INSTITUTIONAL BIOSAFETY COMMITTEE MEETING
July 15, 2020
2:00 PM, Zoom Meeting

MEMBERS PRESENT:	Chair –Elizabeth Fozo, Vice Chair-Stephen Kania, Marc Caldwell, Lori Cole, Doris D'Souza, Lezlee Dice, George Dizikes, Reza Hajimorad, Jun Lin, Ling Zhao
	Ex-Officio – Linda Hamilton, Ahmad Mitoubsi, Sandra Prior, Sarah Pruett, Brian Ranger, David White, Jessica Woofter
MEMBERS ABSENT:	Feng Chen, Paul Dalhaimer, Brittany Isabell, Melissa Kennedy, Deidra Mountain
OTHERS PRESENT:	David Anderson, Terry Hazen

Opening:

The IBC Chair called the meeting to order at 2:02 PM. The minutes of June 17, 2020, were reviewed and approved as written.

Full Member Review IBC Registrations:

#IBC-17-502-2 (Paul Dalhaimer) Recombinant DNA & Human Derived Materials, III-F-8 (Appendix C-1), 3-year rewrite
Dr. Dalhaimer's research targets lipid droplets of adipocytes in white adipose tissue. To achieve their goal, his lab will modulate a natural process of lipid droplet breakdown whereby the droplets are guided to lysosomes so that the contents of the droplets, neutral lipids, can be converted into energy or building blocks for phospholipids. They will genetically modify PLIN2 (a lipid droplet surface protein) and LAMP (a lysosome protein) with intein sequences so that the lipid droplet has a high affinity (2 nM) for lysosomes. The effectiveness of our therapy will be measured by staining the droplets and quantifying their number and size distributions with microscopy in human embryonic kidney cells (HEK293) that are expressing our constructs from plasmids. Containment was set at BSL-2. The committee approved the registration as written.

#IBC-20-548-2 (David Anderson) Infectious Agents, New registration
Dr. Anderson was present to discuss his research on osteomyelitis, an inflammatory bone disease caused by an infecting microorganism that affects both humans and animals. The result is progressive bone loss and destruction, accounting for significant morbidity and expense. Opportunistic Gram-positive staphylococci, specifically *Staphylococcus aureus*, are responsible for up to 75% of clinical cases. Recent studies have demonstrated that bone cell invasion contributes to the development of infection, and bacteria initiate this invasion process by adhering to the osteoblast extracellular matrix components through the expression of adhesins. Once *Staphylococcus aureus* has adhered to bone cells and has become internalized, it is then capable of stimulating a shift in the relative levels of osteoblastic activity that can result in inflammatory bone pathology. The overall goal of this proposal is to better understand the

pathogenesis associated with osteomyelitis induced hypertrophic mineralization initiated by *Staphylococcus aureus* infection in long bones, specifically the effect on osteoblasts. Containment was set at BSL-2. The committee approved the registration pending correction of a typographical error in nontechnical summary; the addition of detail about ST 398 strain and the potential for transmission; removal of animal housing locations; the addition of a statement clarifying volumes for *Staphylococcus aureus* strains and that it will be treated as a zoonotic agent; an update to the biosafety cabinet certification date and spill response.

#IBC-20-549-2 (Terry Hazen) Infectious Agents & Human Derived Materials, New registration

Dr. Hazen was present to discuss his research to determine which buildings at UTK (especially dorms) may have SARS CoV-2 virus signals (Covid-19) in the wastewater from the building. This is simply a presence/absence test so that we can determine if further testing is needed. Positive outcomes will not be handled by this team (pooled surveillance testing by floor or section of the building followed by individual testing by the student health center for CLIA certified testing and Contact-Tracing). SARS CoV-2 has been detected in wastewater by many others. This surveillance will last until Covid-19 is no longer a significant health threat at the UTK campus. Containment was set to BSL-2. The committee approved the registration pending the following corrections which were approved by a designated review on July 27, 2020:

1. Points to address within the non-technical summary:
    a. Swap the technical and non-technical summaries.
    b. Purpose section: Human waste/sewage samples will be collected from about 30 UTK campus bldgs weekly. Please define how long this surveillance may last. 'Positive outcomes' sounds vague.
    c. Research Design section:
        i. Clarify the sampling size and frequency. "We anticipate sampling 1-20 buildings in one day every week", which seems not consistent with previously proposed 30 bldgs.
        ii. It is not clear if all sampling sites (~30) have a similar design/setting. Detailed information (or protocol) for collecting human waste/sewage samples were not described, but are critically needed for risk assessment of this registration. It was indicated that 'UTK EHS will review all sampling sites, manhole/dip sampling may require additional controls'.
        iii. Please provide SOPs for the different types of sampling sites, particularly addressing how "samples will be collected in 250 ml sealed centrifuge tube and immediately decontaminate", PPE handling throughout the collection of sewage samples in various sites within a single day, accidental spills, waste disposal, transportation, and sample delivery. Note, given that there are sampling sites internal and external depending upon the building, different template SOPs should be developed to address the differences in protocols for sampling inside and outside of buildings.
        iv. Personnel involved in the study will be required to complete Biosafety training, receive appropriate vaccinations (Hep A & B, Tetanus), and maintain COVID-19 surveillance after being initially tested for a negative result. Please also address these requirements.
        v. It seems that cleaning contaminated work clothing (coveralls) using 0.05%

chlorine is not sufficient. Bleach is typically recommended at a use dilution of 1:10 to 1:100 of standard concentrated bleach (0.5% to 0.05% sodium hypochlorite). In this range, it is considered an intermediate-level disinfectant. In the context of fecal contamination, and in consideration of the array of pathogens that may be present as well as organic inhibitors, Brian recommended for the higher end of the spectrum (1:10 dilution; 0.5% sodium hypochlorite).

vi. Additional rooms in SERF that may be used (dependent upon how PPE will be removed/decontaminated, etc) need to be identified in the report both in the technical summary and in facilities used section. If a room will be used for such procedures, a detailed SOP for what activities will be performed in such rooms (PPE cleaning, decontamination, etc) must be provided.

d. Project Procedures section: In addition to the above points, please provide a more complete description of the "enclosed rotor" and how it meets engineering control requirements. Provide more information about how this mixed waste will be chemically treated to render it non-infectious.

2. Section 6.3 should be “YES” because they proposed to use Centricon Plus-70 ultrafilter to concentrate on infectious agents.
3. Section 6.5 states that the project does not involve the use of sharps in conjunction with an infectious agent.
4. Section 6.8 should be “YES” because they proposed to use a high-speed centrifuge to process infectious agents-containing samples (initial centrifugation as well as the final step using Centricon Plus-70).
5. Section 9.1 should only be BSL-2.
6. Section 9.2 requires clarification of the biosafety cabinet certification date.
7. Section 9.4 should include the use of booties.
8. Section 9.5 requires further clarification concerning the reusable PPEs used during sewage sampling (e.g. coveralls, rubber boots).
9. Section 9.7 requires identification of contact times and shelf life for Bleach and alcohol disinfectants. Bleach is typically recommended at a use dilution of 1:10 to 1:100 of standard concentrated bleach (0.5% to 0.05% sodium hypochlorite). In this range, it is considered an intermediate-level disinfectant. In the context of fecal contamination, and in consideration of the array of pathogens that may be present as well as organic inhibitors, Brian recommended for the higher end of the spectrum (1:10 dilution; 0.5% sodium hypochlorite).
10. Section 9.8 requires an update to the spill response.
11. Section 9.9-c requires additional information regarding the commercial transportation of biohazards involved with this study. If materials will be transported on campus and not in commerce, uncheck 9.9 c.
12. Section 10.3 requires clarification of the autoclave listed in SERF 432.
13. Section 11.6 should list the medical contractor, Advantra.
14. Section 12.1 should be “Yes” to indicate the generation of sharp waste.
15. Section 15.1 requires a statement indicating the appropriate vaccinations (Hepatitis A & B, Tetanus), and that personnel will maintain COVID-19 surveillance after being initially tested for a negative result.

Designated Member Review IBC Registrations:

None.

Old Business:

Administrative Report

i. *Contingencies*
Following up on June 17, 2020, IBC Meeting, Dr. Brad Binder's registration (#08-331-1) was edited to include the correction of typographical errors and a statement clarifying autoclave usage in the technical summary. Dr. Marc Caldwell's registration (#17-449-2) was transferred to Dr. Andrea Lear and corrected to include a statement regarding work completed on the study in the technical summary as well as the updated biosafety cabinet certification date. Dr. Paul Dalhaimer's registration (#17-451-2) was corrected for minor typographical errors; to include source locations for the HeLa strains; to clarify volumes, handling and disposal procedures of the nanoparticles; and to include an update to the biosafety cabinet certification date, biohazardous spill response, and medical contractor, Advantra. Dr. Rajan Lamichhane's registration (#20-546-1) was updated to include an edited working and full title for continuity and the technical summary was expanded to include the source of the protein as well as indicating how biotinylation is done and what type of hose will be used. Dr. Frank Loeffler's registration (#20-547-2) was edited to include the removal of the oral and nasal swabs, and to include a statement that his lab will be using an inactivated virus and proxy bacteriophages (non-pathogenic surrogates) will be used instead of live SARS-CoV-2 virus. They will work with a variety of methods, both virus-inactivating and non-inactivating. Note that no live virus will be used during the development phase; will be working with self-collected saliva samples from lab volunteers that have been tested negative for COVID-19.

ii. *Administrative Approvals*
Dr. Timothy Sparer's registration (#06-277-2) was administratively approved by the IBC Chair on 6/29/2020 for the amendment covering non-SARS coronaviruses. USDA permit has been received for those affecting livestock (porcine) and poultry. Changes do not change the NIH review category or approved containment level.

iii. *Administrative Terminations*
None.

iv. *Administrative Exemptions:*
None.

v. *Accidents, Injuries/Exposures:*
None.

vi. *Laboratory Report (Hamilton)*
None.

vii. *iMedRIS Update, Manual Reviews, & System Orientation (Woofter)*
None

Reduced laboratory activities for holidays, field work, or emergencies
Dr. Fozo presented the committee with an edited version of the charter amendment addressing reduced research laboratory activities for holidays, field-work, or emergencies. The committee approved the draft for incorporation into the IBC Charter.

Approval Process Escalation SOP
Jessica presented the draft workflow diagram and IBC Charter Registration, Reporting, Review, and Recordkeeping Procedures. The diagram and SOP were both accepted and approved by the committee pending one minor edit regarding the timing of notification for the Department Head.

New Business:

Introduce New IBC Members
Dr. Fozo introduced the new committee members Dr. Feng Chen, Lezlee Dice, and Dr. Stephen Kania. Dr. Fozo has replaced Dr. David White as the IBC Chair and Dr. Stephen Kania will be serving as the Vice Chair.

iMedRIS Form Updates
Jessica presented the committee with a draft of the new iMedRIS form for comment by the committee. The committee was asked to review the document for the next meeting.

The meeting was adjourned at 4:46 PM. The next meeting scheduled for August 19, 2020, via Zoom.