Lundquist Institute for Biomedical Innovation
at Harbor-UCLA Medical Center
Institutional Biosafety Committee
Meeting Minutes
01/13/2026
Zoom Virtual Conference

MEMBERS PRESENT	MEMBERS ABSENT
David Applebaum, M.S.	Fawzia Bardag-Gorce, Ph.D.
Helen Chun, Ph.D.	Scott Filler, M.D.
Rami Doueiri, Ph.D.	Fang Wang, Ph.D.
Adrienne Zweifel, Ph.D.	

STAFF PRESENT	STAFF ABSENT
Elizabeth Burrola, CIP	Rosemary Madnick, MBA
Rosa Harmon, CPIA	
Annie Hilo	

1. CALL TO ORDER

The meeting was called to order by David Applebaum, M.S. at 3:01 PM.

2. MEETING MINUTES

The minutes of the December 9, 2025 meeting were presented.

A motion was made and seconded to APPROVE the minutes.

Vote: For - 4, Opposed - 0, Absent – 0, Abstained - 0, Recused – 0

3. BUA REVIEW

a. Continuations

IBC #: IBC 22808-01
PI: Shu Li
iRIS Ref #: 063359

Summary: The experiments include treating rodent models with an engineered probiotic to determine whether it reduces methionine and homocysteine levels. Bacteria grown in the sponsor's facility will be used in the labs for study. Bacteria E.coli contains recombinant DNA will be fed to the animal.

Inserts: Methionine Gamma Lyase

Vectors: pV12

Pathogens: NA

Risk Assessment: Risk Group 1

Containment: BSL-1

Training: Training has been verified by the Research Compliance Office Staff and EHS.

NIH Guidelines: III-E

Conflicts: NA

Motion: A motion was made and seconded to REQUIRE MODIFICATIONS TO SECURE APPROVAL of the BUA.

Modifications Required to BUA:

1. **Section 4.0 - Background Information**
   - For item 4.4, the PI is to create an entry for each study personnel and clearly state their name and date of Biosafety Training, and email the certificate of training to Research Compliance Staff.

2. **Section 5.0 - Description of Procedure(s)/Research**
   - **Overall Goal:**
     - The PI is to remove justification for why mice and rats are being used in this study as it is unnecessary.
     - The PI is to explicitly state that Fgf21 is a marker produced by the body (not supplied by the recombinant E.coli) and explain why this particular protein is important.
     - The PI is to introduce Methionine Gamma Lyase and explain how it fits into this work.

   - **Experimental Procedures -** The majority of what's written in this section is outside the scope of IBC review (blood draws, diet, initial Met challenge). The PI is to revise this section and limit the information to:

     - How lab staff handles recombinant E.coli before administration into rodents
     - How recombinant E.coli will be administered into rats/mice (hand restrained v. restrainer, use of pipette tips for delivery, etc)
     - Collection of samples after recombinant E.coli has been administered including any tissues, organs being harvested
     - Processing of samples listed in #3. Discussion of processing should continue until the use of chemicals/other procedures that would be expected to inactivate the recombinant material present.

   - **Hazardous Potential Assessment** –
     - The PI is to explicitly state that the E.coli used in this work is:

       - Considered Risk Group 1, which means that it is not expected to cause disease in immunocompetent individuals.
       - Is a commensal.

- For paragraph #1, instead of outlining how a risk assessment would be performed, the PI is to write up the actual risk assessment for the E.coli Nissle 1917 and include how the presence of the plasmid or the expression of the gene of interest is expected to affect the host compared to the wild-type Nissle.
- For paragraph #1, the PI is to revise the wording from ".. this should be followed by..." and "...strain should be considered..." to "this will be followed by..." and "strain will be considered...."
- The PI is to delete "Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials and ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics)."

- **Containment Conditions** - This section is written as a theoretical, the PI is to revise this section to show what is the lab actually doing.

  - Will a biosafety cabinet going to be used when handling the E.coli culture? If a BSC will not be used in this work, as provided in Section 6, then it doesn't make sense to reference one here.
  - Is the concentration of E.coli received by the sponsor exactly what is needed for the gavage or will the lab need to dilute or modify it in some way?
  - Will the animals be expected to shed the recombinant bacterial in feces/urine and if so, how will the contaminated bedding be contained (filter-top caging/IVC system?)
  - How will tissues harvested from inoculated mice be processed?

  - If the lab and sponsor are completely separate entities (and the BUA covers just the lab), the PI is to start this narrative when the lab officially takes possession of the E.coli culture and stop if/when the samples are either inactivated or transferred back to the sponsor. Discussion of the "propagation and growth of cultures" when the lab isn't actually performing this step is unnecessary and is to be removed.
  - The PI is to state how the lab will dispose of (1) solid waste, (2) liquid waste, and (3) sharps waste (if generated).

- **Emergency Procedures:**
  - The PI is to replace "Work surfaces are decontaminated once a day" with "after work with E.coli or recombinant materials has concluded, as needed, and after any spill of viable material."
  - The PI is to replace "Spills and accidents" with "Spills and/or other incidents".
  - The PI is to provide details regarding how staff are to respond to an exposure that is likely to occur in the lab (splash to face/mucous membranes and skin exposure).
  - The PI is to provide details regarding expected symptoms of an exposure and state whether treatment is readily available.
  - The PI is to add a sentence acknowledging that the TLI Research Compliance Office will be notified if an occupational exposure occurs as this is an NIH-reportable incident.

3. **<u>Section 6.0 - Risk Assessment</u>**

- For item 6.1, the PI is to provide responses to the following questions, if not applicable, state NA:
    - Identify all equipment (besides BSC) to be used with Biohazardous Materials (e.g., autoclave, incubators, centrifuge, etc.). If autoclave will be used to inactivate waste, please include this information.
    - Identify the location of each piece of equipment (Building and Room #).
- For item 6.2, the PI is to select III-E as the applicable section of the NIH Guidelines.

4. **Section 9.0 - Vectors for Recombinant or Synthetic DNA**

- For supplier, it's unclear whether the lab is separate from the sponsor. The lab references the sponsor as a separate entity in other parts of this application (Section 6.0), but then states that the spobsor is the supplier of the vector in item 9.2, which makes the follow-up text in the parentheses confusing. The PI is to revise the section to reconcile the discrepancy.
- The PI is to change the response to the "Potential Hazards" question from “none” to “unknown” or "not expected to be hazardous".

5. **Section 11.0 - Research with Whole Plants or Animals as Hosts**

- For item 11.1, the PI is to revise the response from "No" to "Yes" since the recombinant E.coli Nissle will be administered to the rodents via gavage, and complete all questions that will appear in this section as the result of this revision.

Vote: For - 4, Opposed - 0, Absent - 0, Abstained – 0, Recused – 0

IBC #: IBC 22926-01
PI: Xiling Shen, Ph.D.
iRIS Ref #: 063213

Summary: Researchers are developing an intravital window system to allow direct visualization of the placenta and embryo during development in an animal model, and using viral vectors will assess the development of tissues during the post-implantation phase of fetal development. To understand how neurons migrate into tissues and how tissues and organs mature during this period, researchers will use viral vectors expressing fluorescent proteins injected into rodents.

Inserts: GFP, RFP

Vectors: Adenovirus-associated virus, Lentivirus

Pathogens: NA

Risk Assessment: Risk Group 2

Containment: BSL-2

Training: Training has been verified by the Research Compliance Office Staff and EHS.

NIH Guidelines: III-D, III-E, III-F

Conflicts: NA

Motion: A motion was made and seconded to REQUIRE MODIFICATIONS TO SECURE APPROVAL of the BUA.

Modifications Required to BUA:

1. **Section 5.0 - Description of Procedure(s)/Research**
   - Hazardous Potential & Containment Conditions – The PI is to replace "should be" with "will be" for AAV's disinfection procedures.
   - Containment Conditions - The BUA stated that AAV will be handled at BSL2 containment in the Assessment of Hazardous Potential section, but the Precautions for safe handling section states that BSL1 guidelines will be used. The PI is to address this discrepancy. AAV may be handled at BSL1/ABSL1, while Lentivirus is handled at BSL2/ABSL2.
   - Emergency Procedures (Skin) – The PI is to add "for 15 minutes".
   - Emergency Procedures (Eyes) – The PI is to change "several minutes" to "15 minutes".

2. **Section 6.0 - Risk Assessment**
   - For item 6.2, "III-F (Exempt Experiments)" was selected. The PI is to clearly identify the work that falls under this exempt category. If this was selected in error, the PI is to de-select.

Vote: For - 4, Opposed - 0, Absent - 0, Abstained – 0, Recused – 0

OTHER BUSINESS

a. Safety Committee Report – Accidents/Spills
Mr. Applebaum stated no incidents were reported.

b. Verbal update on new BUA form
Ms. Harmon and Dr. Zweifel shared the updated BUA form with the Committee and reviewed the changes that had been made. The Committee discussed the form and provided feedback for minor editorial revisions to improve clarity. An Incident Report Form will be developed in iRIS, following the OSP incident reporting template.

The revamped BUA will be published (activated) in iRIS next week with an announcement sent to the research community via iRIS. In the announcement, researchers will be advised not to convert their existing IBC forms to the new BUA until their triennial renewal, at which point they will be required to use the updated BUA. The Committee agreed that this provides an opportunity to remind researchers of their obligation to provide and review their approved BUAs with their laboratory staff, maintaining documentation of this training for potential requests from the NIH or TLI IBC.

c. Self-Assessment Tool: Physical Containment – Laboratory Environment section
The Committee discussed concerns about proper personal protective equipment (PPE) usage and access control in laboratory areas, particularly regarding facilities and IT staff

entering restricted areas without appropriate PPE. The Committee noted that while signage is in place, enforcement and training need improvement, with suggestions made to provide lab coats for visitors and implement stricter protocols for facility staff entering restricted areas. The Committee also discussed the need for continuous training and reinforcement of PPE protocols. The Vice President of Facilities and Support Operations will be included in training efforts.

d. Other Business

Dr. Zweifel inquired if a BUA involving a bacteriophage that kills a non-human pathogen should be reviewed by the IBC. Dr. Doueiri reminded the Committee that bacteriophages can spread rapidly and emphasizes the need for appropriate engineering controls to prevent contamination of others' work. For this reason, the Committee agreed that it will review the addition of bacteriophages, even when they do not pose a risk to humans.

With no further business, the meeting adjourned at 4:09 PM

Respectfully submitted,

Signed by:
Dave Applebaum
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David Applebaum, M.S.
Member, Institutional Biosafety Committee

cc: Research Committee Agenda