

MINUTES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE MEETING

October 21, 2015

3:00 PM, 410 Plant Biotechnology Building

MEMBERS PRESENT: Jun Lin, Chair; Patti Coan, Vice Chair; Seung Baek, David Bemis, Tamara Chavez-Lindell, Doris D'Souza, Paul Dalhaimer, Reza Hajimorad, Al Iannacone, Brittany Isabell, Melissa Kennedy, Reggie Millwood, Deidra Mountain, Ling Zhao

Ex-Officio – Linda Hamilton, Brian Ranger, Jessica Woofter

MEMBERS ABSENT: Elizabeth Fozo, Jae Park

OTHERS PRESENT: Rachel Morgan

Opening:

The meeting was called to order by the Chair, Jun Lin at 3:00 PM.

Minutes of September 16, 2015, were reviewed and approved as written.

IBC Applications:

#292-15 (Guoxun Chen) Recombinant DNA & Human Derived Materials, III-D-3, 3-year rewrite

Dr. Chen's research investigates the role(s) of various metabolic proteins in mediating the roles of Vitamin A in energy metabolism and the development of metabolic diseases, such as obesity and diabetes. To achieve efficient transfection of various mammalian cell lines (mouse, rat, and human), Dr. Chen is proposing the use of recombinant, replication incompetent adenoviral vectors to deliver/express genes of interest. Briefly, the adenoviral system is based on a binary plasmid system in combination with HEK 293 packaging cells (which express the E1 gene region necessary for viral replication). The proposed containment level was set at BSL-2. The committee approved the registration pending correction to minor typographical errors and the addition of the IACUC protocol reference.

#390-15 (Deidra Mountain) Human Derived Materials & Infectious Agents, 3-year rewrite

Dr. Mountain was present to discuss her research on the contribution of cytomegalovirus (CMV) infections to restenosis and vasculopathy following solid organ transplants. Human CMV (provided by Dr. Tim Sparer; clinical isolate from urine) will be used for *in vitro* assays with human aortic smooth and endothelial cells. CMV-infected cells will then be used for migration, proliferation, and invasion assays as well as RNA isolation. The committee approved the registration pending addition of Dr. Sparer to the personnel list. BSL-2 practices and containment are to be used for human CMV experiments.

#396-15 (Elizabeth Howell) Recombinant DNA, III-E, 3-year rewrite

Dr. Howell's registration covers her research on chromosomal dihydrofolate reductase (DHFR) vs. R-plasmid-encoded DHFR (R67 DHFR). The registration proposes site-directed mutagenesis of the 2 DHFRs and the resulting effects on their ability to catalyze folate synthesis. Additionally, osmotic stress assays will be used to test tolerance of various accessory enzymes involved in the folate pathway. All recombinant proteins are produced in *E. coli* BL-21. Containment was set at BSL-1. The committee approved this registration pending minor administrative revisions to the non-technical summary.

#433 (Subimal Datta) Recombinant DNA, III-D-4-a, new registration

Dr. Datta's research studies the cellular and molecular mechanisms involved in homeostatically regulated rapid eye movement (REM) sleep in a rat model. A combination of canine-associated virus

(CAV) and adeno-associated virus (AAV) will be used to over-express designer muscarinic-like receptors in specific neural circuits to test whether pharmacological activation of these receptors initiates REM sleep. AAV will be delivered intracranially to the pedunculopontine tegmentum, and CAV will be delivered in the same fashion to the subthalamic nucleus. Viral vectors carrying the transgene of interest are purchased from the UNC Chapel Hill Vector Core Facility (no onsite production). The committee approved the registration pending minor terminology corrections in the technical summary. Containment was set at BSL-1/ABSL-1.

Old Business:

Administrative Report

Brian Ranger provided the Committee with the administrative report. Following up on September 16, 2015, IBC meeting, Dr. Jonathan Wall's registration (#342-15) was corrected administratively so that the project title reiterated the NIH grant title. Dr. Ahmed Bettaieb's registration (#432) was corrected administratively to include the IACUC approval number, training information for all lab personnel, and the approval contingency for completion of laboratory setup and biosafety cabinet purchase/certification is still pending. The IBC Chair administratively approved an amendment to Dr. Ling Zhao's registration (#344-12) to include the use of 3rd generation lentiviral vectors pLKO.1 and pGIPZ to generate lentiviral-based ShRNA knockdown constructs for murine SIRT1, Runx2, GR, and PPARGgamma gene. Also, report constructs GAL4-PGC-1 α & PGC-1 α promoter-luciferase will be obtained from AddGene. The amendment did not change the registration's review category, III-D-3, or approved containment level, BSL-2. Dr. Brynn Voy's registration (#388) terminated as of September 18, 2015, and all human tissue/cells are no longer in use and will be maintained in secure storage.

BSL-3 Progress Updates

Brian Ranger gave the committee an update on the BSL-3 progress. The lab recently completed pre-verification. All control systems, ventilation, and security are working properly. The lab is currently awaiting receipt and installation of a biosafety cabinet. Once that is installed, a final verification and HEPA filter checks will be performed and testing completed. The SOPs and Emergency Response Plans are in the process of being completed.

Policy & Teaching Lab Framework Updates

Brian updated the committee on the general program policy and teaching framework which were circulated to several campus committees and the faculty senate. The review period is until the end of October, and Brian is currently awaiting responses and comments. He will notify the committee once those have been returned to him.

iMedRIS Updates

Brian updated the committee concerning the iMedRIS system. We are currently awaiting an updated form to review as of November 1, 2015. A beta test version of the system is projected to be completed by January 1, 2016.

IBC/Biosafety Program Self-Audit Updates

Dr. Fozo, Dr. Coan, and Brian went through a self-assessment audit using the most recent IBC self-assessment tool available from NIH OBA. A draft will be available for the committee to review at the December meeting. The subcommittee identified a few gaps, some of which will be addressed by the next meeting.

Lentiviral Vector Exposure – NIH Follow-up

Brian notified the committee that he received a response from the NIH concerning the lentiviral vector exposure. The NIH appreciated the notification and said no further actions were required regarding the incident.

Other

Brian notified the committee that the campus safety offices collaborated on bringing Dr. Bob Emery, Southwest Center for Occupational and Environmental Health, to campus to speak at the EH&S Academy. The academy provided insights and constructive program management tools/strategies for safety managers (particularly at academic institutions). The academy was hosted at the UT Conference Center on October 19th and 20th and was a success and very informative for all parties involved.

New Business:

BSL-3 Policies/Management Plan Review Subcommittee

Brian asked the committee to establish a subcommittee to review space and operational policies/procedures for the new BSL-3 laboratory. Dr. Lin, Dr. Kennedy, and Al Iannacone volunteered to review the documentation.

IBC Management Best Practices – State College, PA

Brian notified the committee that he and Linda Hamilton will be out of town from November 17th-20th to attend a symposium on IBC Management & Best Practices. The symposium is being held in State College, PA.

November Meeting Date

Brian notified the committee that the November meeting would be canceled due to the IBC Management & Best Practices symposium conflicting with the scheduled meeting. Brian proposed fusing the November and December meetings into one, possibly for the first or second week of December.

Other

Brian circulated an email he received from Dr. Joh Stier, Associate Dean for CASNR, regarding ethical and ecological concerns related to CRISPR-Cas9 genome editing technologies, particularly those introduced into wild/natural systems. Brian has reached out to the NIH Office of Biotechnology Activities regarding the use of genome editing tools (CRISPR, TALEN, simple site-directed mutagenesis) and applicability of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids* (response shared with committee). Brian indicated that the IBC should continue to monitor these developing technologies, particularly those that are outpacing the U.S. regulatory framework, as institutional policies may be necessary. Brian and Reggie Millwood suggested that Dr. Neal Stewart be invited to an upcoming meeting and talk about these technologies in more detail and help give the IBC a better understanding of the factors/considerations involved.

The meeting was adjourned at 3:57 PM. The next meeting has been canceled, and the new (December) date is to be determined.