1785
The University of Georgia

Office of the Vice President for Research
*Institutional Biosafety Committee*

May 7, 2006

Edward H. Hammond, Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

Dear Mr. Hammond,

Enclosed are the approved minutes of the University of Georgia Institutional Biosafety Committee meeting held on March 23, 2006. These are the only meeting minutes on record for the University of Georgia since May 2003. In February, 2006, I took over as Director of Biosafety at the University of Georgia. We have formed a new IBC, and will be meeting on a monthly basis from this point forward. I must apologize for the tardiness of my response. I recently learned of your inquiry. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Tru Twedt, DVM, CBSP
Biosafety Officer, Responsible Official

Enclosure

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# University of Georgia
# Institutional Biosafety Committee Meeting
# Thursday, March 23, 2006
# Riverbend South Auditorium

**Attendance:**

| | Voting Members | | Non-voting Members |
|---|---|---|---|
| X | Fu, Zhen (Chair) | X | Bloom, Barry |
| - | Chin, Jean | | |
| X | Dukes, William | | |
| - | Hartzell, Diane | | |
| X | Harvey, Steve | | |
| X | Hogan, Jeff | | |
| X | Hope, Daniel | | |
| - | Lee, Margie | | |
| - | Mohnen, Debra | | |
| X | Moreno, Silvia | | |
| X | Parrott, Wayne | | |
| X | Robacker, Carol | | |
| X | Sanchez, Susan | | |
| X | Schell, Mark | | |
| X | Twedt, Tru | | |

Key: X = present; - = absent
The meeting was open to the public.

**CALL TO ORDER:**

Tru Twedt, BSO, called the meeting to order at 12:15 p.m.

**PREVIOUS MEETING MINUTES:**

Not available
Vote to approve: NA

**OLD BUSINESS**

Not available

**NEW BUSINESS:**

1. Introduction of committee members and Office of Biosafety staff.

2. Discussion of IBC mission.

- ⇨ According to NIH regulations, Select Agent regulations and the past committee charter, the committee must review all rDNA protocols (regardless of exemption status), all BSL-3 protocols and all Select Agent protocols.
  - o The committee must decide if BSL-2 (human pathogens), strict animal pathogen and strict plant pathogen protocols will be reviewed.
  - o The committee must decide if biological toxin protocols, beyond the Select Toxins, will be reviewed.

- The committee will decide if they will review human blood, human body fluid and human cell protocols. The Office of Biosafety will conduct training on bloodborne pathogens and training records will be kept in the office. This will put the University in compliance with OSHA. The Institutional Review Board (human subjects) has agreed to accept OSHA Bloodborne Pathogen Training records in place of approved protocols. Certain human blood and body fluid projects still need to be reviewed by the committee. It was discussed that we need to be clear that protocols including human blood or human cells known, or highly suspected, to be infected with a pathogen must be reviewed by the committee. It was also discussed that we need to be clear that if the intention is to isolate pathogens form the human blood, the IBC must review the protocol. Tru will compose a statement and forward to the committee.

⇨ CDC importation permits and APHIS permits were discussed and tabled for now. Some members suggested that the IBC require copies of required permits for protocol approval. The guidelines set by the Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS), Plant Protection and Quarantine (PPQ) and the CDC are unclear and many investigators are not yet aware of the need. APHIS Biotechnology Regulatory Services (BRS) permit and notification requirements are very straight forward and link directly to the intent of the NIH guidelines. It was decided that any PI planning for "importation, movement, and (/or) field release of genetically engineered (GE) plants, insects, microorganisms, and any other organism that is known to, or could, be a plant pest" must possess a current APHIS notification or permit prior to protocol approval. The committee can grant approval with the understanding that approval will be rescinded if the PI fails to obtain the permit or notification, or abide by the permit or notification conditions. The protocol review form will be changed to make PIs aware of the need for permits and notifications. The Office of Biosafety is available for any questions concerning CDC and APHIS requirements.

3. Expedited Review was discussed and tabled
   - ⇨ Do all committee members need to review all protocols?
   - ⇨ It was recommended that a Flow Chart be done by Biosafety, outlining what the committee is looking for in the protocols. Dr. Twedt agreed to do the chart and send it out to committee members.
   - ⇨ The Office of Biosafety will do a pre-review of all projects and will get missing information from the Principle Investigator prior to dissemination to members.
   - ⇨ It was also suggested that committee members look at protocols pertaining to their expertise.
   - ⇨ For now, all protocols will go to all members, but only two members (at least one with expertise) will be assigned official review of each protocol and report back to Kelly. All members are welcome to comment.

4. Should PIs determine the NIH section that an experiment falls into, or just determine the correct containment level required by the NIH guidelines? This issue was discussed and it was suggested that the review form have standard text regarding NIH sections that can be used by the PI for commonly used procedures/organisms.

5. The new Protocol Review Form. The form was discussed, with no definite approval or disapproval. Modifications will be made to the form as needed.

**PROJECTS FOR DISCUSSION:**

1. # 2006 0001

   Overview:

   Determine ways to kill or inhibit Clostridium perfringens.

   - The objective of this research project is to determine ways to kill or inhibit Clostridium perfringens. Cultures of Clostridium perfringens will be grown in solid and liquid media in contact with varying amounts of the inhibitor and measured. Measurements will consist of colony counting, optical density, and area of zone clearing. Cultures will be on petri dishes or in test tubes containing small

3 -5 ml volumes. Experiments will also test the effectiveness of the inhibitor under different environments such as pH, in the same manner. Additional experiments may be conducted to measure the alpha-toxin activity of the inhibitor and control cultures. Toxins will be obtained by French pressing cell pellets, and enzyme assays will be conducted in test tubes, with the results being measured spectrophotometrically.

- The proposed containment levels in the application is BSL2.

Committee discussion:

- PI stated that "several sources cite the appropriate Biosafety Level to be 2..." In the future the BSO will confirm these statements for committee

Review:

- The Chair called for a vote to approve:

| Vote: | 10 For | 0 Against | 0 Abstain |
|---|---|---|---|

**2.** 2006 0002

Overview:

Pathogenesis and Virulence of a Bovine Enterovirus-1 Isolate in Cattle – Year 1

- During the first year, the purposed work will characterize the clinical signs, laboratory clinical parameter alterations, viral shedding, and gross and microscopic tissue alterations associated with a BEV-1 Oklahoma isolate obtained from a fatal enteric disease case in a 2-year-old pregnant Angus heifer.
- The project involves work with 8, 2-3 year old calves, will be inoculated intranasal with BEV-1 infected MDBK cells. Similarly, a control group equal size will be inoculated with non-infected MBDK cells. Calves will be euthanized at 0 ( 4 hours post inoculation ) 5 and 10 days PI.

Committee discussion:

- It was discussed that until the PI can characterize the pathogenicity and shedding properties of the isolate, all animal waste must be collected and decontaminated or incinerated.
- Approve with restrictions:
    - Prior to approval, Dr. Twedt, Dr. Fu, and Dr. Harvey will decide where the animals will be housed and come up with decontamination process. When more data is available, the PI can request that the decontamination procedures be modified.

Review:

- The Chair called for a vote to approve: One member abstained due to vested interest

| Vote: | 7 For | 0 Against | 1 Abstain |
|---|---|---|---|

**3.** 2006 0003

Overview:

Role of Ca2+-independent phospholipase A2 in breast cancer cell physiology and death.

- This proposal tests the novel hypothesis that iPLA2 isoforms mediate breast cancer cell physiology and death by production of arachidonic acid. Data supporting this hypothesis will identify novel therapeutic targets for treatment of breast cancer and identify the mechanisms of lipid signaling in breast cancer cells that mediates proliferation.
- The project include cell culture of MCF-7 and MDA-MB-231 cells, small inhibitor RNA (siRNA) knock down of individual iPLA2 isoforms, real time PCR and western blot analysis for quantitation of the expression of lipid metabolism proteins, and several cell death assays, including those that use flow cytometry and confocal microscopy.

Review:

- The Chair called for a vote to approve:

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

**4.** 2006 0004

Overview:

Development of Diagnostic tool for detection of Leptospira borgpetersenii

- To identify unique sequences present in Leptospira borgpetersenii serovar hardjobovis using subtractive hybridization. To develop and validate a sensitive and specific PCR to differentiate in Leptospira borgpetersenii serovar hardjobovis from other species or strains of Leptospira.

Review:

- The Chair called for a vote to approve:

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

**5.** 2006 0005

Overview:

Arkansas Infectious Bronchitis virus Persistence in Commercial Chicken

- This work will help determine whether the Ark-DPI vaccine is persisting by monitoring the level and persistence of the vaccine strain in relationship to other IBV vaccine strains or emerging field viruses in commercial chickens. It will also determine the nature if the persisting or emerging viruses by testing selected isolates for their pathogenicity in susceptible chicks.
- The project involves work with Infectious Bronchitis Virus ( coronavirus ). The proposed containment level in the application are BSL-1 and ABSL-1.

Committee discussion:

- Containment, practice and procedures consistent with BSL-2 will be required.
- Although not a human pathogen, the committee recommends that laboratorians wear gloves when working with the virus for containment reasons.
- Question raised as to whether ethanol was an effective disinfectant. Will ask for expert opinion of PI

Review:

- The Chair called for a vote to approve:

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

**6.** 2006 0006

Overview:

Experimental Infection of white-tailed deer with Borrelia lonestari

- Borrelia lonestari, a spirochete related to B. burgdorferi ( agent of Lyme Disease), will be used in an experimental infection of white-tailed deer. Deer will be inoculated with either B. lonestari or uninfected cell culture ( negative control ). Blood will be drawn twice weekly for PCR, culture and serologic test to monitor infection, for total of three weeks and then deer will be euthanized. Tissue will be collected for use in immunohistochemistry to look for organism.
- The project involves work with Borrelia lonerstari. The proposed containment levels in the application are BSL-2 and ABSL-2.

Committee discussion:

- Concern for vector (tick) transmission of agent to animal caretakers, lab staff and the environment was discussed. Committee experts explained why ectoparasite transmission would not be a problem
- The committee will require eye and mucous membrane protection while drawing blood from inoculated animals.

Review:

- The Chair called for a vote to approve:

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

7. 2006 0007

Overview:

Establishment of C. elegans tissue culture cell lines

- The laboratory will use recombinant DNA techniques for standard molecular biological purposes. Use of recombinant DNA will be to : 1) amplify C. elegans genes by polymerase chain reaction. (PCR); 2) clone genes into expression plasmids; 3) growth of expression plasmids in E. coli bacteria ( to amplify plasmids); 4) introduction of expression plasmids into C. elegans to express genes of interest; 5) introduction of expression plasmids into human, mouse, and insect cells to produce recombinant proteins. C. elegans is non-pathogenic, and there are no toxins or other biohazards associated with C. elegans genes.
- The proposed containment level in the application is BSL-1.

Review:

- The Chair called for a vote to approve :

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

8. 2006 0008

Overview:

Adenoviral hepatic insulin gene therapy for feline diabetes mellitus

- The prevalence of diabetes mellitus is increasing at a rapid rate in cats. Burdens of twice daily insulin injections and blood sugar monitoring frequently induce owners to choose euthanasia over treatment. Hepatic insulin gene therapy enables the liver to produce insulin in response to changes in blood sugar and has the potential to eliminate insulin injections.
- The project involves using the adenovirus to introduce DNA encoding insulin into cat liver cells. The proposed containment level in the application is BL2 and BL2-N

Committee discussion:

- Concern was raised regarding sending treated pet animals home with owners. It was discussed that the chance for reversion to replication competent vector was very low.
- The Vet Med Clinical Research Committee has tabled the client owned portion of this study. The IBC will approve lab animal work only, and work closely with the Clinical Research Committee to approve the pet animal portion.

Review:

- The Chair called for a vote to approve on the condition that only lab animals be used.

| Vote: | 8 For | 0 Against | 0 Abstain |
|---|---|---|---|

**FOR THE GOOD OF THE ORDER:**

The next committee meeting will be April 27, 2006 at 12pm. Location to be determined.

**ADJOURNMENT:**

The meeting was adjourned at 2:30 p.m.

Recorded by: Kelly Crumley and Tru Twedt