



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, April 19, 2017

Time: 10:00 AM – 12:00 PM

Location: Foegen N-130A

- Members Present:**
1. Richard Grant, Washington National Primate Research Center
 2. Garry Hamilton (*Community Member*)
 3. Kevin Hybiske, Allergy and Infectious Diseases
 4. David Koelle, Allergy and Infectious Diseases
 5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 6. Scott Meschke, Environmental & Occupational Health Sciences
 7. Matthew R. Parsek, Microbiology
 8. David Scarsella, Pacific Northwest Diabetes Research Institute (*Community Member*)
 9. Jason Smith, Microbiology (*IBC Vice Chair*)
 10. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
 11. 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 March 15, 2017 meeting.
 - A member made a motion to approve the March 15, 2017 minutes. Another member seconded the motion.
 - The committee voted unanimously, with one abstention, to approve the March 15, 2017 meeting minutes.
4. **OLD BUSINESS**
 - At the January IBC meeting, Dr. Shendure's BUA was approved pending a demo of the air sampler. This was completed and the BUA approval letter was sent out.
 - At the February IBC meeting, Dr. Morishima's BUA was approved pending biosafety officer review of the BSL-2 with BSL-3 practices SOP. This was completed and the BUA approval letter was sent out.
 - At the February IBC meeting, Dr. Phillip's BUA was approved pending biosafety officer review of the IACUC protocol submission. The IACUC protocol has not yet been submitted.
 - At the March IBC meeting, Dr. Klavins' BUA was approved pending a final lab inspection checking for floor drain filters and covers. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Sellers' BUA was approved pending modification of the BUA letter to list third generation lentiviral vectors, and editing the IACUC application to make sure all rooms match up. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Berndt's BUA was approved pending modification of the BUA letter to list AAV with oncogenic inserts at BSL-2. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Grant's BUA was approved pending a final lab inspection and finalized SOPs. The finalized SOPs are still pending.
 - At the March IBC meeting, Dr. Maggio-Price's BUA was approved pending correction of the BUA letter to list human cells and human feces under NIH section NA rather than III-D. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Mullins' BUA was approved pending completion of the PI's biosafety training. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Reniere's BUA was approved pending correction of the BUA letter to delete duplicate Listeria entries. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Stetson's BUA was approved pending the biosafety officer's review of the IACUC protocol. This was completed and the BUA approval letter was sent out.
 - At the March IBC meeting, Dr. Hyde's BUA was approved pending modification of the BUA application to clarify that the virulence of TC-83 will not be enhanced. This was completed and the BUA approval letter was sent out.
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. Gelb received a new BUA approval involving human blood.
- Dr. Raskind, Dr. Hauschka, Dr. Disteché, and Dr. Zweifel each added the cell analysis facility to their respective BUA approvals.
- Dr. Klavins added transgenic plant work to his approval. The plant expert on the IBC reviewed this change. The work takes place in the Electrical Engineering building. An IBC member asked about how the waste is disposed. The waste is sent off-site for incineration.
- Dr. Giacani, Dr. Theberge, Dr. Isoherranen, Dr. Perkel, Dr. Kwon, and Dr. Jiao each added a new room to their respective approvals.
- Dr. Zhang added the SLU 3.1 vivarium to her approval.
- Dr. Chen, Dr. Thaler, and Dr. von Moltke each added the K-wing vivarium to their respective approvals.
- Dr. Eaton received a new BUA approval involving human blood and cells.
- Dr. Silber renewed a BUA involving human tissue and blood.
- Dr. Taya renewed a BUA involving wild-type Epstein-Barr virus and human and non-human primate blood and cells.
- Dr. Lutz received a new BUA for human blood.
- Dr. Wordeman renewed a BUA involving baculovirus and human cells.
- Dr. Liu renewed a BUA involving human blood, tissue, and cells.
- Several investigators at the Washington National Primate Research Center received updated BUAs because of lab space reorganizations.
- Dr. Totah renewed a BUA involving human blood and cells.
- Dr. Werth renewed a BUA involving several non-recombinant Risk Group 2 bacterial species.
- Dr. Wood received a new BUA involving snails infected with schistosomiasis. An IBC member asked how the water from the snail tanks will be decontaminated. It will be treated with chlorine bleach.
- Dr. Sweet received two new BUAs both involving human tissues.
- 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. CATEGORY III-D AMENDMENTS

1. Jerome, Keith, new, *Targeted nanocarriers to accelerate depletion of the HIV reservoir*
 - The biosafety officer presented the project.
 - Dr. Jerome's research involves human specimens from patients known to be positive for HIV (human immunodeficiency virus) and non-human primate specimens from SHIV-infected animals (simian human immunodeficiency virus). SHIV falls under section III-D of the NIH guidelines.
 - The lab was inspected and no deficiencies were found. All of the required trainings have also been completed.

- The draft BUA letter was shown.
 - The assigned IBC member made a motion to approve the draft BUA for Dr. Jerome.
 - The Committee voted unanimously to approve the draft BUA for Dr. Jerome.
2. Van Voorhis, Wesley, change, *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium 5. Giardia*
- The biosafety officer presented the project.
 - This is a change adding the use of recombinant *Shigella flexneri* in mice. Dr. Van Voorhis is already approved to use *Shigella flexneri* in vitro.
 - The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
 - 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. Van Voorhis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.

7. INDIVIDUAL PROJECT REVIEWS

3. Buckner, Fred, change, *Buckner antiparasitic and antibacterial drug discovery*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to add two recombinant strains of *Staphylococcus aureus*, Xen8.1 and Xen31. They express the lux operon. These strains will be used in vitro and in mice.
 - The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Buckner.
 - The Committee voted unanimously to approve the draft BUA for Dr. Buckner.
4. Byers, Peter, change, *Collagen Diagnostic Laboratory and Research Repository for Heritable Disorders of Bone, Blood Vessels and Skin*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to add non-integrating Sendai virus to create induced pluripotent stem cells (iPSCs) from human skin fibroblasts.
 - The lab was inspected and there are no remaining deficiencies. The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Byers.
 - The Committee voted unanimously to approve the draft BUA for Dr. Byers.
5. Catterall, William, renewal, *Catterall Biohazards*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The overall goal of the research is to understand the pathophysiological mechanisms that cause severe epilepsy, autism, cognitive impairment, and heart failure.

- AAV (adeno-associated viral vectors) and baculoviral vectors are used in mice. Human cells are also used.
 - The committee discussed baculoviral vectors. Baculovirus is listed as ABSL-2 and section III-E on the BUA letter. In this project, it is used as a method of gene delivery, so the correct way to list it is “baculoviral vectors.” The correct biosafety level is ABSL-1 and the correct NIH section is III-D. The biosafety officer will make the correction.
 - The lab was inspected and no deficiencies were found. The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Catterall.
 - The Committee voted unanimously to approve the draft BUA for Dr. Catterall, pending modifying the biosafety level and NIH section of baculoviral vectors on the BUA letter.
6. Clark, John, renewal, *Development and Maintenance of Lens Transparency*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The lab uses transgenic zebrafish as a model to observe the expression and behavior of disease proteins.
 - The lab has been inspected and no deficiencies were found. The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Clark.
 - The Committee voted unanimously to approve the draft BUA for Dr. Clark.
7. Cui, Julia, renewal, *Regulation of drug metabolism by developmental exposure to environmental chemicals and the gut microbiome*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - One member declared a conflict of interest.
 - The lab studies how developmental exposure to environmental chemicals affects the regulation of drug metabolism.
 - *Clostridium sporogenes* and human feces are administered to mice.
 - The lab has been inspected and no deficiencies were found. The required trainings have been completed.
 - The draft BUA letter was shown.
 - An IBC member raised a question about which rooms are used on the project. The biosafety officer will verify the locations before sending out the approval letter.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Cui.
 - The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Cui, pending clarification of the rooms that will be used.
8. Fuller, Deborah, change, *DNA Vaccine Therapy*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request.
 - Previously, the Fuller lab proposed to do experiments involving serial passaging of two influenza strains, Vietnam H5N1-deltaH5-PR8 and Hong Kong H9N2-PR8, in mice. The IBC ruled that animal work with the Vietnam H5N1-deltaH5-PR8 strain

should occur at ABSL-3 and that work with the Hong Kong H9N2-PR8 strain should occur at ABSL-2 with ABSL-3 practices.

- The Fuller lab is no longer planning to do the mouse passaging experiments with these influenza virus strains, and they are requesting that the IBC remove the raised containment requirement now that the serial passaging will not occur. They would like to work with the Vietnam H5N1-deltaH5-PR8 strain at ABSL-2 with ABSL-3 practices and the Hong Kong H9N2-PR8 strain at ABSL-2. This is what the CDC BMBL (*Centers for Disease Control Biosafety in Microbiological and Biomedical Laboratories*) recommends.
- A discussion occurred about the rooms used on the project and whether special precautions to isolate different influenza viruses need to be enacted. The biosafety officer said that only one strain of influenza is currently approved for that location, but she will discuss with Comparative Medicine and make sure that they consider influenza strains when assigning animal housing rooms.
- The IACUC protocol has not yet been submitted. The biosafety officer will need to review the IACUC protocol before the approval is issued.
- The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Fuller.
- The Committee voted unanimously to approve the draft BUA for Dr. Fuller, pending biosafety officer review of the IACUC protocol & discussing animal housing room assignments with Comparative Medicine.

9. Garden, Gwenn, renewal, *Cell-Cell Communication in Neurodegeneration*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The lab researches the interactions between cells in neurodegenerative diseases including Alzheimer's disease and other inherited neurological disorders.
- Adeno-associated viral vectors and human cells are used on the project.
- Mice are used on the project, but no biohazardous agents are administered to the animals, and so the IACUC protocol is not formally associated with this BUA.
- The lab has been inspected and no deficiencies were found. The required trainings have been completed.
- The draft BUA letter was shown.
- The PI still needs to retake the biosafety training.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Garden.
- The Committee voted unanimously to approve the draft BUA for Dr. Garden, pending completion of the PI's biosafety training.

10. Hoffman, Lucas, renewal, *Microbiology of people with cystic fibrosis and other chronic infections*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab researches the microbial composition of tissues with chronic infections (like cystic fibrosis) and is attempting to ascertain the mechanisms at play in complex microbial community interactions.
- *Pseudomonas aeruginosa* and *Staphylococcus aureus* are used on the project. Human samples are also used.

- The lab has been inspected and no deficiencies were found. The required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hoffman.
- The Committee voted unanimously to approve the draft BUA for Dr. Hoffman.

11. Hybiske, Kevin, change, *Chlamydia pathogenesis and immune evasion*

- The assigned IBC Primary Reviewer presented the Primary Review.
- One member declared a conflict of interest.
- This is a change request. The investigator is requesting to add the use of a recombinant *Chlamydia trachomatis* strain containing tetracycline-resistance markers for use in cell culture infections of human and murine cell lines. The work will occur at BSL-2 with BSL-3 practices.
- This work falls under section III-A of the NIH Guidelines. NIH Director approval and RAC (Recombinant DNA Advisory Committee) review are required. Another investigator at UW has previously obtained these approvals.
- The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hybiske.
- The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Hybiske.
- *Post-Meeting Update: Dr. Hybiske submitted an amendment to NIH stating that the principal investigator has changed since the original approval was issued in 2007. His approval will be issued after the NIH approval is issued.*

12. Lagunoff, Michael, renewal, *Molecular Virology of Human Herpes Virus 8*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The researcher studies how human herpes virus 8 (HHV8) causes cell transformation. He studies how viruses affect cell metabolism, signal transduction, and gene expression.
- Several other viruses are used on the project as controls. Strains of vaccinia and cytomegalovirus expressing GFP (green fluorescent protein) are used. Wild-type strains of dengue and herpes simplex virus 1 are also used.
- Third-generation lentiviral vectors and amphotropic gammaretroviral vectors are also used.
- Researchers on this project will receive medical counseling and be offered the vaccinia vaccine, as stated in the UW Vaccinia Virus Research Safety Policy. Vaccinia virus is not new to Dr. Lagunoff's approval, so the researchers have already received this information.
- The lab was inspected and all deficiencies were corrected. All of the required trainings have also been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lagunoff.
- The Committee voted unanimously, with one abstention, to approve the draft BUA for Dr. Lagunoff.

13. Lin, Shin, change, *Epigenomics of Heart Failure*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator is requesting to add human induced pluripotent stem cells. These cells were generated with lentiviral vectors.
- The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lin.
- The Committee voted unanimously to approve the draft BUA for Dr. Lin.

14. Lingappa, Jaisri, renewal, *Capsid Assembly Studies*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The overall goal of the research is to understand HIV and other retroviral capsid assembly and genome packing.
- Recombinant strains of HIV-1 and HIV-2, as well as SIV and FIV (feline immunodeficiency virus), are used on the project. Lentiviral vectors are also used.
- The lab has been inspected and no deficiencies were found. The required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lingappa.
- The Committee voted unanimously to approve the draft BUA for Dr. Lingappa.

15. Mizumori, Sheri, change, *Neuromodulatory Control of Reward Neurocircuitry*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request. The investigator would like to administer canine adenovirus to rats, and add new, non-oncogenic AAV gene inserts.
- The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mizumori.
- The Committee voted unanimously to approve the draft BUA for Dr. Mizumori.

16. Murphy, Sean, change, *Immunity to malaria infection*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request. The investigator would like to use a vaccine strain of yellow fever virus that expresses a malarial parasite antigen.
- The researchers on this project may need to be offered the yellow fever vaccine. The biosafety officer will consult with the Employee Health Physician.
- The researchers on this project will receive occupational health recommendations written by the occupational health nurse after the IACUC protocol is submitted.
- The lab has recently been inspected and did not need to be re-inspected for this change. All of the required trainings have been completed.
- The draft BUA letter was shown.
- The gene inserts footnote (*An updated list of recombinant gene inserts used in this research project must be kept on file with EH&S Research and Occupational Safety.*) should be added to the BUA letter.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Murphy.

- The Committee voted unanimously to approve the draft BUA for Dr. Murphy, pending (1) employee health physician's decision on whether yellow fever vaccine should be offered to workers on this project (2) biosafety officer review of the IACUC protocol (3) modification of the BUA letter to list the gene inserts footnote.
- *Post-Meeting Update: The researchers will be required to meet with an Employee Health medical provider and be offered the yellow fever vaccine before working on this project.*

17. Palmiter, Richard, renewal, *Genetics of Mouse Behavior*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The overall goal of the research is to use mouse genetics and viral transduction to study neural circuits that underlie behavior.
- Adeno-associated viral vectors and canine adenoviral vectors are used on the project, both in mice and in vitro.
- The lab was inspected and all deficiencies were corrected. All of the required trainings have also been completed.
- An updated bloodborne pathogens exposure control plan needs to be submitted.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Palmiter.
- The Committee voted unanimously to approve the draft BUA for Dr. Palmiter, pending submission of the updated bloodborne pathogens exposure control plan.

SUBCOMMITTEE REPORTS:

18. Disis, Mary Nora, renewal, *A Phase 1 Trial of the Safety and Immunogenicity of a Multiple Antigen Vaccine (STEMVAC) in HER2 Negative Advanced Stage Breast Cancer Patients*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a renewal of a clinical trial. A multiple-antigen, plasmid-based vaccine (SEMVAC) targeting proteins involved in epithelial to mesenchymal transition (EMT) that are implicated in breast cancer initiation and progression.
- The vaccine is manufactured at Fred Hutchinson Cancer Research Center and administered at the UW Clinical Research Center.
- All required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Disis.

19. Woolfrey, Ann, renewal, *"A Study Evaluating BPX-501 T cells and AP1903 for Prevention of GVHD after HLA-Haploidentical, Related, T Cell-Depleted HCT for Non-Malignant Diseases"*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a renewal of a clinical trial.
- About 50% of patients who have a disorder of the bone marrow lack what is considered a suitable donor, meaning one who matches them on all or most HLA alleles. When there is not a match for all or most HLA alleles, graft versus host disease (GVHD) is much

more likely to occur. This protocol involves patients who only have a haploidentical bone marrow donor (e.g. a parent or child, and sometimes siblings) available to them. The study aims to minimize GVHD and optimize engraftment and immune recovery in these patients.

- If the patient does develop GVHD, the T-cells are transduced with a ‘suicide switch’ that can be activated to avoid complications.
- The subcommittee also reviewed the proposed consent forms and finds them to accurately describe the risks of the trial to potential participants.
- All required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Woolfrey. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Woolfrey.

20. West, Timothy Eoin, renewal, *DTRA Bps Persistence*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The overall goals of the research are to understand the environmental and genetic basis of antibiotic tolerance in *B. pseudomallei* infection, and to determine whether antibiotic tolerance is responsible for treatment failure in relapsing infection. The lab studies how different elements of the host immune system regulate the response to infection with *Burkholderia pseudomallei*, the etiologic agent of melioidosis. This research focuses on the hosts of *B. pseudomallei*. The goal of the research is to define the mechanisms by which *B. pseudomallei* resists death by antibiotics, thereby allowing for recurrent infection. The genes identified are potential targets for novel melioidosis therapeutics.
- A pool of *B. pseudomallei* transposon mutants will be generated using a transposon and mutants selected for on kanamycin-containing media. Pools of transposon mutants of *B. pseudomallei* will be cultured under various experimental conditions in the presence of antibiotics, and the fraction of persisting cells is quantified. Mice are will also be infected with these mutant pools and are then treated with antibiotics to control the infection. After a short time, the antibiotics are withdrawn to facilitate relapse. These experiments seek to identify genes that are required for bacterial persistence in the host.
- *Burkholderia pseudomallei* is used on the project, both in vitro and in mice. This is a select agent requiring BSL-3 / ABSL-3 containment. This agent also falls under the Dual Use Research of Concern regulations. Dr. West has submitted a DURC application, which was approved by the Dual Use Research of Concern (DURC) Institutional Review Entity (IRE) earlier this month. The DURC IRE determined that Dr. West’s experiments do not meet the definition of dual use research of concern.
- The CDC inspectors requested additional information about this project during the last CDC inspection in October 2016. These documents clarify that no experiments are intended to create antibiotic resistance strains of *B. pseudomallei*. This CDC response document is attached as an appendix to Dr. West’s DURC application and BUA application.
- The draft BUA letter was shown.
- Some rooms listed on the BUA application do not match what is on the IACUC application. The biosafety officer will wait to issue the approval letter until the rooms on both applications match up.

- A member made a motion to approve the draft BUA letter for Dr. West. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. West, pending the rooms on the BUA and IACUC applications matching up.

21. West, Timothy Eoin, renewal, *Host genetics and response to infection*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The overall goal of the research is to understand how genetic variation alters the response to infection, especially in the lung.
- *Burkholderia pseudomallei* is used on the project, both in vitro and in mice. This is a select agent requiring BSL-3 / ABSL-3 containment. This agent also falls under the Dual Use Research of Concern regulations. Dr. West has submitted a DURC application, which was approved by the Dual Use Research of Concern (DURC) Institutional Review Entity (IRE) earlier this month. The DURC IRE determined that Dr. West's experiments do not meet the definition of dual use research of concern.
- *Burkholderia thailandensis*, a Risk Group 2 organism, is also used on the project.
- The lab has been inspected and no deficiencies were found. The required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. West. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. West.

OTHER VOTING ITEMS:

- Biohazardous Waste Management Plan Revision
 - The 2017 revision of the Biohazardous Waste Management Plan has been completed.
 - Information about transgenic plants and plant waste was added to the plan.
 - Contact information was updated for individuals who are responsible for the plan.
 - The Committee voted unanimously to approve the draft Biohazardous Waste Management Plan Revision.

FOR YOUR INFORMATION:

- NIH Reportable Incident
 - An incident report was recently submitted regarding an investigator who did not obtain IBC approval prior to conducting research with human induced pluripotent stem (iPS) cells, which fall under section III-D of the NIH Guidelines.
 - The investigator has a BUA in place, but only unmodified human cells were included. The researchers were not aware that IBC approval is required prior to working with iPS cells for each PI in the University's shared stem cell core facility. The graduate student and postdoctoral employee thought that the UW stem cell core facility had general IBC approval for all users in the

facility. Each PI is required to have IBC approval for work in the core facility in addition to the stem cell core's general IBC approval.

- There was no loss of containment exposure concerns with this incident as the proper BSL-2 containment and procedures were followed.
- The investigator has now received IBC approval for human induced pluripotent stem cells.
- The incident report was submitted to NIH. The IBC will be updated once a response is received.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

MEETING ADJOURNED AT APPROXIMATELY 11:59 a.m.