# INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

**Meeting Minutes**

**Date:** Wednesday, November 19, 2014
**Time:** 10:00 AM – 12:00 PM

**Location:** Health Sciences Building T-269

**Members Present:**

1. Michael Agy, Washington National Primate Research Center
2. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
3. H.D. "Toby" Bradshaw, Biology *(Plant Expert)*
4. Elizabeth Corwin, Community Member (*Human Gene Transfer Expert; IBC Vice Chair*)
5. Jean Haulman, UW Travel Clinic
6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
7. David Koelle, Allergy and Infectious Diseases
8. Jeanot Muster, Pharmacology
9. Matthew R. Parsek, Microbiology
10. Mei Y. Speer, Bioengineering
11. Eric Stefansson, Environmental Health & Safety *(Biosafety Officer)*
12. Paul Swenson, Community Member, Seattle-King Co. Dept of Public Health

1. **CALL TO ORDER:** The IBC Chair called the meeting to order at 10:00 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 October 15, 2014 minutes were projected on the screen for members to review and discuss.
   - A motion was sought to approve the minutes from the October 15, 2014 minutes meeting.
   - A member made a motion to approve the October 15, 2014 minutes. Another member seconded the motion.
   - The committee voted unanimously, with three abstentions, to approve the October 15, 2014 meeting minutes.

4. **BIOSAFETY OFFICER (BSO) REPORT***:* The BSO report is for administrative updates (such as room additions), for project reviews involving non-recombinant infectious agents, and for projects falling under Section III-E and III-F of the *NIH Guidelines*.

   - Human feces was added to Dr. Miller's BUA (Biological Use Authorization) letter.
   - New rooms were added to Dr. Savan's BUA letter.
   - Two new non-recombinant *Bacillus* species were added to Dr. Yager's BUA letter.
   - Dr. Cui was issued a new BUA letter that includes human cells and tissues.
   - Dr. Simpson renewed a BUA letter involving the use of human source material.
   - Human source material was added to Dr. Chamberlain's BUA letter.
   - New rooms were added to Dr. Jayadev's BUA letter. RCV (replication-competent virus) testing results were also submitted. The results were negative, and so the work with these cells can now be performed at BSL-2 (biosafety level 2).
   - Dr. Risques was issued a new BUA letter involving the use of human source material.
   - New rooms were added to Dr. Wang's BUA letter.
   - Dr. Cross is now the principal investigator of the project "Animal Imaging Using Positron Emission Tomography". Dr. Minoshima was previously the PI of this project. All locations and procedures with biological agents remain unchanged.
   - Dr. Zabetian was issued a new BUA letter involving the use of human source material.
   - Dr. Smedley is now the PI of the three "Operation of WaNPRC Animal Housing and Support Facilities" core BUA letters. Dr. Lee was previously the PI of this project.
   - A motion was sought 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.

5. **CATEGORY III-D AMENDMENTS**

   1. Childers, Martin, change, *Gene Therapy in Canine Myotubular Myopathy*
      - The assigned IBC Primary Reviewer presented the Primary Review.
      - The lab studies XLMTM (X-linked myotubular myopathy), a fatal pediatric disease of skeletal muscle.

- The investigator is transferring three dogs to UW from other institutions. The dogs 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.
- The dogs have been vaccinated for rabies.
- ABSL-1 (animal biosafety level 1) containment will be used.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Childers. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Childers.

**2.** Moon, Randall, change, *Micro- and nanoengineering of the cell microenvironment for stem cell therapy and tissue engineering*

- One member declared a conflict of interest because he works in the Moon lab.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of *Danio rerio* (zebrafish) cells transfected with lentiviral vectors. Lentiviral vectors are already approved on the BUA letter, but this particular combination of zebrafish cells and lentiviral vectors needs to be added. BSL-2 containment will be used.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Moon. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Moon.

## 6. INDIVIDUAL PROJECT REVIEWS

**3.** Update regarding non-human primate eye tissue request

- Three investigators, Dr. Rieke, Dr. Neitz, and Dr. Dacey, have submitted a request to use eye tissue from non-human primates previously infected with primate lentiviruses.
- These investigators already use non-human primate eye tissue in the course of their research. They are currently approved only for eye tissue requiring ABSL-2 containment. The addition of eye tissue from non-human primates previously infected with primate lentiviruses would generally necessitate ABSL-2 with 3 practices containment.
- Dr. Neitz attended the meeting to discuss her reasoning for making the request and the safety precautions that she would take if the request was approved.
    - The demand for non-human primate eye tissue is higher than the supply. The primate center is committed to sharing tissue whenever possible, to avoid wasting any material.
    - The lentivirus infection may potentially impact the experiments that Drs. Rieke, Neitz, and Dacey are trying to perform. Preliminary studies will need to be performed to determine whether or not eye tissue from non-human primates previously infected with primate lentiviruses would be suitable for the long term.

        - Because the investigators are not sure if experiments will be successful, it is not practical to renovate the lab to meet ABSL-2 with 3 practices standards.
    - Dr. Neitz described the safety practices that would be used. During the proposed experiments, the potentially infectious eye tissue would be fully contained within the chamber of the equipment. Temporary shielding measures would also be used.
    - Dissecting the eye would be the biggest risk and would be performed in a biological safety cabinet.
    - The committee discussed the risk assessment regarding this eye tissue.
    - Dr. Neitz thanked the committee for considering her request and exited the meeting.
    - The IBC Primary Reviewer assigned to these projects stressed that more work to develop standard operating procedures needs to be done before approval can be granted. Discussions with the three investigators will continue and the projects will be brought before the committee for a vote at a future meeting.

**4.** Bumgarner, Roger, renewal, *Bumgarner Lab cDNA Research Projects*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the Bumgarner lab is to characterize sequence variation that may be associated with phenotypic differences in viruses, bacteria, and parasites.
- The lab isolates and cultures *P. acnes* from human skin. There is one individual in the Bumgarner lab who goes to another investigator's BSL-2 with 3 practices suite to collect DNA. Then, the DNA is brought back to the Bumgarner lab.
- At the time the Primary Review was written, two questions on the BUA application were answered incorrectly. The investigator has now corrected those questions.
- Training records are in place and the lab inspection has been successfully completed.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Bumgarner. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Bumgarner.</u>

**5.** Curnow, Eliza, new, *Reproductive Biology and Stem Cell Program - ESC chimeras*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This project represents a combination of two existing BUA letters (which will now be archived).
- The primary goals of the project are to develop non-human primate embryo and stem cell resources and to investigate methodology for the efficient production of non-human primate embryonic stem cell chimeras.
- The work will be done at BSL-2/ABSL-2, not ABSL-2 with 3 practices. The review will be amended.
- Training records are in place and the lab inspection has been successfully completed.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Curnow. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Curnow.</u>

**6.** Dhaka, Ajay, change, *Circuit Tracing Cool Sensation*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies the molecular basis of somatosensory perception.
- The investigator is requesting the addition of AAV (adeno-associated viral vectors) and a rabies virus vector, both for use in mice.
- The rabies virus vector is avian pseudotyped. This means that it does not have the correct capsid gene to infect mammalian cells. The rabies virus vector is also missing the glycoprotein that would allow the virus to spread across synapses.
- A discussion occurred regarding this viral vector. The mice cannot shed the rabies virus vector.
- If this rabies virus vector were to be accidentally injected into a human, no immune response or disease would occur because humans lack Cre recombinase.
- The vector is being used as a retrograde tracer. It will be bought from a vendor rather than made by the investigator.
- The draft BUA letter was shown.
- The committee was asked if the language 'rabies virus vector, avian pseudotyped' was suitable. The committee decided that the genetic designation for the virus, RVΔG-EnvA, should be added.
- Training records are in place and the lab inspection has been recently completed.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Dhaka. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Dhaka, contingent upon editing the BUA letter language.</u>

**7.** Kennedy, Scott, new, *Somatic mutagenesis in aging and neurodegenerative diseases*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of the research is to understand the role of mitochondrial DNA mutations on lifespan and the propensity to develop neurodegenerative disease.
- Recombinant drosophila (mosquitos), which fall under section III-D of the NIH Guidelines, are created and used on this project.
- The draft BUA letter was shown.
- Training records are in place and the lab inspection has been successfully completed.
- Michael Agy made a motion to approve the draft BUA for Dr. Kennedy. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Kennedy.</u>

**8.** Kim, Deok-Ho, change, *Micro- and nanoengineering of the cell microenvironment for stem cell therapy and tissue engineering*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of second-generation lentiviral vectors.
- Toby Bradshaw exited the meeting at 10:51.
- Because the lentiviral vectors are second generation and the work involves oncogenes, BSL-2 with 3 practices containment will be required.
- There are pending items that need to be completed before the lab can be certified as BSL-2 with 3 practices.
- The PI needs to take biosafety training.
- The draft BUA letter was shown.

- The Primary Reviewer made a motion to approve the draft BUA for Dr. Kim. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Kim, contingent upon completion of biosafety training and the lab inspection.

**9.** Manoil, Colin, change, *Genetic analysis of Gram-negative bacterial pathogens (BSL-2 experiments)*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of *Klebsiella pneumoniae*.
- In order to eliminate inadvertent transmission of the antibiotic resistance trait, the plasmid involving drug resistance has been deleted.
- A discussion occurred about *K. pneumoniae*. It is a risk group 2 organism.
- Training records are in place.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Manoil. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Manoil.

**10.** Morrissey, Colm, new, *SRRM4 as a target to disrupt the transition to the neuroendocrine/neuronal phenotype in CRPC*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new project from an established investigator.
- The goal of the research is to transduce established prostate cancer cell lines with second generation lentiviral vectors.
- No oncogenes are involved in this project, so the work with the second generation lentiviral vectors will be conducted at BSL-2.
- Training has been completed.
- The lab space was recently inspected.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Morrissey. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Morrissey.

**11.** Neitz, Maureen, renewal, *Exploring plasticity of the adult visual system using viral gene delivery*

- The assigned IBC Primary Reviewer was unable to attend the meeting, but wrote a Primary Review. Another member presented the Primary Review on her behalf.
- This is a three-year renewal unrelated to the eye tissue issue discussed earlier.
- The investigator studies the visual system. The long-term goals of the research are to study neural plasticity of the adult visual system, to investigate genetic risk factors for human vision disorders, and to investigate the evolution of spectral tuning in photopigments by sequencing the opsin genes in a variety of species and taking a comparative approach.
- Biohazardous agents used on this project include AAV (adeno-associated viral vectors) and human and non-human primate blood.
- The biosafety officer clarified that no baboons are used on this project.
- Training records are in place and the lab inspection has been successfully completed.

- The draft BUA letter was shown.
- An IBC member made a motion to approve the draft BUA for Dr. Neitz. A second is not needed since he endorsed the Primary Review.
- The Committee voted unanimously to approve the draft BUA for Dr. Neitz.

**12.** Pepper, Marion, renewal, *The Differentiation and Protective Function of CD4+ memory T cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the lab is to understand how cells of the adaptive immune system develop to either prevent disease or cause allergic reactions.
- Biohazardous agents used on this project include *Listeria monocytogenes*, *Plasmodium* species, and LCMV (lymphocytic choriomeningitis virus).
- A discussion occurred regarding the biosafety level of LCMV. Certain strains are considered to be ABSL-2, and LCMV when used in hamsters is generally considered ABSL-2. The strain used in this project is worked with at ABSL-2 containment.
- Training records are in place and the lab inspection has been successfully completed.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Pepper. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Pepper.
    - *Post Meeting Update: On the BUA letter, the NIH section for two Risk Group 2 organisms used in mice (LCMV and T. gondii) was corrected to III-D*.*

**13.** Polyak, Stephen, change, *Virus-Host Interactions in Cell Culture*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of a plasmid vector that carries poliovirus sequences. Infectious poliovirus particles can be generated in human cell lines.
- The lab workers will be offered poliovirus vaccine. Any staff working with the virus must contact UW employee health two to three weeks before beginning work.
- A discussion occurred about vaccination of lab workers. UW is obligated to offer the vaccine to workers who may be potentially exposed to polio. The PI will not allow anyone who has not received a vaccine to work on the project.
- The draft BUA letter was shown.
- The polio footnote on the BUA letter reads "*The Principal Investigator must offer the polio vaccine to all laboratory workers who directly handle polio virus and/or animals infected with polio. All staff working with polio must contact UW Employee Health at 206.685.1026 at least two to three weeks before working with the virus*."
- Training records are in place.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Polyak. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Polyak.

**14.** Singh, Pradeep, renewal, *Determinants of virulence and antimicrobial tolerance in biofilm and acute infections*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Matt Parsek entered the meeting at 11:28.

- A variety of Risk Group 1 and Risk Group 2 bacterial species are used on this project, including *B. thailandensis*, *S. aureus*, and *P. aeruginosa*.
- Training records are in place and the lab inspection has been successfully completed.
- The draft BUA letter was shown.
- The 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, with one abstention, to approve the draft BUA for Dr. Singh.

**15.** Giacani, Lorenzo, change, *1) Genetic Manipulation of T. pallidum 2) Treponema pallidum sigma factors and pathogenesis of syphilis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting the addition of strains of *Borrelia burgdorferi,* to be used in rabbits.
- A discussion occurred regarding the associated IACUC (Institutional Animal Care and Use Committee) protocol. The investigator submitted a corresponding request for change to the IACUC in September.
- The biosafety level for *Borrelia burgdorferi* should be amended to 2 on the BUA letter
- A discussion occurred regarding antibiotic resistance. The investigator needs to clarify what antibiotic resistance markers he is using to express the plasmid.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Giacani. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Giacani, contingent upon correction of the BSL of *Borrelia burgdorferi* and clarification of antibiotic resistance markers.
- The committee will be updated in December after the investigator provides more information about the antibiotic resistance markers.

**16.** Skerrett, Shawn, renewal, *Host Defense Against Bacterial Pneumonia*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new project submitted by an established investigator.
- The overall goals of the research are to understand the mechanisms of resistance against bacterial infections of the lungs, and to identify new ways to treat respiratory tract infections.
- A variety of bacterial species are used on this project, including *B. thailendensis*, *Francisella* species, *P. aeruginosa*, *S. aureus*, and *Listeria monocytogenes*.
- The *Francisella* strains used on this project are exempt from select agent regulations.
- Training records are in place and the lab inspection has been successfully completed.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Skerrett. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett.

**17.** Trapnell, Cole, new, *Trapnell lab general operations*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Biohazardous agents used on this project include lentiviral vectors and human cells.
- The lab is in the process of being set up. Some equipment has been ordered but has not yet arrived. The biosafety officer will visit the lab again once everything is in place.
- The draft BUA letter was shown.
- The Primary Reviewer made a motion to approve the draft BUA for Dr. Trapnell. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Trapnell, pending completion of the lab inspection.</u>

**FOR YOUR INFORMATION:**

- UW Biosafety Manual
  - The UW Biosafety Manual has been revised. A major rewrite of the manual was completed in 2013. This year's revisions were regulatory updates and corrections.
    - The sharps waste definition was updated in response to regulatory changes.
    - DOT (Department of Transportation) requirements were added for shipping biohazardous waste via a contracted carrier.
    - A subsection on best practices for inventory control was added in response to national biosafety stewardship and awareness.
    - Bloodborne Pathogens (BBP) regulations are no longer referenced for work with non-human primate material.
    - Immediate response information was updated to match the EH&S Exposure Response Poster.
    - Typographical and formatting corrections were made throughout the manual.
  - A motion was sought to approve the revisions to the UW Biosafety Manual.
  - A member made a motion to approve the revisions to the UW Biosafety Manual. Another member seconded the motion.
  - <u>The Committee voted unanimously to approve the revisions to the UW Biosafety Manual.</u>
- Glenn McLean, EH&S Biosafety Officer, has left UW and relocated out of state.
- Dr. Zheng's project was presented at the October 15th IBC meeting. Since that time, the viral vector work was removed from the project. The investigator has decided to work with plasmid DNA, which is exempt from the NIH Guidelines.

**MEETING ADJOURNED AT APPROXIMATELY 11:55 am.**