

MINUTES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE MEETING

December 19, 2012

3:00 PM, 410 Plant Biotechnology Building

MEMBERS PRESENT: Chunlei Su, Chair; Jun Lin, Vice-Chair; Seung Baek, Patti Coan, Paul Dalhaimer, Doris D'Souza, Al Iannacone, Melissa Kennedy, Dan Kestler, Reggie Millwood, Jae Park, Ling Zhao
Ex-Officio – Brian Ranger, Jonathan Phipps, Mark Smith

MEMBERS ABSENT: David Bemis, Tamara Chavez-Lindell, Bonnie Ownley

OTHERS PRESENT: Jessica Woofter

Opening:

The meeting was called to order by Chair, Chunlei Su at 3:01 PM.

Brian Ranger introduced Dr. Jonathan Phipps to the committee as the new Biosafety Specialist hired to replace Sarah DiFurio.

Minutes of September 19, 2012 were reviewed and approved as written.

IBC Applications:

#292-12 (Guoxun Chen) Recombinant DNA/Human Derived Materials Registration, III-D-3/E, 3-year rewrite

Dr. Zhao summarized Dr. Chen's research investigating 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 BSL-2. The committee approved the registration pending administrative correction of personnel training dates and source of the insert genes. There was one abstention.

#295-12 (Stephen Kennel) Recombinant DNA/Human Derived Materials Registration, III-D-4-b/E, 3-year rewrite

Dr. Kennel's registration covers the development of scFv that bind to tumor blood vessels. ScFv production is based on a standardized, commercially-available system using recombinant phagemids bearing the genes encoding the hypervariable regions of antibody heavy and light chains, M13 filamentous phage and *E. coli* TG-1 and HB2151 strains. Dr. Kennel's proposed use of this system also includes a brief, terminal enrichment step in mice (III-D-4-b). Containment levels were set at BSL-1/ABSL-1. The committee approved the registration as written with one abstention.

#298-12 (Doris D'Souza) Infectious Agent Registration, 3-year rewrite

Dr. D'Souza's recapped her registration covering methodologies for the detection and inactivation of multiple foodborne pathogen isolates, the development of mitigation strategies to control microbes in

ready-to-eat products, and methods to study stress responses and gene expression of various Risk Group 2 bacterial (e.g. EHEC, *Salmonella spp.*, *Listeria spp.*) and viral (e.g. noroviruses, hepatitis A virus) pathogens. Containment was set at BSL-2. The committee approved the registration pending administrative correction of a minor typographical error, the lab coat laundering protocol, and clarification of detection/enumeration assays. There was one abstention.

#344-12 (Ling Zhao) Recombinant DNA/Human Derived Materials Registration, III-D-3, 3-year rewrite

Dr. Zhao's registration covers her research on the importance of pattern recognition receptors in the cellular response(s) to insulin and the role that they may play in inducing insulin resistance in fat cells. Briefly, replication incompetent adenoviral vectors (as described for #292-12 above) will be used to deliver plasmids over-expressing target genes or siRNA knock down target gene expression. The containment level was set at BSL-2. The committee approved the registration pending administrative correction of personnel training dates. There was one abstention.

#345-12 (Jason Collier) Recombinant DNA/Human Derived Materials Registration, III-D-3, 3-year rewrite

Dr. Zhao summarized Dr. Collier's registration covering his research on gene function in an effort to better understand how to protect against losses in insulin producing cells that lead to diabetes mellitus. The registration proposes generating plasmids and recombinant, replication incompetent adenoviruses (as described for #292-12 above) to express/deliver genes related to function and viability in rat insulinoma cell lines and islets. Containment was set at BSL-2. The committee approved the registration pending administrative correction of personnel training dates. There was one abstention.

#393 (Neal Stewart) Recombinant DNA Registration, III-E, new registration

Reggie Millwood summarized Dr. Stewart's registration covering his research on transgene flow and introgression using model transgenic plants (e.g. Arabidopsis, rice, switchgrass) produced with a traditional Agrobacterium-mediated gene transfer. Insert genes include commonly used resistance and fluorescent markers as well as various inducible restriction endonucleases or recombinases involved in conditional pollen ablation or transgene removal (bioconfinement). Containment was set at BSL-1/BL-1-P. The committee approved the registration pending clarification of "*glufocinate ammonium (basta)*" in the addendum table d and whether it is a chemical or gene name. There was one abstention.

#396 (Elizabeth Howell) Recombinant DNA Registration, III-E, new registration

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 as written.

Old Business:

Administrative Report

Brian Ranger provided the committee with the administrative report. Following up on the September 19, 2012 IBC meeting, Dr. Jon Wall's registration (#342-12) was corrected administratively to include IACUC reference #1628 to the technical summary. Dr. Josh Bembenek's registration (#392) was corrected administratively with the Principal Investigator to add a few minor clarifications to the technical summary. Dr. Doris D'Souza's amendment to her registration (#298-09) was approved by the IBC Chair on September 26, 2012. The amendment included the addition of Tulane virus (primate calicivirus, RG2) and Rhesus macaque cell line (LLC-MK2). Dr. Liz Fozo's amendment to her

registration (#352) was approved the IBC Chair on November 13, 2012. The amendment included the generation of Str-R and Nal-R EHEC. Two registrations were administratively terminated (Dr. Naima Moustaid-Moussa's #242-11 & Dr. Madhu Dhar's #355).

Max Cheng-Registration #296-12 Update

Brian Ranger gave the committee a brief update about Dr. Cheng's extension request on his registration proposal.

Annual Refresher Training for BSL-2/BBP

Brian Ranger provided the committee with a brief update on the annual refresher training for Biosafety Level 2 and Bloodborne Pathogens training. The trainings have been extended to remain open until the end of December.

IBC Registration Form User's Guide

Brian Ranger informed the committee that guide has been posted to the Biosafety Office website.

New Business:

Update to NIH Guidelines (to be implemented by 03/13)

Brian Ranger notified the committee that the *NIH Guidelines* now include synthetic nucleic acids capable of base pairing/replicating and/or gene expression. Institutional compliance is expected by March 2013. The Biosafety Office will send a formal announcement to the research community.

NIH Automated Registration System for IBCs

Brian Ranger notified the committee that Office of Biotechnology Activities is piloting a new electronic registration for IBC membership.

Select Agent Regulations Updates (10/5/2012)

Brian Ranger notified the committee that implementation of the Select Agents changes were effective October 5, 2012 and institutions or facilities now subject to the regulation but not meeting requirements have until March/April of 2013 to make necessary changes. However, this does not have any direct impact on the University of Tennessee at this time.

2012 ABSA Conference Highlights

Brian Ranger notified the committee that he attended the ABSA 2012 Conference, providing brief highlights from the conference including updates/FAQs relative to the recent *NIH Guidelines* and Select Agent Regulations changes.

Meeting Announcements

Brian Ranger notified the committee that one of the items that resulted from the ABSA 2012 Conference was that only posting IBC meeting announcements/dates on a website may not meet the NIH expectations for community transparency. The committee brainstormed on a few ideas about how to make the public better aware of the monthly IBC meetings.

Autoclaved Waste Collection Concerns/Complaints

Brian Ranger notified the committee that the Knoxville campus has removed their third party contractor for waste collection, and is now using UT employees. Brian met with the janitorial staff and trained them about autoclaved waste collection and procedures.

User Satisfaction Survey

Brian Ranger notified the committee that User Satisfaction Survey was launched in late November and will remain open until January 31, 2013.

Lab Inspections-New iAuditor Reporting

Brian Ranger notified the committee that the Biosafety Office is now using iAuditor, which is a new application on the iPad, to inspect laboratories and facilities. The application helps streamline a lot of the questions or items to look for while inspecting a facility..

Meeting with Dr. Taylor Eighmy, VC-Research

Brian Ranger notified the committee that he met with Dr. Taylor Eighmy the new Vice Chancellor for the Office of Research.

Coverage of Nanoparticle Research

Brian Ranger addressed the committee concerning nanoparticle research and whether the committee should start reviewing this type of research. The committee agreed that nanoparticles used for intentional delivery to/modification of biological systems may be best addressed by the IBC. A more thorough discussion and possible adoption into the Charter are pending.

Community Storage Solutions

Brian Ranger notified the committee that the iAuditor application used for inspections will also help track community and shared equipment and that it is properly stored and contained.

Human Gene Transfer

Brian Ranger notified the committee that UT Cancer Institute is looking for an IBC to review a human gene transfer protocol under the auspices of a biotech company. The IBC Charter defers all human clinical trials to the UTHSC in Memphis and does not provide "fee-for-service" reviews. The committee agreed that it was not within its purview to review this protocol.

The committee will reconvene January 16, 2013.

The meeting was adjourned at 4:23 PM.