



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, October 15, 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
3. Lesley Colby, Comparative Medicine
4. Elizabeth Corwin, Community Member
5. Jean Haulman, UW Travel Clinic
6. Stephen Libby, Laboratory Medicine
7. Scott Meschke, Environmental & Occupational Health Sciences
8. Jeanot Muster, Pharmacology
9. Eric Stefansson, Environmental Health & Safety

Members Absent:

10. H.D. "Toby" Bradshaw, Biology
11. Matthew R. Parsek, Microbiology
12. Mei Y. Speer, Bioengineering
13. Paul Swenson, Community Member, Seattle-King Co. Dept of Public Health
14. Valerie Yerkes, Community Member

Guests Present:

1. David Anderson, Executive Director, Health Sciences Administration
2. Linda Arnesen, Biosafety Officer, EH&S Research & Occupational Safety
3. Andrea Badger, IBC/Research Coordinator, EH&S Research & Occupational Safety
4. Jacqui Bales, Biosafety Officer, EH&S Research & Occupational Safety
5. Tony Han, Biosafety Officer, EH&S Research & Occupational Safety
6. Lauren Habenicht, Senior Fellow, Comparative Medicine
7. Katia Harb, Assistant Director, EH&S Research & Occupational Safety
8. Lesley Leggett, Biosafety Officer, EH&S Research & Occupational Safety
9. Glenn McLean, Biosafety Officer, EH&S Research & Occupational Safety
10. Angela Rasmussen, Research Assistant Professor, Microbiology

1. **CALL TO ORDER:** Steve Libby called the meeting to order at 10:01 a.m. A quorum was present.
 2. **REMINDER:** Steve Libby 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:**
 - Steve Libby sought a motion to approve the minutes from the September 17, 2014 minutes meeting.
 - Jeanot Muster made a motion to approve the September 17, 2014 minutes. Eric Stefansson seconded the motion.
 - The committee voted unanimously, with one abstention, to approve the September 17, 2014 meeting minutes.
 4. **BIOSAFETY OFFICER (BSO) REPORTS:** The BSO reports are for project reviews involving infectious agents and for projects falling under Section III-E and III-F of the *NIH Guidelines*.
 - a. Biosafety Officer Report
 - A discussion occurred about the Covey bat research. All of the researchers, as well as any inspectors, are offered the rabies vaccine. The colony has existed for about ten years with no known cases of rabies.
 - A question was raised about Dr. Mizumori's project. She has previously been approved for adeno-associated virus (AAV) in mice and this approval is for AAV in rats.
 - A discussion occurred regarding Dr. Colby's Biological Use Authorization (BUA) letter. This is a core facility BUA letter for centralized ABSL-2 space in the Comparative Medicine vivarium. Any users of this space will also have their own BUA letter.
 - Steve Libby sought a motion to approve this month's Biosafety Officer Report.
 - Eric Stefansson made a motion to approve this month's Biosafety Officer Report. Michael Agy seconded the motion.
 - The Committee voted unanimously, with two abstentions, to approve this month's Biosafety Officer Report.
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5. **INDIVIDUAL PROJECT REVIEWS**
 1. Barria, Andres, renewal, *Regulation of glutamatergic synapses*
 - Mei Speer served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. On behalf of Mei Speer, Michael Agy presented the Primary Reviewer Report.
 - The lab studies the regulation of glutamatergic synapses in brain slices.
 - Biohazardous agents used on this protocol include Sindbis viral vectors and human cells.
 - A discussion of the Sindbis viral vector work occurred.
 - The lab inspection and training have both been completed.
 - The draft BUA letter was shown.
 - Michael Agy made a motion to approve the draft BUA for Dr. Barria. A second is not needed since he endorsed the Primary Reviewer.

- The Committee voted unanimously to approve the draft BUA for Dr. Barria.
2. Fields, Stanley, renewal, *Genetic interaction profiling of p53 mutations in transcription and blood cancer; Functional analysis of mutant version of human genes*
 - Steve Libby served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Steve Libby presented the Primary Reviewer Report.
 - The lab aims to determine the effects of mutation on the function of human proteins.
 - Biohazardous agents used on this project include lentiviral vectors and human cells.
 - The investigator lists siRNA with three knocked-down tumor suppressor genes. siRNA is exempt from the NIH Guidelines, but it is not clear whether or not they will be doing the same tumor suppressor experiments in lentiviral vectors. The investigator will need to clarify this before the final approval is given.
 - The draft BUA letter was shown.
 - Steve Libby made a motion to approve the draft BUA for Dr. Fields. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fields, contingent upon clarification of tumor suppressor experiments.
 3. Fuller, Deborah, renewal, *Immunogenicity and efficacy of universal influenza DNA vaccine in nonhuman primates*
 - Thea Brabb served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Thea Brabb presented the Primary Reviewer Report.
 - The goal of this project is to investigate the efficacy of a DNA vaccine against contemporary circulating strains of influenza A virus.
 - Biohazardous agents used on this protocol include human cells, lentiviral vectors, contemporary circulating strains of influenza, FluMist influenza vaccine, and plasmid DNA.
 - A discussion of Staphylococcal enterotoxin B (SEB) occurred. The biosafety officer performed the toxin consult during the lab inspection.
 - A question was raised about the use of “Lentiviral vectors, influenza HA pseudotyped” on the BUA letter. Normally, lentiviral vectors are only specified as ‘HIV pseudotyped’ or ‘non-HIV pseudotyped.’ The committee decided that the language on this BUA letter should state ‘Lentiviral vectors, non-HIV pseudotyped.’
 - The draft BUA letter was shown.
 - Elizabeth Corwin entered the meeting at 10:30 a.m.
 - Thea Brabb made a motion to approve the draft BUA for Dr. Fuller. 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. Fuller, contingent upon editing the BUA letter to state ‘Lentiviral vectors, non-HIV pseudotyped.’
 4. Gordon, Sharona, renewal, *Mechanisms of TRP Channel Modulation*
 - Toby Bradshaw served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. On behalf of Toby Bradshaw, Eric Stefansson presented the Primary Reviewer Report.

- The lab is interested in chronic pain conditions and studies the molecular basis for inflammatory pain-related hypersensitivity with the goal of identifying targets for future drug development.
 - A discussion of baculovirus occurred. The recombinant baculovirus falls under section III-E because it is a risk group 1 virus. The letter currently states 'III-D', but should be amended to state III-E.
 - A discussion of question 57a on the BUA application occurred. The investigator has marked BSL-1 and BSL-2, and ABSL-1, which is correct, because she is not doing any human cell work (or other BSL-2 work) in animals.
 - Questions 25 and 26 on the BUA application should be completed.
 - The draft BUA letter was shown.
 - Eric Stefansson made a motion to approve the draft BUA for Dr. Gordon. A second is not needed since he endorsed the Primary Review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gordon, contingent upon completion of question 25 and 26, and correcting the letter to state III-E.
5. Hellstrom, Karl, renewal, *Tumor Vaccines*
- Lesley Colby served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Lesley Colby presented the Primary Reviewer Report.
 - The lab seeks to develop more effective immunotherapy for several tumor types. Biohazardous agents used on this project include human cells, and several types of viral vectors.
 - A discussion of the project description occurred. Sometimes, project descriptions provided by PIs are too brief. EH&S and the chair will work more closely with the PI and ask them to add more information when it is needed.
 - The lab inspection has been completed, and training records are in place.
 - The draft BUA letter was shown.
 - Lesley Colby made a motion to approve the draft BUA for Dr. Hellstrom. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hellstrom.
6. Hladik, Florian, renewal, *Mechanisms of HIV-1 Transmission in Genital Mucosa of Women and the Role of Exosomes in Semen for HIV Infection in the Genital Mucosa of Women*
- Steve Libby served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Steve Libby presented the Primary Reviewer Report.
 - The lab studies the mechanisms by which HIV gains entrance into the host.
 - Biohazardous agents used on this project include HIV and human source material.
 - The investigator stated on the application that his work with HIV falls under section III-F of the NIH Guidelines. HIV was previously listed under section III-D on his BUA letter. The committee discussed which section of the NIH Guidelines the HIV work falls under. The committee decided that III-D was more appropriate because there is a recombination event to make the HIV go into the cell.
 - The draft BUA letter was shown.
 - The lab inspection is scheduled for later in the week.
 - Steve Libby made a motion to approve the draft BUA for Dr. Hladik. A second is not needed since he is the Primary Reviewer.

- The Committee voted unanimously to approve the draft BUA for Dr. Hladik, pending completion of the lab inspection.
7. Hu, Shiu-Lok, change, *Oral immunization against HIV/AIDS with prime-boost strategies*
 - Michael Agy served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Michael Agy presented the Primary Reviewer Report.
 - This change requests the addition of a DNA vaccine for use in macaques. The agent is called 'recombinant or synthetic DNA/RNA (non-viral)' on the BUA letter.
 - The draft BUA letter was shown.
 - The biosafety level for the recombinant DNA is listed as BSL-1 on the letter. The correct level is BSL-2 because macaques themselves necessitate BSL-2 containment because they are known to sometimes carry herpes B virus.
 - Michael Agy made a motion to approve the draft BUA for Dr. Hu. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hu, contingent upon correction of the BUA letter.

 8. Katze, Michael, renewal, *Gene expression analysis of SIV/HIV/SHIV infected cells and tissues*
 - Matt Parsek served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Matt Parsek presented the Primary Reviewer Report.
 - The overall goal of this project is to examine the transcriptomic and proteomic profiles of tissues and cell lines infected with HIV, SIV, SHIV, or HCV.
 - The lab processes body fluids, cells, and tissues from both uninfected animals and animals infected with SIV, HIV, SHIV, or HCV.
 - The lab has detailed protocols for handling samples. Many precautions and safeguards are in place.
 - The hepatitis C work is not currently taking place, but the studies will resume at some point in the future.
 - The draft BUA letter was shown.
 - Matt Parsek made a motion to approve the draft BUA for Dr. Katze. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Katze.

 9. Klatt, Nichole, change, *Mucosal Immune Dysfunction After SIV Infection*
 - Elizabeth Corwin served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Elizabeth Corwin presented the Primary Reviewer Report.
 - The investigator is requesting the addition of three humanized monoclonal antibodies. These antibodies recognize Ebola and are contained in the ZMapp 'cocktail.'
 - No Ebola virus will be used. No DNA from the Ebola virus will be used. Although the investigator refers to "ZMapp vaccine" several times, ZMapp will not be used. Only the DNA encoding three humanized monoclonal antibodies will be worked with.
 - The goal of the project is not to create an immune response, but rather to create artificial antibodies.
 - The work will be conducted at ABSL-2.

- The committee discussed the wording used in the BUA change form. The investigator describes the agent as a vaccine, but a more appropriate term would be 'therapeutic treatment' or 'gene therapy.'
- The biosafety officer will work with the lab to ensure that the language is clear and that the scope of the requested change is clear.
- The DNA encoding the humanized monoclonal antibodies would be listed on the BUA letter as 'Recombinant or synthetic DNA/RNA, non-viral.' The PI already has this agent on her BUA letter, and so an updated BUA letter does not need to be issued.
- The draft BUA letter was shown.
- Elizabeth Corwin made a motion to approve the draft BUA for Dr. Klatt. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Klatt, contingent upon revising the application to state 'gene therapy' instead of vaccine.
- Lesley Colby exited the meeting.

10. Salipante, Stephen, new, *Next-generation sequencing for clinical translation*

- Steve Libby served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Steve Libby presented the Primary Reviewer Report.
- The lab focuses on the clinical applications of next-generation DNA sequencing. The goal of the lab is to advance the capabilities of next-generation sequencing and to use it to advance the understanding of human genetics.
- Biohazardous agents used on this protocol include recombinant strains of *S. aureus* and *P. aeruginosa*, as well as human cells.
- Lesley Colby re-entered the meeting.
- The draft BUA letter was shown.
- Training has been completed.
- The lab inspection still needs to be completed.
- Steve Libby made a motion to approve the draft BUA for Dr. Salipante. 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. Salipante, pending completion of the lab inspection.

11. Stetson, Daniel, change, *Mechanisms and Consequences of Innate Immune Detection of Nucleic Acids*

- Eric Stefansson served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Eric Stefansson presented the Primary Reviewer Report.
- The investigator is requesting to add the use of herpes strains that are thymidine kinase deficient.
- The risk of an accidental parenteral exposure is reduced because the lab is not using sharps in the procedure. Instead, micropipettes with a blunted tip are used.
- The lab was recently inspected in April 2014.
- The draft BUA letter was shown.
- Eric Stefansson made a motion to approve the draft BUA for Dr. Stetson. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Stetson.

12. Zheng, Ying, renewal, *Microfluidic control of vascular growth and remodeling*

- Jeanot Muster served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Jeanot Muster presented the Primary Reviewer Report.
- A discussion occurred regarding the genes Sox2 and Oct4. The IBC has previously decided that these are not causative oncogenes, but rather genes that are often observed as tumors develop. However, while reviewing this project, the reviewers found several 2014 papers that may indicate that the genes are actually oncogenic.
- The committee discussed oncogenes and gene inserts.
- It would be helpful to the committee if a representative from the FHCRC vector generation core facility would give a presentation at an upcoming IBC meeting. EH&S will work to schedule this.
- A discussion of whether or not the lentiviral vectors are third generation occurred. The committee decided that the documentation to show that the vectors are third generation was sufficient.
- The draft BUA letter was shown.
- Jeanot Muster made a motion to approve the draft BUA for Dr. Zheng. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Zheng.

SUBCOMMITTEE REPORTS:

- Michael Gale, new, Host Response to BSL3 Pathogens
 - The investigator has submitted a proposal to conduct research with highly pathogenic influenza.
 - There are many steps in the approval process. The application could be denied at any point.
 - If the work is eventually approved, it will be conducted at ABSL-3/BSL-3 facilities.
 - The committee is not being asked to approve any methodologies today.
 - The request presented to the committee is to grant the investigator permission to initiate the select agent approval process with the Centers for Disease Control (CDC) select agent program.
 - The IBC subcommittee has met several times and decided upon several requirements and recommendations. Many of the subcommittee's requirements and recommendations for approval overlap with select agent requirements.
 - The lab must obtain standard operating procedures (SOPs) from the CDC and USDA (United States Department of Agriculture). This will be a requirement to obtain IBC approval and is also a standard condition of the select agent program.
 - The lab must have a robust medical surveillance program. This will be a requirement to obtain IBC approval and is also a standard condition of the select agent program.
 - The lab must develop a stringent training plan for laboratory workers. This will be a requirement to obtain IBC approval and is also a standard condition of the select agent program.
 - The SOPs must describe how lab workers will be screened for seasonal influenza and how workers with influenza will be prevented from entering the facility.

- The SOPs must include a stringent no-bird contact. Lab workers cannot handle or interact with wild birds, poultry, or pet birds.
- The lab must work with only one strain of influenza at a time.
- The SOP must provide a plan for decontamination when changing work with one strain to another.
- Animal husbandry staff must be trained, educated, and offered vaccinations where applicable. This will be a requirement to obtain IBC approval and is also a standard condition of the select agent program.
- The lab must develop a very clear and robust post-exposure plan. This will be a requirement to obtain IBC approval and is also a standard condition of the select agent program.
- This project will require an inspection by the CDC, the USA, and the CDC Director's signature. The regulatory agencies can decline to approve this project at any point.
- The investigator would also be required to enroll and comply with all facets of the select agent program.
- Scott Meschke made a motion to allow Dr. Gale to move forward and start the formal application process. Eric Stefansson seconded the motion.
- The Committee voted unanimously to allow Dr. Gale to move forward and start the formal application process.

FOR YOUR INFORMATION:

- NIH OBA Reportable Event
 - Eric Stefansson reported an exposure event to the agent recombinant *Listeria monocytogenes*. *Listeria* from a syringe was accidentally splashed onto a research scientist's eyes and nose during a tail vein injection into a mouse. The researcher followed proper post-exposure protocols by washing his face for 15 minutes and consulting with the UW Employee Health Clinic. He was seen at the Employee Health Clinic and is being monitored. The event was reported to NIH.
 - When the accident occurred, he was performing a tail vein injection in a biosafety cabinet, but was looking under the sash. The tail vein injection is a delicate procedure and it can be difficult to see while working in a biosafety cabinet. The PI, Sean Murphy, has ordered face shields, which will be worn from now on to help prevent similar accidents.
 - The committee discussed the accident and decided that the lab worker should be retrained regarding how to perform tail vein injections safely.
- IBC Minutes on EH&S Website
 - The UW received an email asking for four months of IBC minutes, along with any NIH reportable incident reports occurring during this time.
 - Washington state law requires that those who wish to receive public records file a public records request with the UW Public Records Office. The information was not requested using this process.
 - EH&S has been working to make the records available, while also abiding by Washington state law and ensuring security is not compromised. The information has been posted online following guidance by the NIH.
 - The committee discussed the format of the minutes and the NIH expectations for the content. EH&S will form a subcommittee to review the IBC minutes template.

- DURC Policy
 - A federal policy regarding dual use research of concern (DURC) was recently unveiled. It takes effect next September.
 - UW is already following many steps listed in the new policy. Some action items may be to provide training to PIs, to appoint a DURC contact person, and to develop a risk mitigation plan.

MEETING ADJOURNED AT APPROXIMATELY 12:01.