will be an authentication process. Prior to implementing this process, O'Geary stated that more information will be provided to members. He also stated that IBC members who prefer to receive printed documents need only notify Research Compliance personnel and printed documents will continue to be forwarded via mail.

D. Laboratory Biosafety Incident Report
   1. Dr. [redacted] submitted an incident report to the IBC in July, which was initially reviewed by Gilliland, the university's Biosafety Officer. The incident involved a Beckman service representative and the director of Dr. [redacted] laboratory deciding not to don protective gear prior to entering a BSL-3 facility. Gilliland forwarded the

biosafety incident report to the IBC for review and consideration at the August 24, 2005 meeting. Convened committee members decided to table consideration of the report until Gilliland is present at an IBC meeting to share his views on the matter. Committee members also asked that additional information be gathered regarding requirements of the Select Agent Final Rule and access to BSL-3 facilities.

E. Future IBC meeting dates and times:
   1. O'Geary announced that the committee needed to establish future meeting dates and times. After discussion, members agreed to establish a standing meeting date (3rd Wednesday of every other month, at 3:00).

   NOTE: After considerable input from committee members via E-mail, the standing meeting day was later changed. The committee's standing meeting is set for the fourth Wednesday of every other month at 3:00 P.M. CT. The next meeting of the Institutional Biosafety Committee is scheduled for October 26, 2005 in Room 204 of Life Sciences East.

Miscellaneous Business
None

Adjournment
Action: Strange moved and Bale seconded a motion to adjourn.
Motion Carried: Unanimously. (In Favor=11/Opposed=0/Abstained=0)

The meeting adjourned at 5:00 P.M. CDT.

DRAFT

Institutional Biosafety Committee
Oklahoma State University
Minutes
October 26, 2005
004 Life Sciences East

Attendance

Members Present:	Members Absent:	Non-Members Present:
E. Ackerson	B. Fathepure	J. Bruner Gailey
M. Anderson	J. Fletcher (ex-officio)	
M. Bale	G. Fox	
W. Barrow	R. Miller	
C. DeWitt	L. Mullikin	
R. Essenberg	J. Veenstra	
S. Gilliland	J. Verchot-Lubicz	
M. Karns		
D. Marlow		
R. Matts		
S. O'Geary		
M. Strange		
R. Van Den Bussche		

Call to Order

The meeting was called to order at 3:04 p.m. by O'Geary. A quorum was present.

Approval of August 24, 2005 meeting minutes

A motion was made to approve the minutes. Essenberg pointed out that Dr. de la Fuente's name was misspelled. With that correction to be made, the motion to approve the minutes was seconded. Motion was approved by unanimous decision.

Old Business

A. [redacted] Incident Report

O'Geary stated this item had been on the August 24th meeting agenda but the committee decided it wanted to wait for discussion of the incident until the Biosafety Officer could be present. Gilliland said he had no clear answer on the issue. This incident raised an important question that needs to be considered. There will be times when equipment in BSL-3 labs will need to be worked on and biosafety cabinets will need to be certified. O'Geary mentioned that at some institutions a release form is signed by the person doing the repair work prior to entering the space. It was suggested that Legal Council be contacted regarding that option. Bale wasn't sure something like that would stand up. It would depend on how it was written. More discussion centered on adding a procedure to the labs SOPs, decontamination methods and their effectiveness, when a lab was considered decontaminated, the different requirements for BSL-2's and BSL-3's and what could and couldn't be decontaminated. At the conclusion of the discussion, it was decided that a subcommittee would look at this issue and work on developing a policy. The subcommittee would be Barrow, Gilliland, O'Geary, and Strange. Anyone else who is interested should contact O'Geary. As to the handling of the incident, Gilliland was comfortable with how Wyckoff dealt with it. The response back to [redacted] should indicate the IBC believes he handled the situation in an appropriate manner. Also, that the committee is appreciative of him drawing attention to situations like this and that the committee will be working on guidance on how to more formally handle similar situations of this nature in the future.

New Business

A. Protocols for Review by Committee

1. **05-19** – "Epidemiology of American Canine Hepatozoonosis", PIs [redacted]

   Discussion began with Barrow asking for clarification on how they were going to collect the ticks. He's concerned that the ticks might carry other microorganism other than what the PI is looking for. How are the people going to be protected. DeWitt asked if it was known how the trapped animals would get from the trap to the container. There was more discussion on transportation methods. Barrow also asked Marlow if the animal facility had been inspected. Marlow indicated yes it had and that the animal protocol had already been to the IACUC and approved. That committee felt those issues had been adequately addressed. Barrow still expressed concern with the possibility of other pathogens being present.

   Upon conclusion of the discussion, a recommendation was made that the PI address the following: 1) clarify the procedures involved during the necropsy and assurance that protection against other pathogens is taken; 2) provide PI title to second question of 1.1.; and 3) obtain initials to question 1.9.

   A motion was made to approve the protocol pending satisfactory response to issues listed. Motion was seconded and approved unanimously.

   NOTE: After the meeting, Gailey checked the animal protocol to verify what procedures had been listed for protection against possible tick transfer. The protocol listed that protective clothing would be worn including heavy gloves and insect repellent.

2. **05-20** – "Natural history of tick-borne disease agents", PI: [redacted]

   Discussion began with Gilliland stating that the lab had been inspected and is approved. Gailey said the animal protocol had been reviewed by the IACUC at the October meeting and approval is pending minor corrections.

   Upon conclusion of the discussion, a recommendation was made to approve the protocol with the PI submitting page 2, question 1.9. initialed.

   A motion was made to approve the protocol as noted. Motion was seconded and approved unanimously.

3. **05-21** – "Effect of metabolic mutants on Brucella abortus metabolism and macrophage survival", PI: [redacted]

   Discussion began with Gilliland stating that the lab had been re-inspected and the date in 1.4. should be changed. He didn't recall specifics but believes some minor corrections are needed in the lab before work can begin. The PI should expand his experience listed in 1.9. It was noted the contact information in the SOPs is dated. The PI in-charge of that lab space should update it.

   Upon conclusion of the discussion, a recommendation was made to approve the protocol with the PI expanding the experience section in question 1.9.

   A motion was made to approve the protocol as noted. Motion was seconded and approved with [redacted] abstaining. A reminder will be included that work cannot start in the lab until it is fully approved. And, a note will be sent to the PI in-charge of the lab about updating contact information.

4. **05-22** – "Initiation and regulation of prophenoloxidose activation", PI: [redacted] (Renewal)

Discussion opened with Gilliland noting that the building had not been listed in question 1.4. The building is listed in other areas of the protocol. It was clarified that the PI is only working with invertebrate animals. Matts stated this is very low risk work and made a motion to approve the project. Motion was seconded and approved unanimously.

Marlow had an administrative question after the motion passed. The form was submitted hand-written. Should it be the policy to require the forms typed? It was discussed and a note would be added to the website and form stating the form should be typed or completed using the electronic version.

B. Protocols Reviewed by Subcommittee

- None

C. Laboratory Biosafety Incident Reports

1. [redacted]

Barrow pointed out on the incident report that they had O'Geary listed as the Biosafety Officer which is incorrect. Gilliland was contacted and was aware of the incident. Strange stated that he had seen the individual and a full exam was done. Everything checked out fine. The risk level was low. Bale asked for confirmation that no safety glasses were being worn. That was affirmed and the PI changed their SOPs to include the use of safety glasses. All felt the corrective action taken is appropriate and recommended that this be communicated to the PI.

2. [redacted]

Strange asked if it was known what the fluid was and yes it was known. Discussion took place on the practice of putting water in the bags. Some felt it was not necessary. However, the practice is in the PI's standard operating procedures and everyone thought the incident was handled well. Communication to the PI should confirm that the handling of the incident was appropriate and handled correctly.

D. BSL-2 Laboratories and Custodial Services

Gilliland gave a summary of what happened to the committee. Access to a BSL-2 lab by a custodial crew occurred after hours without prior notification to the PI or lab manager. Gilliland contacted the custodial crew supervisor and as a result all custodial services were suspended to BSL-1 and BSL-2 labs. Gilliland and O'Geary met with Jeff Stewart, Interim Chief Facilities Officer, and Adrian Self, Director of Maintenance and Operations concerning how to handle custodial services to labs. Blagden had contacted PIs with BSL-2 labs to see what was currently done. Most did their own custodial services. It was decided that no custodial services would be done by Physical Plant staff to any BSL-2 labs after hours or without a lab manager or PI present. Training would be given to Physical Plant staff to recognize signage. Custodial services would be provided to BSL-1 labs. Karns brought up the question of exactly how many people have keys to areas they probably shouldn't. It was suggested that maybe BSL-2 labs be keyed differently. Development of a policy specifically outlining how these items should be handled needs to be developed.

E. Changes for the IBC

From attending various national meetings, Gailey and O'Geary recognized the need for changes to occur in how the IBC operates. The authority of and for the IBC comes from NIH Guidelines for rDNA research. Some of the requirements of those guidelines do not flow to other types of biomaterials research. In order to protect sensitive information and follow the rDNA guidelines, some changes will be made to forms, how protocols are reviewed, how meetings are conducted, and how information is distributed, as well as other aspects yet to be determined. A question was asked regarding how this would impact PIs. These changes should appear seamless to them. The only change PIs will likely

notice is the change in application forms. But, these changes need occur for various reasons including complaints by PIs. The committee should begin to see changes with the December meeting.

F. Miscellaneous Business

O'Geary informed the committee that the annual review process has started for the select agent program. Information was sent to those PIs, departments, and colleges effected. Included in the letter was a list of required changes that must be addressed. All information should be submitted to the Office of University Research Compliance by November 4th, 2005.

Adjourn

A motion was made to adjourn the meeting at 5:02 p.m. Motion was seconded and approved unanimously.