INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, January 21, 2016
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. William Glover, Washington State Public Health Laboratories (*Community Member*)
5. David Koelle, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
7. Scott Meschke, Environmental & Occupational Health Sciences
8. Jason Smith, 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 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. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the December 16, 2015 minutes meeting.
   - A member made a motion to approve the December 16, 2015 minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the December 16, 2015 meeting minutes.

4. **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
      - The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
      - One member declared a conflict of interest because of a shared grant with one of the investigators listed on the report.
      - Dr. Cangelosi renewed a BUA involving clinical and environmental bacteria and human blood.
      - Dr. Chen and Dr. Reh each added a new room to their respective approvals.
      - Dr. Childers has several approvals, and added new imaging rooms to each of them.
      - Dr. Coombs added processing of human blood from persons under investigation for Ebola Virus disease. This change also adds use of sterile nucleic acid from Ebola virus for purposes of developing a clinical diagnostic assay. "Persons under investigation" is a term used by the CDC (Centers for Disease Control) to describe a person who has traveled to a high-risk region or come in contact with an Ebola patient and has signs or symptoms of Ebola Virus disease. The Coombs lab will be using CDC guidelines when performing any laboratory diagnostic tests. The samples are inactivated to kill any potential Ebola virus. CDC guidelines dictate that universal precautions are sufficient when processing blood or other clinical samples from persons under investigation for Ebola Virus disease. No intact Ebola virus is used or cultured on this project.
      - Dr. Muczynski renewed a BUA involving human cell lines and Epstein-Barr virus transformed human cell lines.
      - Dr. Hsu renewed a project involving creating transgenic mice.
      - 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.

5. **DUAL USE RESEARCH OF CONCERN (DURC) REPORT***:* The DURC Report is an overview of projects that were presented at the DURC Institutional Review Entity meeting.
    - The December DURC Institutional Review Entity meeting was cancelled due to a lack of agenda items and projects to review. Therefore there are no DURC items to present at this meeting.

6. **CATEGORY III-D AMENDMENTS**

    1. Hu, Shiu-Lok, change, *Glycan modification, CD4 independence, and Env Immunogenicity*
    - The biosafety officer presented the project.
    - A variety of DNA vaccines are used on this project. DNA vaccines used in macaques have been previously approved and are listed on the BUA letter under the agent "Recombinant or synthetic DNA/RNA."
    - The PI is adding a new DNA vaccine that will be delivered via liquid nanoparticles. The agent "recombinant or synthetic DNA/RNA -- enhanced gene delivery methods" has been added to the BUA letter.
    - 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 for Dr. Hu. A second is not needed since he endorsed the review.
    - <u>The Committee voted unanimously to approve the draft BUA for Dr. Hu.</u>

7. **INDIVIDUAL PROJECT REVIEWS**

    2. Chamberlain, Jeffrey, renewal, *Gene Therapy for Neuromuscular Disorders*
    - The assigned IBC Primary Reviewer presented the Primary Review.
    - The overall goal of this project is to study potential gene therapies for Duchenne muscular dystrophy.
    - Lentiviral vectors and adeno-associated viral vectors (AAV) are used in vitro and in mice. Human cells are also used.
    - The lab has been inspected by the biosafety officer, and the required trainings have been completed.
    - The draft BUA letter was shown.
    - There are some biosafety levels missing from the BUA letter. The biosafety officer will fix these blank spaces.
    - "Murine cells transduced with lentiviral vectors," used in mice should be added to the BUA letter.
    - The footnote G is not relevant to the project and will be deleted from the BUA letter.
    - AAV used in mice needs to be added to SLU Brotman.
    - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chamberlain, contingent on the four corrections mentioned above. A second is not needed since she is the Primary Reviewer.
    - <u>The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain, contingent on the four corrections mentioned above.</u>

    3. Pun, Suzie, renewal, *Biomaterials for biomedical applications*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to develop drug delivery vehicles and biomaterials for biomedical applications.
- Various viral vectors, including adenoviral vectors, lentiviral vectors, gammaretroviral vectors, and adeno-associated viral vectors, are used in the project.
- Nanoparticles are also used as delivery systems.
- A discussion occurred regarding the antineoplastic drugs that are used on the protocol. Occupational health recommendations have been written about the hazards associated with these drugs and distributed to those who are working with these substances.
- A discussion occurred regarding transportation. They transport biohazards and biohazardous mice within the Foege building, but not from one building to another. Secondary containment is used.
- The lab has passed the inspection, and all of the required training has been taken.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pun. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Pun.

4. Veesler, David, new, *Structural studies of the type II secretion sys*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of the research is to understand the molecular structure of the Type II secretion system in *Vibrio cholerae*. Cryo-electron microscopy is used to visualize these structures, which are purified from *V. cholerae*.
- The principal investigator anticipates growing up to 9 liters of *V. cholerae* at a time to purify the membrane-bound complexes he wishes to study.
- A discussion occurred regarding the volume of cholera that will be grown. Spill cleanup is a concern. The biosafety officer discussed the contents of the spill kit present in the lab and the measures that the principal investigator has taken to prevent spills (planning to only transport cholera in quantities less than one liter, using secondary containment, etc.)
- A discussion occurred regarding the cholera strain. The strain is recombinant, and the genes for cholera toxin A and B have been deleted, so the strain does not produce any cholera toxin. Cholera toxin is responsible for the symptoms of cholera infection, so the strain of *Vibrio cholerae* used by this investigator is much less virulent than wild-type *V. cholerae*.
- A discussion occurred regarding the *E. coli* strains used on the project. The primary review mentions BL21, which is not a K-12 derivative strain, but the strain listed on the application is actually DH5alpha. The DH5alpha strain is a K-12 derivative, and therefore exempt from the NIH Guidelines.
- The lab inspection and trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Veesler. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Veesler.

5. Worlein, Julie, renewal, *Behavioral Management Research*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this project is to conduct research aimed at improving the well-being of macaques housed at the Washington National Primate Research Center (WaNPRC).
- The majority of this research consist of behavioral observations. Researchers may collect saliva, urine, feces, or hair from animals who have previously been experimentally infected with biohazardous agents. No agents will be administered on this project.
- No samples will be collected from animals infected with vaccinia. Samples may be taken from animals previously infected with other risk group 1, 2, or 3 pathogens, including *Chlamydia trachomatis* and simian human immunodeficiency virus.
- The draft BUA letter was shown.
- No lab inspection was required for this project, because only previously inspected vivarium rooms are used. All required trainings have been completed.
- A discussion occurred regarding the shipping training. The principal investigator doesn't need to take the Shipping Hazardous Materials training.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Worlein. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Worlein.</u>

SUBCOMMITTEE REPORTS:

6. Influenza Policy Subcommittee

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report, which is attached.
- A subcommittee was formed to look at two aspects of the IBC's influenza policy: re-examining the medical/scientific rationale for our requirement to offer the influenza vaccine to animal care personnel, and determining the appropriate biosafety level for work with mouse-adapted influenza strains (ex. A/PR8/34, A/WSN33).
- The subcommittee recommends that all animal care personnel be offered the influenza vaccine. The subcommittee reviewed scientific literature and determined that influenza strains (including mouse-adapted strains) can retain the receptor binding characteristics, indicating that they remain infectious for humans. Transmission is unlikely during normal cage changing, but is possible if proper technique isn't used. The primary laboratory hazard is inhalation from aerosols while infecting animals or from samples. Also, infected tissues, feces, or secretions from animals could be infectious via transmission from infected gloves.
- A discussion occurred regarding what "proper technique" during cage changes meant. The subcommittee reviewer clarified that transmission is unlikely when ABSL-2 precautions are in place & personal protective equipment is used.
- The subcommittee determined that influenza transmission is extremely unlikely if someone is in the animal room, and not directly handling animals or their contaminated bedding. Mice do not transmit influenza efficiently (they do not cough or sneeze, or otherwise produce aerosols).
- Regarding the appropriate biosafety level for mouse-adapted influenza strains, the subcommittee reviewed the scientific literature and determined that the process of serially passaging an influenza strain in mice does not necessarily alter the virus so that it is no longer pathogenic in humans. A study conducted in the 1970s found that human study volunteers who were injected with X31 developed influenza symptoms. The

symptoms were mild, but this study indicates the X31 strain is pathogenic to humans. It is clear that in some cases, mouse-adapted viruses can remain infectious for humans. Therefore, the subcommittee determined that BSL-2/ABSL-2 containment should be used for these viruses.
    - Investigators will be able to submit requests for the IBC to consider lowering containment to BSL-1 and/or ABSL-1 if they can provide documentation that their mouse-adapted strain is not pathogenic or infectious to humans.
- The committee discussed these recommendations and how they would be enacted. Currently, some mouse-adapted influenza strains are listed on BUA letters under BSL-1/ABSL-1 containment. These investigators will be contacted and informed of the new containment requirements. Many investigators are already working at BSL-2/ABSL-2.
- A formal written vaccine policy will need to be developed. Anyone whose job duties involve handling an influenza virus (including mouse-adapted strains) or an influenza-infected animal, or cleaning the cages and bedding of these animals, will be required to be offered the seasonal influenza vaccine. Vaccination will not be required or recommended for individuals who are entering an animal room but not directly handling the animals or soiled cage bedding.
- Current occupational health guidance is that investigators are required to offer the vaccine to research personnel working with influenza.
- There will be a process in place for individuals to decline the vaccine if they choose. EH&S and the Department of Comparative Medicine will begin drafting this policy and notifying affected investigators.
- The IBC chair sought a motion to approve the IBC Influenza Policy Subcommittee's recommendations:
  (1) Require that all animal care personnel (those who handle an influenza virus, an influenza-infected animal, or the cages and bedding of an infected animal) be offered the seasonal influenza vaccine. For risk group 2 strains of influenza, workers can decline the vaccine and still be allowed to perform their job duties. The vaccine will not be an entry requirement, and will not be recommended for people who enter an animal room but do not handle animals or bedding. Documentation of receiving an influenza vaccine is an entry requirement for risk group 3 influenza research laboratories.
  (2) Require a minimum containment level of BSL-2/ABSL-2 for work with mouse-adapted influenza strains.
- A member made a motion to approve the recommendations set forth by the Influenza Policy Subcommittee. Another member seconded the motion.
- <u>The Committee voted unanimously to approve these recommendations.</u>

FOR YOUR INFORMATION:

- NWABR IBC Conference
    - The conference was held last Friday. Many IBC members and EH&S employees presented at and attended the conference. It was well-attended and the reviews from attendees were positive. NWABR is planning to host another conference next year.
- 2015 IBC Metrics
    - The IBC reviewed over 350 projects last year. More projects than ever are coming from departments outside of the School of Medicine (such as WaNPRC, the pharmacy departments, and the engineering departments). There were 21

subcommittee reviews in 2015. Two new members joined the committee. Other accomplishments in 2015 include posting the IBC minutes and IBC agenda online and enacting the DURC policy & forming the DURC Institutional Review Entity.

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.