INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, October 21, 2015
Time: 10:00 AM – 12:00 PM

Location: Foege N-130A

Members Present:

1. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
2. H.D. "Toby" Bradshaw, Biology *(Plant Expert)*
3. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
4. Elizabeth Corwin (*Human Gene Transfer Expert; IBC Vice Chair*)
5. David Koelle, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
7. Scott Meschke, Environmental & Occupational Health Sciences
8. Angela Rasmussen, Microbiology
9. Jason Smith, Microbiology
10. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)

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 Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:02 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. **INTRODUCTIONS:**
   - A new ad-hoc reviewer was introduced. He will assist with reviews involving aquatic species, but is not a full voting member of the committee.

4. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the September 16, 2015 minutes meeting.
   - A member made a motion to approve the September 16, 2015 minutes. Another member seconded the motion.
   - <u>The committee voted unanimously to approve the September 16, 2015 meeting minutes.</u>

5. **BIOSAFETY OFFICER (BSO) 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. Doty added three new plant pathogens to her approval. The work will be conducted at P2 containment. The designated plant expert on the IBC reviewed this change.
      - Dr. Doty also renewed a separate project involving transgenic poplar plants. No field work occurs on this project. The designated plant expert on the IBC reviewed this renewal.
      - Dr. Doty initiated a new project involving several species of plants. The designated plant expert on the IBC reviewed this new project.
      - Dr. Berger, Dr. Murry, Dr. MacLellan, and Dr. Jayadev each added new rooms to their respective approval letters.
      - Dr. Baird, Dr. Bulger, and Dr. Wurfel each renewed a project involving human source material.
      - Dr. Prichard, Dr. Ferreira, and Dr. Prasad each received a new BUA letter involving human source material.
      - Dr. Baker received a new BUA letter for work with non-pathogenic strains of *Escherichia coli*. These strains are listed on the BUA letter because they are not exempted from the NIH Guidelines.
      - Dr. Ramakrishnan's project "Assessing bacterial and host contributions to *Mycobacterium marinum* pathogenesis in frogs and fish" was transferred to Dr. Hernandez.
      - Dr. Bamford's project "Genetic Analysis of Mouse Behavior" was transferred to Dr. Darvas. The note stating that this transfer took place is missing from the BUA letter. The biosafety officer will add it.
      - 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 unanimously voted to approve this month's Biosafety Officer Report.

6. INDIVIDUAL PROJECT REVIEWS

1. Chen, Eleanor, change, *Druggable pathways in rhabdomyosarcoma*
- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The investigator is requesting to add human cells transduced with lentiviral vectors, for use in zebrafish.
- A discussion occurred regarding where the zebrafish would be housed.
- There are standard operating procedures in place regarding transporting the zebrafish from the procedure room (where the human cells will be administered) to the housing location.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chen. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Chen.

2. Bair, Wyeth, renewal, *Functional circuitry in the macaque visual system*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to understand how neurons in the primate brain, in particular, the cerebral cortex, encode and process information.
- Biohazardous agents used on the project include adeno-associated viral vectors and non-human primate tissue.
- The biosafety officer has reviewed the IACUC protocol.
- The BUA application questions mentioned on the Primary Review have now been corrected.
- A discussion occurred regarding adeno-associated viral vectors and the biosafety level. All work with macaques is conducted at a minimum of ABSL-2 containment, because they are known to sometimes carry herpes B virus.
- The draft BUA letter was shown.
- The non-human primate blood, tissue, body fluids, and cells will be removed from the BUA letter when used in the vivarium. This agent isn't necessary because there is a core BUA letter covering non-human primate tissue used in the vivarium.
- The training has been completed, and the lab has successfully passed the inspection.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bair. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Bair, contingent upon correction of the BUA letter.

3. Childers, Martin, renewal, *Induced pluripotent stem cells (iPSC) derived dystrophin-deficient Cardiomyocytes for High throughput Screening*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to further identify potential effective drugs that are potentially beneficial for Duchenne muscular dystrophy patients with heart problems.

- This project was difficult to review because the descriptions included on the application are unclear. The viral vector systems have not been fully described, and it is still unclear exactly which vector systems will be used. Also, the replication competent virus (RCV) testing results have not yet been submitted and it is still unclear whether the investigator intends to submit RCV testing results so that work with oncogenes can proceed at BSL-2, or whether he intends to work at BSL-2 with BSL-3 practices.
- There were lab inspection issues that have not been followed up on.
- The committee discussed the status of the application and project. The committee will require that Dr. Childers start a new application. A letter will be sent to the PI detailing the steps that need to happen before the project is approved (submit a new BUA application, submit RCV testing results, and correct the lab inspection items that are currently deficient).
- The IBC Primary Reviewer made a motion to reject the draft BUA for Dr. Childers, and instead send a letter detailing that the application was not approved and what steps need to happen before approval could be granted. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to reject the draft BUA for Dr. Childers, and instead send a letter detailing that the application was not approved and what steps need to happen before approval is granted.

4. Dichek, David, renewal, *Gene Transfer in Cardiovascular Disease*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goals of the research are to understand the mechanisms through which blood vessels become diseased and to develop genetic or other molecular therapies to prevent or reverse blood vessel disease.
- The lab utilizes both in vitro and in vivo mouse and rabbit models. Human tissue and two different types of adenoviral vectors (E1a deleted and gutless) are used.
- The committee discussed the biosafety level of the adenoviral vectors. The adenoviral vectors are administered to rabbits at ABSL-2 containment. The rabbits are kept at ABSL-2 containment for one hour, and then can be moved to ABSL-1 housing.
- The draft BUA letter was shown.
- The training has been completed, and the lab has successfully passed the inspection.
- The IACUC protocol renewal has not yet been submitted. The biosafety officer will need to review the IACUC protocol.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Dichek. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Dichek, contingent upon biosafety officer review of the IACUC protocol.

5. Fuller, Deborah, renewal, *Immunogenicity of conserved elements (CE) therapeutic DNA Vaccine in SHIV infected macaques*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This project has two primary goals: the first is to develop a therapeutic HIV vaccine using the primate SIV model of infection, and the second is to assess the immunogenicity and gene therapy potential of an adeno-associated viral vector in primates.

- A question was raised about whether SHIV (simian/human immunodeficiency virus) will also be used. SHIV is mentioned in the title, but not anywhere else on the application. The biosafety officer will contact the lab for clarification about whether SHIV or SIV.
- The draft BUA letter was shown.
- The letter will be changed to list primate lentivirus as falling under section III-D of the NIH Guidelines.
- The training has been completed, and the lab has successfully passed the inspection.
- The IACUC protocol renewal has not yet been submitted. The biosafety officer will need to review the IACUC protocol.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Fuller. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Fuller, contingent upon correction of the BUA letter and biosafety officer review of the IACUC protocol.</u>

6. Hallstrand, Teal, renewal, *Secretory Phospholipase A2s in Asthma Pathophysiology*

- The assigned IBC Secondary Reviewer presented the Primary Review.
- The overall goal of the research is to understand the regulation of airway inflammation in asthma, with a major focus on the regulation of lipid mediators by the airway epithelium.
- Biohazardous agents used on the protocol include human blood and cells, lentiviral vectors, and respiratory syncytial virus (RSV).
- The draft BUA letter was shown.
- The training has been completed, and the lab has successfully passed the inspection.
- The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Hallstrand.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Hallstrand.</u>

7. Polyak, Stephen, renewal, *Virus-Host Interactions in Cell Culture*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Polyak lab studies the innate immune response to HCV (Hepatitis C virus) infection in hepatocytes, the impact of HIV (human immunodeficiency virus) on HCV pathogenesis, and botanical medicines to treat HCV and liver disease.
- Several viruses are used in this research, including Sendai virus, vesicular stomatitis virus, poliovirus, Newcastle disease virus (vaccine strain), HIV, and HCV. Lentiviral vectors and human blood are also used.
- A question was raised about the lentiviral vectors. The lab needs to clarify how the lentiviral vectors are pseudotyped.
- A discussion occurred regarding poliovirus. Policies regarding global eradication are beginning to be phased in. Dr. Polyak may be unable to work with certain strains of poliovirus. The biosafety officer clarified that no work with polio was currently occurring in the Polyak lab.
- The draft BUA letter was shown.
- A question was raised about the Newcastle disease virus. Dr. Polyak is using the vaccine strain of Newcastle virus. The committee asked that the agent on the BUA letter be changed from “Newcastle Disease virus” to “Newcastle Disease virus, vaccine strain.”

- The training has been completed, and the lab has successfully passed the inspection.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Polyak. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Polyak, contingent upon clarification of the lentiviral vector pseudotyping, and correction of the BUA letter.

8. Singh, Pradeep, change, *Determinants of virulence and antimicrobial tolerance in biofilm and acute infections*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The PI is requesting to add a recombinant strain of *Klebsiella pneumoniae* in their list of approved biohazardous agents for use in both in vitro and in Mice. Exposures to mice will occur both through aerosol and wound infections.
- A discussion occurred about the *K. pneumoniae* and which strains would be used. The investigator is requesting to add a deletion mutant of *K. pneumoniae*. Some members thought the application may imply that the parent clinical strain is also being used. The PI will be asked to clarify this.
    - *Post-Meeting Update: Only the deletion mutant of K. pneumoniae (already described on the BUA change application) will be used.*
- The draft BUA letter was shown.
- The IACUC protocol significant change has not yet been submitted. The biosafety officer will need to review the IACUC protocol.
- The PI's biosafety training has expired.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Singh. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Singh, contingent upon clarification of the K. pneumoniae strains, completion of the biosafety training, and submission of the IACUC protocol.

9. Van Voorhis, Wesley, renewal, *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The investigator is requesting to add a new parasite, *Cryptosporidium parvum*, for use both in vitro and in vivo.
- The research will be conducted at ABSL-2 and BSL-2.
- The draft BUA letter was shown.
- The training has been completed, and the lab has successfully passed the inspection.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Van Voorhis. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.

SUBCOMMITTEE REPORTS:

10. Gale, Michael, change, *The Host Response to Virus Infection*

- Three members of the IBC served as the Subcommittee Reviewers.

- This is a change request. The investigator is already approved to work with the Seoul strain of hantavirus. The original application requested three new strains of Hantavirus: Hantaan, Sin Nombre, and Andes.
- The Andes strain has been shown to spread from person-to-person. The occupational health nurses and doctors are currently working on a plan that covers exposure response and what steps should be taken if a researcher feels unwell and may be potentially infected with Hantavirus. Until this plan is ready to be implemented, the Andes strain has been removed from the application. The motion today will be to approve the Hantaan and Sin Nombre strains of Hantavirus.
- A discussion occurred about the storage of the viruses. Only a secured freezer with restricted access will be used.
- The committee requested that the comment of the BUA letter should specify that the Andes strain described on the original application was not included in this BUA approval.
- There is a distinction in the CDC guidelines between "lab-scale" and "large-scale" production of virus. The Gale lab will be using amounts of virus that fall under "lab-scale" production. The committee decided that the amount of virus that will be produced should be added to the BUA application.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Gale. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Gale, contingent upon correction of the BUA application, and addition of a note to the BUA letter clarifying that the Andes strain is not currently approved.

FOR YOUR INFORMATION:

- Next month, the committee will be voting on a policy involving waste from rabbits that have been experimentally exposed to *Treponema pallidum*. One of the biosafety officers gave a brief overview of this proposal and background of the waste issue. The proposal is on the IBC website.
- NIH has designated October as Biosafety Stewardship month. An outreach email was written and will be sent to principal investigators and other members of the research community next week. Labs are being encouraged to clean their freezers and take an inventory of samples. Magnets were also designed featuring this message. These magnets are being distributed to labs by the biosafety officers during lab inspections.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:
There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 12:05 p.m.