



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, June 17, 2015

**Time:** 10:00 AM – 12:00 PM

**Location:** Foege North 130A

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
  2. H.D. “Toby” Bradshaw, Biology (*Plant Expert*)
  3. William Glover, Washington State Public Health Laboratories (*Community Member*)
  4. David Koelle, Allergy and Infectious Diseases
  5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
  6. Jeanot Muster, Pharmacology
  7. Matthew R. Parsek, Microbiology
  8. Angela Rasmussen, Microbiology
  9. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
  10. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

### Commonly Used Abbreviations

IBC: Institutional Biosafety Committee

BSO: Biological Safety Officer

BUA: Biological Use Authorization

BSL: biosafety level

PI: Principal Investigator

IACUC: Institutional Animal Care and Use Committee

NIH: National Institutes of Health

DURC: Dual Use Research of Concern

SOP: standard operating procedure

1. **CALL TO ORDER:** The IBC Chair called the meeting to order at 10:07 am. A quorum was present.
2. **REMINDER:** The IBC Chair reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.
3. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the May 20, 2015 minutes meeting.
  - A member made a motion to approve the May 20, 2015 minutes. Another member seconded the motion.
  - The committee voted unanimously to approve the May 20, 2015 meeting minutes.
4. **BIOSAFETY OFFICER REPORT:** The Biosafety Officer Report includes (1) projects involving recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines*, (2) proposals involving non-recombinant biohazardous agents requiring BSL-1 and BSL-2 containment, and (3) administrative updates, such as room additions.
  - a. Biosafety Officer Report
    - Dr. McGuire requested to add human source material to his current BUA letter.
    - Dr. Hwang, Dr. Dale, Dr. Weiner, and Dr. Morrissey each renewed a BUA involving human source material.
    - Dr. Klatt received a new BUA letter for non-human primate source material and primate lentivirus. A discussion occurred regarding this project. This work was previously described on a BUA application reviewed by the IBC in 2013. Dr. Klatt needed a new BUA letter because she initiated a new IACUC protocol, and only one BUA letter can be associated with each IACUC protocol.
    - Dr. Klatt received another new BUA letter involving herpes simplex virus, rotavirus, and simian retrovirus 2 used *in vitro* and in macaques.
    - Dr. Kurath renewed a BUA letter involving infectious hematopoietic necrotic virus used *in vitro* and in trout. This agent is listed as BSL-2 on their BUA letter because it is a fish pathogen.
    - Dr. Steiner added a new room to his current approval.
    - Dr. Bumgarner added *Staphylococcus epidermidis*, human source material, and a new BSL-2 room.
    - Dr. Smith added non-human primate source material to his current approval letter.
    - The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
    - A member made a motion to approve this month's Biosafety Officer Report. Another member seconded the motion.
    - The Committee voted unanimously, except for one abstention, to approve this month's Biosafety Officer Report.

## 1. CATEGORY III-D AMENDMENTS

1. Childers, Martin, new, *Canine XLMTM Colony*
  - The biosafety officer presented the project.
  - The lab studies XLMTM (X-linked myotubular myopathy), a fatal pediatric disease of skeletal muscle.

- The dogs on this project have previously been treated with AAV (adeno-associated viral vectors) gene therapy. The dogs were administered AAV several years ago and appear clinically normal. However, section III-D of the NIH Guidelines still applies and this is why the project is being presented for IBC review.
- These are the same dogs that are on Dr. Childers' other BUA letter.
- The dogs have been vaccinated for rabies.
- ABSL-1 (animal biosafety level 1) containment will be used.
- The assigned IBC member endorsed the biosafety officer's review.
- The draft BUA letter was shown.
- The assigned IBC member made a motion to approve the draft BUA letter for Dr. Childers.
- The Committee voted unanimously to approve the draft BUA letter for Dr. Childers.

## 2. INDIVIDUAL PROJECT REVIEWS

2. Chin, Michael, renewal, *Functional analysis of novel genes in cardiovascular development and disease*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The lab studies how genes and environmental factors affect the development of the heart and the susceptibility to heart disease. The lab also works to develop treatments to alleviate and cure heart diseases.
  - Lentiviral vectors and adenoviral vectors are used on this project. No biohazardous agents are administered to animals.
  - A question was raised about diphtheria toxin. The biosafety officer was able to clarify that the principal investigator is not working with diphtheria.
  - The training has been completed. The lab inspection has also been completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA letter for Dr. Chin.
  - The Committee voted unanimously to approve the draft BUA letter for Dr. Chin.
3. Freedman, Benjamin, new, *Differentiation of Human Pluripotent Stem Cells into Kidney Cells*
  - The IBC Primary Reviewer was not available, so the assigned IBC Secondary Reviewer presented the Primary Review.
  - The overall goal of the project is to create laboratory models of human kidney disease and regeneration using pluripotent stem cells.
  - Sendai virus and human cells and cell lines are used on this project.
  - The draft BUA letter was shown.
  - The investigator is in the process of moving and setting up the lab. The approval will be held until the lab has been set up and inspected.
  - An IACUC protocol is in the process of being completed. The biosafety officer will review the IACUC protocol.
  - The training has been completed.
  - The IBC Secondary Reviewer made a motion to approve the draft BUA letter for Dr. Freedman.
  - The Committee voted unanimously to approve the draft BUA letter for Dr. Freedman, pending satisfactory completion of the lab inspection and IACUC protocol.

4. Kim, Jeansok, renewal, *Using molecular biological approaches to understand fear related behavior in predatory prey interactions*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The lab researches fear-related behaviors in semi-naturalistic settings using molecular biology techniques to control neurons in specific fear-related brain circuits.
  - AAV and CAV-2 (canine adenoviral vector) are used in rats. The vectors are replication deficient.
  - The draft BUA letter was shown.
  - The training has been completed, and the lab is in good condition.
  - The IBC Primary Reviewer made a motion to approve the draft BUA letter for Dr. Kim.
  - The Committee voted unanimously to approve the draft BUA letter for Dr. Kim.
  
5. Ladiges, Warren, change, *Mouse Genomics Program*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a change. The investigator is requesting to add adenoviral vectors for *in vitro* use.
  - The draft BUA letter was shown.
  - The lab has previously been inspected and the training has already been completed.
  - The IBC Primary Reviewer made a motion to approve the draft BUA letter for Dr. Ladiges.
  - The Committee voted unanimously to approve the draft BUA letter for Dr. Ladiges.
  
6. Scatena, Marta, renewal, *Endothelial cell for tissue engineering, osteoprotegerin in vascular disease, pancreatic precursor cells*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goal of the research is to create a cell therapeutic aimed at improving the aberrant inflammatory response that characterizes a variety of inflammatory diseases.
  - Lentiviral vectors and gammaretroviral vectors are used on the project.
  - The review mentions that question 55 needs to be corrected on the BUA application, but this has already been done.
  - The training has been completed, and the lab has been inspected.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA letter for Dr. Scatena.
  - The Committee voted unanimously to approve the draft BUA letter for Dr. Scatena.
  
7. Smith, Jason, change, *Antiviral Mechanisms of Defensins*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a change. The investigator is requesting to add wild-type and recombinant strains of *Salmonella typhi*, and wild-type rotavirus.
  - The required training has already been completed, and the lab inspection has previously been conducted.
  - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA letter for Dr. Smith.
- The Committee voted unanimously to approve the draft BUA letter for Dr. Smith.

#### SUBCOMMITTEE REPORTS:

- Vaccinia policy
  - The EH&S vaccinia policy, which includes requirements about the vaccine offering, medical counseling, and declination of the vaccine, has recently been updated.
  - Four members of the IBC served as subcommittee reviewers and submitted feedback about the policy.
  - The main changes to the policy include the following:
    - Medical consultation is required before vaccine declination for people who have direct contact with vaccinia or animals that have received vaccinia.
    - Direct vs. indirect exposure was defined and clarified.
      - Personnel who work directly with vaccinia viral cultures or any items that have come into contact with vaccinia are considered to have a direct potential for exposure. This includes animal husbandry staff and those who work in rooms where animals and procedures are not in primary containment devices. For these individuals, in-person medical counseling is required prior to beginning work, and vaccinia vaccination is required to be offered.
      - Those with indirect contact do not directly handle vaccinia virus, infected animals, or any materials contaminated with vaccinia virus, but are present in the same room where work with vaccinia occurs. For these individuals, medical counseling is available. Vaccinia vaccination is available, but not generally recommended for these employees.
    - Roles and responsibilities were defined.
    - All who work with or enter vaccinia areas will receive hazard awareness training about vaccinia.
  - The policy applies to non-highly attenuated vaccinia virus strains, such as the WR strain and NYCBH strain.
  - The IBC Chair sought a motion to approve the revised EH&S vaccinia policy.
  - A member made a motion to approve the revised EH&S vaccinia policy. Another member seconded the motion.
  - The committee voted unanimously to approve the revised EH&S vaccinia policy.
- Frevert, Charles, new, *Emerging Diseases/Q-fever: Detection and Transmission Risk*
  - This is a new project submitted by an established investigator. The overall goal of the project is to determine if there are specific genes in sheep, goats, and cattle that are associated with shedding rates of *Coxiella burnetii*, the bacteria that causes Q-fever.
  - *Coxiella burnetii* is a Risk Group 3 agent and on the *Select Agents and Toxins* list.
  - Vaginal swabs will be collected by a collaborator, and sent to the Frevert lab. The Frevert lab will test the swabs to determine if that animal is shedding *C. burnetii*.

- Samples that arrive from the collaborator will be handled and opened only in a BSL-3 laboratory. Each sample is presumed to be positive for *C. burnetii* and is handled accordingly.
- Standard operating procedures for opening samples and performing DNA extractions are being developed. These SOPs will need to be reviewed by the biosafety officer and also the subcommittee.
- The committee discussed the project and risk assessment. The PI will be asked to do the following:
  - Submit an inactivation SOP that includes a method for quantitatively determining that no infectious organisms are present.
  - Add the use of an avirulent strain such as *Coxiella burnetii* Phase II to the inactivation SOP and the BUA application to be used as a positive control.
  - Provide more details on how the samples will be used in the BSL-3 facility and an estimate of how many samples will be received. Include information about whether any portion of the samples will be retained.
  - Ensure all laboratory personnel have completed the online EH&S Biosafety Training.
- A discussion occurred regarding occupational health and medical management. The Employee Health Center will medically evaluate all personnel involved with this project. This medical exam is a standard part of the Select Agent program. Additionally, baseline serum samples will be drawn and tested before work with *C. burnetii* commences. Annual testing for *C. burnetii* antibodies will be performed thereafter.
- A discussion occurred regarding the equipment in the lab. The investigator needs to use a qPCR machine that is located in a BSL-2 area of the lab. This would be permissible as long as the investigator The IBC would like the investigator to consider obtaining a qPCR machine that can be placed inside the BSL-3 lab.
- The investigator needs to sign the BUA application.
- The IBC Chair sought a motion to send the investigator a memo detailing the required clarifications and additional information.
- A member made a motion to send the investigator a memo. Another member seconded the motion.
- The committee voted unanimously to send the investigator a memo detailing the following conditions that must be met before approval is granted:
  - Submit an inactivation SOP that includes a method for quantitatively determining that no infectious organisms are present.
  - Add the use of an avirulent strain such as *Coxiella burnetii* Phase II to the inactivation SOP and the BUA application to be used as a positive control.
  - Provide more details on how the samples will be used in the BSL-3 facility and an estimate of how many samples will be received. Include information about whether any portion of the samples will be retained.
  - Ensure all laboratory personnel have completed the online EH&S Biosafety Training.
  - Work with Employee Health Center for the required occupational health consultations and baseline serum samples.
  - Consider obtaining a qPCR machine that can be placed inside the BSL-3 laboratory.
  - Sign the BUA application.
- The PI's response will be reviewed and voted on at a future meeting.

## **FOR YOUR INFORMATION:**

- The IBC coordinator presented the revisions to the BUA application and the new DURC application and flow chart.
- Revisions to the BUA application include the following:
  - Several questions were combined into fewer questions.
  - Two questions about drugs administered to animals were deleted because they were redundant with questions asked on animal protocols.
  - Two columns were removed from the microorganism table.
  - A new personnel registration section was added. This information will be collected every three years. The primary goal of this new section is to help EH&S verify training records for everyone in the lab.
- The revisions to the BUA change form correspond with the revisions to the BUA application.
- DURC was incorporated into the BUA via a separate “supplemental form” section.
- The draft DURC application was briefly presented. The DURC application will function as a supplement to the BUA if the research requires a BUA, or a standalone document if no BUA application is required (for botulinum toxin users).
- The draft DURC flow chart was shown to the committee. Projects involving work with any of the 15 agents and toxins included in the DURC policy will be reviewed by the DURC IRE (Institutional Review Entity). If the IRE determines that the research project meets the definition of DURC, a risk mitigation plan will be developed and reviewed on an annual basis.
- The IBC Chair sought a motion to approve the revised BUA application and BUA change form. The DURC documents will first need to be reviewed by the DURC IRE.
- A member made a motion to approve the revised BUA application and BUA change form. Another member seconded the motion.
- The committee voted unanimously to approve the revised BUA application and BUA change form.

## **ISSUES FROM THE FLOOR & PUBLIC COMMENTS:**

There were no issues from the floor, and no public comments.

**MEETING ADJOURNED AT APPROXIMATELY 11:30 a.m.**