

OFFICE OF THE VICE PRESIDENT AND GENERAL COUNSEL

May 10, 2006

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

RE: Minutes of IBC Meetings since May 2003

Dear Mr. Hammond:

In response to your letter dated March 15, 2006, enclosed are copies of all University of Nebraska-Lincoln Institutional Biosafety Committee Meeting minutes beginning May 2003 through March 2006.

Sincerely,

Trish Henry Legal Assistant

t051006 Enclosures Institutional Biosafety Committee Meeting
Meeting Minutes
May 9, 2003 1:05 PM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on May 9, 2003 at 1:05 pm in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Gerald Duhamel; Roy French; Jill Hyslop-Bohling; Michael Meagher; Abraham Oommen, and Roger Quiring. Norm Braaten was also present.

Minutes:

Weber Protocol: A discussion was held on this BL1 project. No infectious agents are used. The Committee APPROVED the protocol but will seek clarification on sepsis and how it is detected.

Beecher Protocols: The protocols are BL1 and very straight forward. The Committee APPROVED.

<u>Fromm Protocol</u>: This project is BL1. The following items should be added to the protocol: 1) definition of how the material is rendered biologically inactive, 2) a protocol cover sheet is required, and 3) a more complete protocol is needed.

Environmental Health and Safety Discussion

Education requirements for working with select agents and for access to select agents. Need to define support staff. The Committee agreed that the Bachelor's degree requirement should stand. There was a question on the amount of experience. Training from UNMC might be a possible mechanism.

Reporting of Biosafety Conditions: Discussion of procedures for how reporting takes place.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 2:20.

Institutional Biosafety Committee Meeting
Meeting Minutes
June 13, 2003 1:10 PM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on June 13, 2003 at 1:10 pm in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Roy French; Jill Hyslop-Bohling; Michael Meagher; and John West. Others present: Brenda Osthus, Norm Braaten.

Minutes:

<u>Harris Protocol:</u> Dr. Benson introduced this protocol. The mutants were clarified. Mike Meagher made the motion for approval, Tom Clemente seconded. The Committee APPROVED.

<u>Zhang Amendment Protocol</u>: Dr. West introduced the amendment. Points covered: Not clear what is being assayed. – VSV (Indiana) is a known, widely used organism. The type of VSV (Indiana is assumed) should be specified. The source should also be specified. An APHIS permit is required for this research.

The protocol was tabled, pending receipt of the information cited above.

Action item: The question was raised as to whether APHIS permits should be submitted along with protocols as a general rule. The Committee agreed and voted to approve this change in submission requirements.

Environmental Health and Safety Discussion

Revised Safe Operating Procedure (SOP) for Select Agents: The revised SOP looks good. It was moved by Dr. Meagher that the SOP be accepted. Dr. French seconded. Motion APPROVED.

<u>Clarification is needed regarding plasmids</u>: commercially available or things from a culture collection or repository, no map is required; is substance is "home grown", a map is required.

The Committee viewed the electronic Biosafety application form and suggested changes...

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 3:00 p.m.

Institutional Biosafety Committee Meeting **Meeting Minutes** August 15, 2003 1:05 PM Environmental Health and Safety

University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called

to order on August 18, 2003 at 1:05 pm in the Conference Room at Environmental Health and

Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Roy

French; Nick Huser (filling in for Jill Hyslop-Bohling), Rod Moxley: Others in attendance:

Norm Braaten and Michelle Miller.

Minutes:

Funnell Protocol: Discussion: The intent is to make libraries from fungi and bacteria; for

example, in e-coli. The project is straightforward. Funnell wants the protocol to be an

amendment. The protocol needs a new project number. Dr. Clemente and Mr. Huser approved

the project as a new protocol. The Committee APPROVED.

Fromm Protocol: This project was originally submitted as exempt. The committee determined

that the project was actually BL1. The tagging system, multiple vectors will be used. Host has

not been specified, i.e., base vector (backbone). Mr. Huser moved acceptance contingent on a

vector being provided. Dr. French seconded. After all information is provided, Dr. Kenneth

Cassman will need to sign off. The Committee APPROVED.

<u>Clemente Protocols</u>: New material provided in APHIS permit / performance standards. No

recombinants generated; these are field trials. (There was a lab-approved protocol.) These were

treated as new protocols. Mr. Huser and Dr. West moved to approve. Clemente abstained. The

Committee APPROVED.

Follow up to Zhang Protocol: Dr. Zhang identified the strain and is seeking APHIS approval.

Institutional Biosafety Committee Meeting Meeting Minutes

September 16, 2003 11:05 AM Environmental Health and Safety

University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on

September 16, 2003 at 11:05 pm in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Gerald Duhamel; Roy French; Jill Hyslop-

Bohling, Rod Moxley: Michael Meagher, and Roger Quiring. Others in attendance: Norm Braaten, Robert

Braden (Clark Enerson Partners), Naeem Ebrahim, Michelle Miller, Brenda Osthus, Howard Parker, Hugh

Sieck, John Wise, and Mike Zeleny.

Minutes:

Discussion of Proposed BL3 Facility:

Veterinary Basic Science, Room 126. Is there adequate oversight for construction of the installation? A list of

concerns was read. This list of concerns will be sent to all committee members for feedback. A special meeting

will be scheduled to determine how concerns should be addressed.

Barletta Protocol: Discussion on types of mutants. Libraries will need to be classified. Experiment appears to

be sound. Training could be spelled out better.

We do not have a BL3 approved lab. Investigator cannot conduct BL3 work in the facility. It will probably

never meet BL3 specifications.

Schmitz Protocol (introduced by Dr. Duhamel): Vaccine efficacy studies. There were questions on shipping

procedures/permits and protocols for facilities. The volume and dose level was not specified. There was a

question on potential for humans to contact symptoms...

Question on BL2 level: Decontamination protocols are needed. The protocol was tabled for more information

(company documentation).

Becker Protocols: Two very similar protocols. Both are BL1 level work. Drs. Clemente and French approved.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at

12:45 p.m.

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Biosafety Committee Minutes

Institutional Biosafety Committee Special Meeting
Meeting Minutes
September 30, 2003 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

The meeting was called to continue discussion of the BSL-3 facility proposed for VBS and to determine minimum design criteria for future BSL-3 projects. The IBC Chair provided background information on the core questions; Brenda Osthus provided a list of specific issues to be considered by the committee, based on discussion at the previous meeting.

The currently proposed BSL-3 lab was designed to meet minimum NIH Guidelines for such space; however, the design was not based on a specific risk assessment for the proposed use. Committee members expressed a need for external review of the design by NIH or CDC. (The facility would be subject to CDC or APHIS approval as part of the registration process if work with select agents were conducted in the lab). However, this review occurs after the design is implemented, and what is needed is a determination of adequacy before the lab is built. In addition, third-party validation of the facility after it is built is required to confirm that facility construction and operation is consistent with design specifications. Third-party validation needs to occur periodically to ensure continued performance.

It was stated that the architects were constrained in terms of space and budget and designed what they could within these constraints. However, they indicated it was not optimal and not what they would have done elsewhere.

Specific comments/issues:

Multiple agents: The suite is fine as a part of a larger facility, but if it is going to be used with multiple agents, contamination will be a problem.

Multiple users: The design will not fly at NIH with this design and multiple users. It would be OK for a single investigator. Another member thought it could be built for one person or two investigators with similar projects.

Access: Need a larger space with controlled access. But this could be an interim solution while we develop a hard, multi-investigator space. (There was considerable discussion of the possibility of moving it to the second floor and the building a penthouse on the roof to accommodate the air handling and mechanical systems. Alternatively, there might be a way to restrict access by moving the door to a location that is not off the main hallway near classrooms.)

Validation: Need external (NIH or CDC) review of the plans and third-party validation before the research goes on line. Third-party validation needs to occur periodically.

Oversight: There should be oversight of the facility. It needs an expert to oversee it.

The chair called for a vote on whether the currently proposed BSL-3 laboratory is adequate for use with Francisella tularensis. The vote was 5 No (including absentee members) vs. 2 Yes (but that modifications would be needed).

The remainder of the meeting was devoted to reviewing each of the issue raised in Brenda's email letter and making a determination as to which features would be required for any future BSL-3 lab. The committee reached consensus that the following features would be required:

- 1. The laboratory should be located in an area that is not accessible to students, visitors, and the general public. It should not be located near general purpose/unrestricted areas (i.e., conference/meeting rooms, classrooms, offices, etc.).
- 2. Entry to the laboratory must be secured with a card access system that is controlled centrally (not a local system). This requirement also applies to the mechanical area that services the space. In addition, wire should be run to provide for future video surveillance if deemed necessary.
- 3. The entrance to the ante room that serves the BSL-3 lab should not be from a common use hallway, unless the hallway is secured to provide limited access. A nested design is preferred, where entry to the ante room is from an outer laboratory space.
- 4. The design must incorporate three distinct areas- an outer ante room, an intermediate shower/change out area (depending on size and use, male and female areas may be needed), and the inner, actual BSL-3. The shower area(s) should have eyewash station(s).
- 5. Work area should be sufficiently sized to provide adequate work benches and accommodate needed equipment. At a minimum, the space should be designed to allow work by two people. Design should incorporate sufficient space for dedicated freezer space (-70/80).
- 6. The BSL-3 lab must be designed with gas decontamination ports that can be operated/activated from outside of the room.
- 7. HEPA filter housings must be designed with gas decontamination ports to allow for gaseous decontamination of the filter prior to opening of the filter housing. Of course, this implies bubble-tight dampers to isolate the filter/housing area.
- 8. BSL-3 laboratory area must have humidity control and be able to achieve 70%RH.
- 9. A hand washing sink must be included in the BSL-3 area and be operated with sensors, elbow, knee, etc. The sink must be located near the door. It should also include a soap dispenser that operated by sensor, elbow, knee, etc.
- 10. Means for transmitting data and information from the laboratory must be provided (i.e., data ports, voice recording, etc.)
- 11. The design must incorporate a fume hood or a combination fume hood/biological safety cabinet.

- 12. Aerosol producing devices/equipment must be enclosed in HEPA filtered cabinetry.
- 13. The mechanical room should be designed so as to allow for remote gaseous decontamination.
- 14. Vacuum service should not be provided via a house or common system. A dedicated system/pump should be provided and it should be protected with a HEPA filter.
- 15. A kill system should be designed to receive waste flow (i.e., sink discharge, etc.) prior to discharge to the sanitary sewer and common building lines.
- 16. Upon completion of construction, third-party commissioning of the facility is required prior to occupancy. Periodic validation of the facility will also be required.

Note: These apply to standard BSL-3 laboratories only - animal BSL-3 facility.

Adjournment: Chairman Benson thanked everyone for attending this special meeting.

Lisa Crockett

Institutional Biosafety Committee Meeting
Meeting Minutes
October 21, 2003 11:02 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on October 21, 2003 at 11:05 pm in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Roy French; Jill Hyslop-Bohling, Rod Moxley:, Roger Quiring, and John West. Others in attendance: Doug Beals, Norm Braaten, Naeem Ebrahim, and Nick Huser.

Minutes:

<u>Hinkley Protocol (State of Nebraska Johne's Cooperative Agreement #03-9731-1029CA)</u>. Dr. Duhamel introduced this protocol. This is an "isolation protocol". The literature concerning the risk group is contradictory (BL1 vs. BL2). The micobacterium has a possible association with Crohn's disease in humans. Type of disinfectant – spore clenz used, bleach, autoclaving.

Drs. Moxley and Clemente moved to approve. The Committee APPROVED.

<u>French Protocol (Molecular Genetics and Biology of Wheat Streak Mosaic Virus)</u>: Introduced by Dr. French. This new protocol inserts a virus into parts of plants (wheat, corn, sorghum). The previous protocol made clones of viruses. The risk group is BL1P+, treated as BL2P. Drs. Clemente and Duhamel moved approval. Carried. (Dr. French abstained.)

Second French Protocol (Plant RNA Virus Gene Expression Vectors): This is an extension of an approved protocol (#96-3) relating to a new gene expression. The biosafety level is BL2P. Drs. Clemente and Duhamel moved approval. Carried. (Dr. French abstained.)

Other Discussion (BL3 Labs):

Can Dr. Barletta's space (Room 239) ever be converted to BL3? The second floor BL3 lab in Veterinary Basic Science was a concern. Is Room 239 acceptable for BL3 as it stands (based on September 15, 2003 document). The Committee said "no". The current facility is not acceptable and cannot be brought up to current standards. plore other options.

Institutional Biosafety Committee Meeting Meeting Minutes
November 18, 2003 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on November 18, 2003 at 11:00 pm in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Roy French; Jill Hyslop-Bohling, Rod Moxley:, Roger Quiring, and John West. Others in attendance: Naeem Ebrahim and Norm Braaten.

Minutes:

<u>Duhamel Protocol (Mouse Model of Brachyspira and Helicobacter Infection)</u>: This protocol was e-mailed to the committee members in order to speed up the process. After a discussion, Drs. Clemente and West moved to approve. The Committee APPROVED. (Dr. Duhamel abstained).

Angeletti Protocol (Replication of DNA Viruses): This protocol was introduced by Dr. West. It is a detailed a protocol in which vector backbones are identified. The committee would like to see construct maps from collaborators. Additional details for waste handling would be helpful. There was a question on yeast studies. A cabinet should be used where infectious agents might be produced. Aerosols should be done in the cabinet or a closed system. Eyewear should be worn at all times. Drs. Clemente and Duhamel moved approval contingent upon revisions. Motion Carried.

Schmitz Protocol (Development of a New Canine Combination Vaccine Containing Bordetella bronchiseptica Using an Experimental Challenge Model in Young Dogs): The questions raised at the October meeting were responded to by Dr. Schmitz. Drs. Moxley and Clemente moved approval. Motion Carried.

Other Discussion (BL3 Labs):

The BL3 facilities in VBS were discussed. Would the committee approve if the facility meets the discussed design criteria? Deviations were noted. (The committee's primary concern has been location.) The committee realizes that the design should also be subject to the appropriate departmental approvals. Committee consensus was that if the design criteria were used, the committee would approve the facility.

'djournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 11:55 p.m.

Institutional Biosafety Committee Meeting
Meeting Minutes
February 28, 2004 11:00 AM
Room 143, Filley Hall Conference Room
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on February 28, 2005 at 11:00 AM in the Conference Room at Filley Hall.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Roy French, Jill Hyslop-Bohling, Rodney Moxley, Roger Quiring; and John West, Others: Norm Braaten and Farida Ebrahim.

Minutes: Minutes from the January 31. 2005 meeting were discussed. It was noted that the autoclave discussion at the January meeting should be added to the meeting minutes. Contingent on the noted addition, the minutes were approved as well as minutes from the November 11, 2004.

New Business:

1. Correspondence regarding Dr. Benson's project: The letter from the Institutional Biosafety Committee (dated December 19, 2002) to Dr. Benson, and Dr. Benson's reply letter (dated February 15, 2005) were reviewed. Since voting was not required for this project, the committee voiced its appreciation for the updated information.

Note: The two projects to be reviewed were submitted by the chair of the IBC. The committee chose Dr. Duhamel to act as chair during the voting process.

2. Benson protocol "Population genomics of Brucella species": Dr. Benson began the discussion by confirming that the lab will only have DNA and described the DNA only verification process to ensure that no live Brucella would be transferred to UNL. Live Brucella species are considered BL3 organisms as well as select agents. Discussion included biosafety concerns, considering virulence factors for the agent have yet to be identified. The committee reviewed the safety and security sections of the protocol and decided the hazards were adequately addressed. Members noted some typos but had no additional concerns. Dr. Benson was asked to leave the conference room during voting.

Drs. West and French moved for approval. The motion carried.

3. Benson protocol "Monitoring of recombinant Clostridium perfringens on meat surfaces in vitro. The discussion was lead by Dr. Benson, who explained that the toxin from C. perfringens was a select agent but the bacteria itself was not. The cuvettes involved in the electroporation step were discussed as a point of contamination and/or exposure concern. The safety and security sections were reviewed, and it was noted that hazards were addressed appropriately. Dr. Benson was asked to leave the room for voting.

Drs. West and French moved to approve. The motion was carried.

- 4. <u>Autoclave validation.</u> Jill led the autoclave validation discussion. Members agreed that a program needed to be implemented. Plans were discussed for implementation.
 - > Plan 1: Create a standard protocol to follow for testing and assign a designated staff member to be in charge of validation.
 - Plan 2: Create a standard protocol to be followed in campus buildings and let individual departments decide whom to designate as the person in charge of validation. Dr. Crockett volunteered to discuss the issue with Prem Paul because implementation requires financial support.
- 5. <u>Dual Use Dilemma</u>: The dual use dilemma discussion was introduced by Jill. Discussion included the need for individual Principal Investigators to document that they considered the dilemma as part of their registration process. Consideration of dual use could be incorporated as a single question added to the online protocol submission program. The Institutional Biosafety Committee would consider the issue when reviewing a project, and meeting minutes and/or a checklist would be used for documentation that the dual use dilemma was considered for each project submitted.

Adjournment To the delight of all present, Chairman Benson thanked everyone for his or her attendance and the meeting was adjourned at 12:20.

Institutional Biosafety Committee Meeting Meeting Minutes March 16, 2004 11:00 AM Environmental Health and Safety University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on March 16, 2004 at 11:00 AM in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio) Gerald Duhamel; Roy French; Jill Hyslop-Bohling; Rodney Moxley, Roger Quiring; and John West.

Minutes:

- 1. Discussion of on-line protocol submission process. It was agreed to route one protocol through the system as a test.
- 2. Chair raised option of substituting electronic communication for some meetings. Use of electronic communication will permit the committee to meet face to face on a quarterly basis rather than monthly. The Committee agreed, as long as there was a provision for making comments on protocols and getting feedback on those comments. A process will be set up to allow this exchange electronically. The electronic "discussion" will be recorded electronically and will include everyone's comments and a record of the vote.
- 3. <u>Thippareddi Protocol</u> (<u>Microbial Challenge Studies to Evaluate Bacteriostatic and Bactericidal Efficacy of Food Antimicrobials</u>): The protocol was tabled owing to a lack of complete information regarding decontamination procedures and specifics of the research procedure.
- 4. Discussion of providing "ideal" protocols to new faculty for use in drafting their own protocols. Several faculty with good protocols were mentioned; Jill will meet with department heads to identify others.
- 5. Jill reported on campus biosafety audits.
- 6. Jill reported that the Animal Research Facility wants to dispose of waste as BL1 (untreated) not BL2 (incinerated). However, the waste involves a Risk 2 agent, so they will need to either petition for a waiver from Centers for Disease Control or incinerate it.
- 7. Discussed status of BL3 animal facility. A new plan is needed to take back to Veterinary and Biomedical Sciences for departmental approval.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 11:50 a.m.

Institutional Biosafety Committee Meeting
Meeting Minutes
April 20, 2004 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on April 20, 2004 at 11:00 AM in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Roy French; Jill Hyslop-Bohling; Rodney Moxley, Roger Quiring; Support Personnel: Brenda Osthus, Farida Ebrahim; Guests: Doug Beals, Nick Huser, Greg Lattig, and Clinton Jones.

Minutes:

Plans for the proposed Virology Center building and new BSL3 unit were reviewed.

Greg Lattig of Clark Enerson Partners presented the floor plans for the proposed Virology Building. The committee was satisfied with the plans, although some questioned why the full second floor space was not being used for the penthouse rather than as lab space for future growth.

No formal vote was taken.

Doug Beals presented plans for the animal BSL#3 unit. A stand alone unit was envisioned to be located near the Animal Research Facility. He explained that the current plan would meet all of the standards set by the Biosafety Committee for BSL#3 space. There were some questions concerning the recommended location of the site rather than one closer to VBS. Ease of access to the unit was also discussed. However, the committee was generally satisfied with the plan.

No formal vote was taken.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 12.30 p.m..

Institutional Biosafety Committee Meeting
Meeting Minutes
August 31, 2004 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on August 31, 2004 at 11:00 AM in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Roy French; Jill Hyslop-Bohling; Rodney Moxley, Roger Quiring; and John West. Others: Norm Braaten

Minutes:

Meagher Protocol Update: Dr. Meagher is working on a blanket protocol for his projects and his laboratory.

Becker and Duhamel protocol (Studies of Put A and Redox Homestasis in Gastrointestinal Bacteria):

Project was introduced followed by discussion.

Drs. French and Moxley moved approval. Motion passed pending modification of the section on Applicable Regulations to cite the appr4opriate regulations (Section IID-2a) in the NIH Guidelines. Dr. Duhamel abstained.

Duhamel protocol (Campylobacter/Helicobacter Cytolethal Distending Toxin):

Project introduced. There was a discussion of the potential toxicity of the individual subunits. If the toxicity is not known, research will not be able to put A, B, C together.

Drs. Moxley and West moved approval. Motion passed pending incorporation of a section in the application that documents the appropriate applicable NIH guidelines (Section IIID-2a). Dr. Duhamel abstained.

Duhamel protocol (Handling of Monkey Tissue Specimens):

Project introduced. Discussion: One virus is RG4, chance of transmission is low. BL2 procedures commonly used. Need to have procedures in case of cut or puncture wound. Serum samples are required. Informed consent document should incorporate information regarding risks.

Project tabled.

Somerville protocol (Metabolic Regulation of Staphylococcal Pathogenesis):

Project introduced. Section cited should be IIID-1a and Section IIID-2a, not C. The Committee agreed that a biosafety cabinet would not be required for this project.

Drs. Duhamel and French moved approval. Motion passed pending a corrected application. Dr. Moxley abstained.

Benson protocol (Development of Interventions Against Bioterrorism Agents Using Drosophila as a Model System:

Project introduced. Discussion revealed concerns with the inoculation of flies, "escapees", within biosafety cabinets. The committee decided that it was not necessary to use the cabinets for the experiments as described

Drs. Clemente and French moved approval. Motion passed. Dr. Benson abstained.

Zempleni protocol (Recombinant DNA Approval by the Biosafety Committee):

Discussion of protocol. BL1 conditions. There was a question about what etopiside is / does. This will be handled by EHS. List cell lines.

Drs. Duhamel and West moved approval, contingent on cell lines.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 12.00 p.m..

Institutional Biosafety Committee Meeting
Meeting Minutes
September 21, 2004 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on September 21, 2004 at 11:05 AM in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Rodney Moxley, Roger Quiring; and John West. Others: Nick Huser and Lorraine Moon

Minutes from August Meeting: All in attendance voted for approval. Seconded by Nick Huser.

1. Duhamel Protocol Update (Handling of Monkey Tissue Specimens):

The following issues were discussed by the committee: 1) blood samples from personnel collected by the University Health Center as a baseline before project begins, 2) "Identification Cards" being issued indicating participation in handling specimens possibly contaminated with Herpes B virus (who is issuing cards?), 3) emergency response protocol, and 4) exposure report.

Dr. West suggested that the Emergency Response information be posted in appropriate locations.

Dr. Duhamel suggested that the researchers participate in website training on blood borne pathogens.

Dr. Clemente asked how many samples were involved. The response was that there would be 30 samples from each center with a total of 60. After cultures were obtained, the rest of the tissue would be disposed of.

Dr. Moxley moved for approval *. Everyone seconded. (The committee was one vote short of a quorum. An electronic vote will be taken of those members not in attendance before formal approval of the project. Result of electronic vote: Jill Hyslop-Bohling and Roy French voted for approval.)

2. Pattnaik Addendum to Approved Protocol #03-5 "Replication and Assembly of RNA Viruses"

Drs. Duhamel and West explained the changes in the amendment. The virus will be prepared from cells transfected with a full-length cDNA clone and a Vaccinia virus vector producing T7 RNA polymerase. Certain genomic regions of the virulent virus will be exchanged with corresponding regions from an avirulent strain to examine the virulence and attenuation determinants of PRRSV. Animal studies will be carried out in the laboratory of Dr. Fernando Osorio in Veterinary and Biomedical Sciences.

Discussion followed regarding the disposal of the animals and the laboratory manipulation of viruses. This would be considered a BL2 in animals. Work should be done at the Animal Research Facility and incineration of the carcasses and waste treatment would be necessary.

There were questions about the generation and spread of recombinant viruses (recombinants of Vaccinia and PRSSV cDNA) and what measures would be necessary to assure no spread from ARF. The committee decided to table the addendum pending further risk assessment by experts in the field and pending further information from Dr. Pattnaik on animal and waste handling. The following concerns should be addressed by Drs. Pattnaik and Osorio in the amendment: 1) not highly likely that recombination would occur, 2) disposal of animals, and 3) "cooking" of sewage.

According to Dr. Duhamel, waste is a big concern. Protective garments need to be worn by those handling the waste. He suggested that Ruben Donis be contacted regarding the risk of generating recombinants. Dr. Moxley will make the contact. It was emphasized again that the work must be done at the Animal Research Facility so that everything is handled properly. Is APHIS approval needed? Jill should check with Dr. Kathleen Akin.

Dr. Moxley moved that that the amendment be Tabled for more information.

Hygnstrom protocol "Surveillance of Hantavirus in Nebraska"

Dr. Benson questioned the proposed exempt status since the work was being done in the field and the reference to a lab was vague (which lab ?).

Discussion that followed included the following: 1) incineration would take place at the Veterinary Diagnostic Center, 2) the decontamination process was not listed in the protocol, and 3) where is the blood going?

Dr. West's concern was how contaminated carcasses and potentially contaminated items would be handled indoors. Are the researchers gowned? Is everything double bagged? Where is the waste being transported to?

Since not everyone on the committee was acquainted with Hantavirus, a brief review of the hazards of hantavirus were given. Hantavirus is acquired from rodents. It is airborne; therefore, the workers must wear respirators. An individual can have the virus for 11 days before symptoms appear. Hantavirus causes death. Because of these dangers, filters must be changed frequently. The researchers need to aware that the potentially infected traps are a danger.

Dr. West believes that that Dr. Hygnstrom is knowledgeable in this area of study. Dr. Clemente feels that Dr. Hygnstrom needs to clarify a couple of items. This is an RG3 organism. Dr. Hygnstrom should be more specific as far as location of research and cleaning of cages.

Dr. Benson would like to know if this should be considered as a BL2 issue or exempt. Dr. Crockett asked the meaning of Exempt as it relates to the Biosafety Committee. The response was that Exempt means that it is not subject to NIH guidelines for Recombinant DNA.

The proposal was tabled pending further information and clarification from Dr. Hyngstrom.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 12.03 p.m..

Institutional Biosafety Committee Meeting
Meeting Minutes
November 9, 2004 11:00 AM
Environmental Health and Safety
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on November 11, 2004 at 11:00 AM in the Conference Room at Environmental Health and Safety.

Members present: Andrew Benson, Chair; Tom Clemente; Gerald Duhamel; Jill Hyslop-Bohling, Rodney Moxley, Roger Quiring; and John West. Others: Norm Braaten, Farida Ebrahim, Fernando Osorio, and Asit Pattniak

Minutes from September Meeting: Drs. Moxley and Duhamel moved approval. Motion carried.

1. Pattnaik Addendum to Approved Protocol #03-5 "Replication and Assembly of RNA Viruses"

. The protocol was introduced by Dr. Osorio and Dr. Pattnaik. A question regarding the system being used was answered as well as a question on waste handling which was in the revised addendum. Dr. Osorio explained that the appropriate procedure / BL3 or BL2 is used based on the initial pathogen.

The case is BL2; viruses produced are expected to be less pathogenic than initial pathogen.

Drs. Moxley and Duhamel moved approval. The motion carried.

Thippareddi protocol "Microbiological Challenge Testing in Foods"

This protocol was introduced by Dr. Benson. "Grind-it-and-find-it" list of pathogens – all RG2. There is no recombinant work. There is a question of the use of a biosafety cabinet, There was a question on answers to tabular list of toxin producers. There were also questions on volume and use of kitchen mixer. Salmonella – some are select agents – must specifically exclude the select agents. Are there locks on the freezer and outside door?

Tabled. Dr. Thippareddi will be sent a letter asking for clarification.

Announcements / Information (Jill Hyslop-Bohling):

- > R-DNA database no voting online as online excludes the general public
- > Question on membership rotation (Tim Miller's shop)
- > Autoclave program testing: No service contract in Beadle. No house steam. We should implement a procedure.

There was a miscellaneous political commentary provided by Dr. Clemente and marginalized by the rest of the committee.

BL3 Trailer (proposed specifications):

IBC has already presented its (12) criteria. As long as the criteria are used in the design, the committee does not need to be involved (until final design).

This discussion resurfaced because the bid went to a different company.

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 12.10 p.m..

Institutional Biosafety Committee Meeting
Meeting Minutes
January 31, 2005 11:00 AM
Room 143, Filley Hall Conference Room
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on January 31, 2005 at 11:00 AM in the Conference Room at Filley Hall.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Jill Hyslop-Bohling, Rodney Moxley, Roger Quiring; and John West. Others: Norm Braaten

New Business:

1. <u>Meagher Protocol "Process Research and Development and Large-Scale Production of BL-1 Recombinant Therapeutic Proteins"</u>

The protocol was introduced by Dr. Andrew Benson. This is one protocol to cover most of the activities in the laboratory. All the projects are listed; and most involve vaccine production. There was a question about the quality control portion of the protocol. There was a question regarding the biological safety level marked EXEMPT, but BL1 appears more appropriate. There was a question about large-scale production; should this be BL1-LS? There was also a question on criteria that would constitute a new protocol. It was suggested that similar projects should be amendments. The BL1-LS procedures should be spelled out.

Dr. Duhamel moved approval. Dr. Clemente seconded the motion. The motion was passed unanimously.

2. Funnell and Pederson amendment and update for #03-11:

Dr. Pedersen will be receiving transgenic sorghum seed from the University of California, Berkeley. The seed will be stored in a locked freezer.

A protocol amendment or approval is not needed for movement, but will be needed for release. However, the committee appreciated the update.

3. <u>Diagnostics Projects Discussion (brought about by research being done by Dr. Galen Erickson).</u>:

The discussion was introduced by Dr. Moxley. Dr. Erickson needs to identify an existing protocol that this references and provide an update on the projects currently under it. One protocol for a certain diagnostic procedure is required. Dr. Moxley volunteered to follow up and match the activity to the proper protocol.

- 3. Autoclave validation was discussed.
- 4. BL3 Facility Update

There will be a meeting to go through the diagnostic details on Friday, the 11th from 8:30 to 11 A.M. at 1901 Y Street (Facilities Management).

Adjournment: Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 12.00 p.m.

Institutional Biosafety Committee Meeting
Meeting Minutes
March 28, 2005 11:00 AM
Room 143, Filley Hall Conference Room
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on March 28, 2005 at 11:00 AM in the Conference Room at Filley Hall.

Members present: Andrew Benson, Chair; Tom Clemente; Lisa Crockett (ex officio), Gerald Duhamel; Roy French, Jill Hyslop-Bohling, Rodney Moxley, Roger Quiring; and John West, Others: Norm Braaten and Brenda Osthus.

Minutes: Minutes from the February 28, 2005 meeting were discussed. Drs. Duhamel and West motioned for approval. The motion passed.

New Business:

- 1. <u>Thippareddi's protocol revisions "Microbiological Challenge Testing in Foods"</u>: The revisions were a response to a protocol that was reviewed at the November 2004 meeting. This letter successfully addressed the concerns.
 - Dr. French moved approval and Dr. Moxley seconded. The committee approved the motion.
- 2. <u>Cirillo protocol "Molecular Genetic Analysis of Francisella tularensis subsp. novicida":</u> This protocol concerns genetic screens for Francisella tularensis subspecies novicida.

Discussion: These strains are not a select agent. There was a question on the biosafety level. Tularensis is BL3 but certain strains are BL2. There may be concerns with "dual use" as BL2 into BL3 or even as a select agent. Plasmids, transposons, and vector maps are required. There was a question as to what bait is being used. The list of potential origins requires human subjects approval, but the project is probably exempt.

Protocol needs to be more specific. The committee may approve at a future meeting, contingent on vector maps. Aim 1 of the protocol was approved contingent upon additional information being supplied about the potential vector, markers, and reporters. The motion passed and Aim 1 was approved.

3. Meinke protocols "Syngenta event MIR604WR: Corn rootworm control in field corn", "Syngenta event MIR604WR: Corn rootworm adult emergence study", and "Assessing aspects of corn rootworm population dynamics: Corn event DAS-59122-7"

Dr. Clemente led the discussion on notification of transgenic crops grown on UNL property to the Institutional Biosafety Committee. The Meinke protocols were introduced. The protocols appear to be BL1 rather than BL2. Everything appears to be in order.

We will need the plot maps, APHIS notices, and coordinates. Then when the project has ended, the completed performance standards should be sent and the project closed. This should take about two years. Dr. Clemente will draft a letter for the Chair regarding managing field trials.

The Institutional Biosafety Committee acknowledged the receipt of the protocols from Dr. Meinke.

Adjournment Chairman Benson thanked everyone for his or her attendance, and the meeting was adjourned at 12:30 p.m.

Institutional Biosafety Committee Meeting
Meeting Minutes
April 25, 2005 11:00 AM
Room 143, Filley Hall Conference Room
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on April 28, 2005 at 11:00 AM in the Conference Room at Filley Hall.

Members present: Andrew Benson, Chair; Tom Clemente; Gerald Duhamel; Roy French, Jill Hyslop-Bohling, Rodney Moxley, and John West. Others: Norm Braaten, Farida Ibrahim, and Brenda Osthus.

Minutes: Minutes from the March 28, 2005 meeting were discussed. It was noted that there were several corrections concerning the Cirillo protocol discussion. The ocean/bobber line should be eliminated and "approval of Aim 1" should be added. Drs. West and Clemente motioned for approval. The motion passed.

New Business:

- 1. <u>Clemente's protocol "In planta expression of a synthetic E. coli fimbriae major subunit:</u> The project was introduced by Tom Clemente. Discussion followed. Drs. West and French motioned for approval. Motion approved. Dr. Clemente abstained.
- 2. <u>Clemente field trials and transgenic materials:</u> Dr. Clemente explained the procedure. The committee has been notified of the activities for this year.

Jld Business:

- 1. <u>IBC Online Application Form:</u> The online form was presented and discussed by Ms Hyslop-Bohling. The Chair/ Head role was discussed.
- 2. <u>Select Agents:</u> Ms Hyslop-Bohling handed out the final rule for Ag Bioterrorism as well as a checklist for select agents.
- 3. Autoclave Update: Dr. Benson stated that he will be meeting with Dr. Paul regarding autoclave protocols.

Adjournment Chairman Benson thanked everyone for his or her attendance, and the meeting was adjourned at 12:15 p.m.

Institutional Biosafety Committee Meeting Meeting Minutes May 23, 2005 11:00 AM Room 143, Filley Hall Conference Room University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order on May 23, 2005 at 11:07 AM in the Conference Room at Filley Hall.

Members present: Andrew Benson, Chair; Tom Clemente; Gerald Duhamel; John West; Rod Moxley; Quiring; Jill Hyslop Bohling. Others: Brenda Osthus, Farida Ebrahim.

New Business:

- 1. Pattnaik Addendum to protocol "Replication and Assembly of RNA Viruses"
 Dr. West introduced the project. Discussion followed. The Committee discussed concerns with LCMV. The strain that will be used is well characterized. Drs. West and French motioned for approval. Motion approved.
- 2. Somerville protocol: "Bovine Mastitis Pilot Project" This protocol extends from Dr. Somerville's original project. No new recombinant work is introduced. A discussion of biosafety concerns followed. Dr. David Smith will assist with animal care. Committee members suggested use of additional personal protective equipment (PPE) such as safety goggles. Dr. Duhamel raised the question of animal disposal after completion of the research. Discussion ensued of animals used in recombinant research. Drs. Moxley and West motioned for approval. Motion was approved contingent on proper disposal of research animals and use of appropriate PPE.
- 3. Meinke plot maps were acknowledged and therefore, proper notification was given to the IBC.
- 4. Moxley protocol: "Influence of Enterotoxins on Virulence and Colonization of the Porcine Intestine by Escherichia coli" Dr. Moxley introduced the project. Discussion followed. Biosafety concerns were noted. The agents are probably infectious to humans. Drs. Duhamel and French motioned for approval. Motion approved. Dr. Moxley abstained.
- 5. Short discussion on IBC membership. Dr. Benson will contact Norm Braaten.
- 6. IBC members decided to maintain the current meeting schedule. Meetings will be held the last Monday of the month at 11 am in the Filley Hall Conference room.
- 7. Jill announced that IBC members will be receiving training materials in the future in order to comply with the continuing education requirements of the NIH Guidelines.

Training will consist of handouts, meeting discussions, emails and other forms of training materials.

Old Business:

- 1. Jill Hyslop Bohling presented the autoclave validation plan. Suggested changes to distributed Autoclave Validation Safe Operating Procedure were noted.
- 2. Update on BL3 lab. A. Jill reported that the ADA issue had been addressed. B. Scientific Facilities have started building the steel frame. C. A laboratory commissioning company is now on board. BL3 updates will be given at every meeting from now until the end of commissioning.
- 3. Minutes from the last meeting were discussed. Drs. Duhamel and French motioned for approval. Motion approved.

Adjournment: Chairperson Benson thanked everyone for his or her attendance, and the meeting was adjourned at 12:20 pm.

Institutional Biosafety Committee Meeting Meeting Minutes August 16, 2005, 3:30 PM Room 143, Filley Hall Conference Room University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Biosafety Committee was called to order by Rodney Moxley on August 16, 2005, at 3:30 PM, in the Conference Room at Filley Hall.

Members present: Tom Clemente, Rodney Moxley; Acting Chair, Roger Quiring; John West, and Jill Hyslop-Bohling.

Old Business: Minutes from the May 23, 2005 meeting were reviewed. Dr. West moved approval. Dr. Clemente seconded the motion. The motion was passed unanimously.

New Business:

1. Meagher Protocol: "400 L Scale-Up"

Dr. Moxley introduced the protocol. It was noted that project details are proprietary. Discussion included the well described biosafety procedures and the need for the definition of the acronym "AVA." In addition, the appropriate NIH referral needs to be added to the protocol.

Dr. Clemente moved approval contingent upon the AVA definition and the NIH referral update. Dr. West seconded the motion. The motion was passed unanimously. With its accordance of the second depth of the se

2. <u>Benson Protocol: "Functional consequences of genome evolution in Listeria monocytogenes"</u>

Dr. Moxley introduced the project. The project involves an RG 2 organism. DNA clones of L. monocytogenes will be cloned into nonpathogenic E. coli. Dr. West would like Dr. Benson to submit plasmid constructs if they are not currently on file. Discussion included biosafety considerations and it was noted that they were addressed appropriately. Dr. Clemente suggested the section on personal protective equipment (PPE) be updated to include proper footwear and eye protection. It was noted that Dr. Benson needs to submit a new coversheet that includes the proper signatures.

Dr. Clemente moved approval contingent upon the submittal of plasmid constructs and updating the PPE section of the protocol. Dr. West seconded the motion. The motion was passed unanimously.

3. BL3 Facility Update

Weekly teleconference meetings are held every Wednesday. Jill reported that the final hardware has been chosen for the doors. The hardware choice was difficult because of the need to incorporate the UNL keyless entry system and associated security issues. Dr. Moxley reported that the placement and cost of security cameras is currently being worked out with the assistance of the UNL Police Department.

It was noted that the facility site has been flagged and bids are in for the site work and foundation construction. The project is still on schedule for October.

Adjournment: Acting Chairman Moxley thanked everyone for his or her attendance and the meeting was adjourned at 4:20 p.m.

Institutional Biosafety Committee Meeting
Meeting Minutes
September 13, 2005 10:00 AM
143 Filley Hall
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Committee was held on September 13, 2005 a.m. in 143 Filley Hall.

Members present: Andrew Benson, Chair, Gerald Duhamel, Kim Espy (ex officio), Roy French, Jill Hyslop-Bohling, Rod Moxley, Roger Quiring,. Others: Norman Braaten, Farida Ebrahim, and Mark Shepherd.

Minutes: Minutes were approved without corrections.

1. Meagher Protocol: "Quality Control Microbiology Laboratory"

Dr. Benson introduced Dr. Meagher's protocol. It was decided that this protocol does not necessarily involve any recombinant work, but it is a biosafety consideration.

08.10

Drs. Moxley and Duhamel moved for approval. The motion was passed.

2. <u>Velander Protocol: "Production and Purification of Fibrinogen Components"</u> 65-13

Dr. Berton 10/11/05 pm

Dr. Duhamel introduced Dr. Velander's protocol. The protocol identifies mostly commercial products and occupational safety issues.

Drs. Moxley and Duhamel motioned for approval. The motion was passed.

3. <u>Meinke Protocol ""Syngenta Event MIR604WR: Western Corn Rootworm Adult Emergence</u>
Greenhouse Study"

Dr. French introduced this protocol.

Drs. French and Quiring motioned for approval contingent on use of an online database. Motion approved.

4. Biosafety Audit Review

There was a discussion on how to handle the audits. The annual biosafety update may be used to coordinate approval. Jill will introduce any major concerns to the group. When the protocol is updated, all new personnel should be included on the Checklist.

5. BL3 Laboratory Update

The footings were not in yet. October is the month when most activity will begin.

Chairman Benson thanked everyone for their attendance and the meeting was adjourned at 11 a.m.

Institutional Biosafety Committee Meeting Meeting Minutes October 11, 2005 10 AM 143 Filley Hall University of Nebraska-Lincoln

Call to Order: The October scheduled meeting of the UNL Institutional Committee was called to order at 10 AM on October 11, 2005...

Members present: Andrew Benson, Chair, Gerald Duhamel, Roy French, Jill Hyslop-Bohling, Clague Hodgson, Rodney Moxley, Roger Quiring, John West, and Kim Esply (ex officio). Others: Norman Braaten, Farida Ebrahim, Mark Shepherd, and Dan Vasgird.

Minutes: The Septemer minutes were approved with one correction: Dr. Benson introduced Dr. Velander's protocol.

1. Ji-Young Lee Protocol: "Investigation of Reduced HDL in Obesity" 05-/6

Dr. West introduced the protocol. The protocol contains standard, off the shelf expressions and vectors. The adenovirus vector should be listed as well as a description of the mechanism of its attenuation. The PI should address the use of human Hep-G2 cells. BL-2 work is proposed and appropriate.

Drs. West and French moved approval with two contingencies. The motion passed.

2. BL-3 Lab Update

Modular BL-3 lab appears to be on schedule, commissioning, seeking a facilities director.

3. Biosafety Audit Review

The labs of Drs. Robert Weldon, Rod Moxley, Clayton Kelling, and Catherine Chia were inspected.

Chairman Benson thanked everyone for their attendance.

The meeting was adjourned at 10:50 AM.

Institutional Biosafety Committee Meeting
Meeting Minutes
March 27, 2006 1:00 PM
124 Veterinary Basic Science
University of Nebraska-Lincoln

Call to Order: The scheduled meeting of the UNL Institutional Committee was called to order at 1:05 p.m. on March 27, 2006.

Members present: Rodney Moxley, Chair, Andy Benson, Gerald Duhamel, Roy French, Jill Hyslop-Bohling, Clague Hodgson, Roger Quiring, and Mark Versch Others in Attendance: Raul Barletta, Norm Braaten, Farida Ebrahim, Brenda Osthus, and Dan Vasgird

Minutes: Drs. Hodgson and Duhamel moved approval of the minutes. Motion carried with one abstention. Mr. Versch abstained.

Protocols:

1. Raul Barletta active protocol 95-8 "Cloning and Expression of Mycobacterium bovis, Mycobacterium leprae and Mycobacterium tuberculosis Genes in Escherichia coli

This active protocol with modifications was introduced by Dr. Barletta. *Mycobacterium smegmatis* and other mycobacteria are RG2 organisms, with the exception of *Mycobacterium tuberculosis* and *M. bovis*, which are RG3. A study of additional "housekeeping" genes was proposed. RD1 (region of defense) genes restore virulence, but these genes will not be used. Concern with resistance was expressed. There was discussion regarding the cloning of DNA from RG3 into RG2 organisms. The NIH guidelines are unclear on this matter. Drs. Benson and Hodgson moved approval. Motion carried.

2. Raul Barletta protocol "Molecular Genetic Analysis of Drug Resistance, Peptidoglycan Biosynthesis, and Virulence Determinants". This project was submitted in 2004 but not approved because it required the use of a BL3 laboratory.

The committee believed that a revised protocol separating out the BL2 work and referencing the new facility was in order.

Note: The BL3 facility is coming on line in the near future.

3. <u>Jack Morris protocol: Addendum to protocol 92-12 "Investigation of Plant RNA Virus Gene Function"</u>

Three BL1 projects have been added to this protocol. Projects 2 and 3 do not seem to fit with the old protocol of virus gene function.

Dr. French and Ms. Hyslop-Bohling moved to approve project 1 but put 2 and 3 as separate projects and add a memo to obtain a face page for projects 2 and

3. Motion Carried

- 4. <u>Discussion of BL3 Committee</u> Should a separate committee be formed to approve laboratory policies and procedures? Consensus was "No".
- 5. <u>Sunshine Project</u>: The minutes are being compiled and a general counsel is being consulted before responding. (Ms. Hyslop-Bohling distributed a handout regarding the Sunshine project, audits, and other issues of concern. SEE ATTACHED SUPPLEMENT)
- 6. <u>Biosafety Audit Report</u>: There have been 25 audits. Twelve audits were BL2 facilities and thirteen were BL1/Exempt. Some concerns were noted and remedied immediately. A 30 day follow up will take place for those facilities that were not able to comply immediately.

Chairman Moxley thanked everyone for their attendance and the meeting was adjourned at 2:15 p.m..

IBC Meeting

March 27, 2006 at 1 pm VBS, rm124

1. Biosafety Audits

PIs: Atkins, Banerjee, Barletta, Barycki, Blum, Cerutti, Chollet, Cupp, Dweikat, French, Fromm, Funnell, Graybosch, Hyngstrom, Kelling, Meagher, Moxley, Nickerson, Rogers/ARF, Siegfried, Somerville, Van Etten, Weber, Weldon, Zhang,

Biosafety audits performed since last IBC meeting: 25

BL1 and exempt: 13

BL2: 12

No problem reports: 3

Common problems found:

Chemical labeling, old or nonexistent chemical inventories, improper storage of chemicals, improper "used" chemical labeling, improper use of personal protective equipment, lack of training files, lack of emergency response procedures, hazardous sharps handling, cluttered biosafety cabinets and fume hoods.

2. Sunshine Project IBC minutes request

Background:

Sunshine project/Ed Hammond. Activist group which studies bioterrorism policy. Committee members from US, UK, Ethiopia, Malaysia with main office in Germany.

Alan Shipp from NIH referred to -Section IV-B-2-a-(7) of the NIH Guidelines that states that IBC meeting minutes must be available to the public. The Sunshine Project request also includes a question about the Fink Report. We discussed this report at a previous meeting.

NSABB report and the Dual Use training from IBC meeting February 28, 2004.

Plan of Action:

- Lorraine and Jill to gather IBC meeting minutes from 2003.
- Submit to Brenda Osthus.
- Brenda will coordinate submittal of documents to Varner Hall/Legal Council for review.
- Documents submitted to Sunshine project.
- Documents submitted before April 28, 2006.

3. BL3 Status

(Discussion to be lead by Moxley)

- Equipment purchases
- Commissioning delay

4. Current Issues/Radar

- Laboratory equipment sent to inventory without proof of decontamination.
- Human bone used in Chemistry lab. Appropriate paper work and disposal methods in place.
- Whole steers pickled and used in AnS necropsy. Remodeling required as well as monitoring for formalin. Have contacted Iowa State for additional information.
- Discussion of proximity of Thippareddi's research and the ice cream store.
- Renovations to Ruth Leverton Hall for Dr. Albrecht's research, "Clostridium Perfringens in meat products.
- Meagher's group wants to test intact Botulinum toxin. May fall under select agent rule. Currently discussing quantity limits with laboratory.