Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center Institutional Biosafety Committee Meeting Minutes

08/12/2025 MRL 107 & Zoom Virtual Conference

MEMBERS PRESENT

MEMBERS ABSENT

David Applebaum, M.S.
Fawzia Bardag-Gorce, Ph.D. (attended via Zoom)
Helen Chun, Ph.D. (attended via Zoom)
Rami Doueiri, Ph.D.
Scott Filler, M.D.
Fang Wang, Ph.D. (attended via Zoom)
Adrienne Zweifel, Ph.D.

STAFF PRESENT

STAFF ABSENT

Elizabeth Burrola, CIP Rosa Harmon, CPIA Annie Hilo

Rosemary Madnick, MBA

1. CALL TO ORDER

The meeting was called to order by Scott Filler, M.D. at 3:02 PM.

2. MEETING MINUTES

The minutes of the June 10, 2025 meeting and July 22, 2025 emergency meeting were presented.

A motion was made and seconded to APPROVE the minutes from the two meetings.

Vote: For - 7, Opposed - 0, Absent -0, Abstained - 0, Recused -0

3. BUA REVIEW

A. Initial Reviews

IBC #: IBC 2025-U-C. albicans MS

PI: Marc Swidergall, Ph.D.

iRIS Ref #: 062670

Summary: Experiments involve the use the opportunistic pathogenic fungus Candida albicans to understand immune responses to fungal colonization and infection. The lab uses the fungus as a model organism to infect or colonize their mice model orally or systemically followed by analysis of different immune responses. Alternatives to mammalian: in vivo model, non-human animal model. No genetic modifications of Candida albicans strains will be performed.

Inserts: NA

Vectors: NA

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Pathogens: Candida albicans

Risk Assessment: Risk Group 2

Containment: ABSL-2

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

NIH Guidelines Section: III-F

Conflicts: None

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

Modifications Required to BUA:

1. Section 5.0 - Experimental Procedures

- Assessment (Bloodborne Pathogens) The BBP Standard does not limit its scope to
 primary material. The PI is to update what is currently written with "Handling any human
 materials poses a risk of exposure to bloodborne pathogens such as HIV, Hepatitis B/C
 Virus. Staff will be trained on the safe handling of sharps and be offered the Hepatitis B
 vaccination series at no cost."
- Containment The PI is to explicitly state the homogenization will be done in a fume hood or using a face shield and a surgical mask as it's an aerosol generating procedure.

2. Section 8.0 - Infectious Agents

- Candida albicans The PI is to limit chemical disinfectant for spills to 10% household bleach (final concentration).
- The Board recommends proactively including genetically modified candida in this BUA
 in case the lab intends to study mutants in the future. If added, the risk assessment will
 not increase.

3. Section 12.0 - Research with Eukaryotic Hosts

- 12.4 Based on the in-person conversation on 8/11/2025, the PI is to confirm whether a selection marker is present in this cell line.
- 12.5 The entire lab is Biosafety Level 2 space. The PI is to clarify what will be done at BSL1 or deselect BSL-1.
- 12.5 The references for how this cell line was constructed was for the Biosafety Officer's information to help determine whether this line is exempt from the NIH

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Guidelines and does not need to be included here. The PI can leave the URL, but the other references should be deleted.

Vote: For - 7, Opposed - 0, Absent - 0, Abstained -0, Recused -0

B. Amendments

IBC #: IBC 2024-U-CRISPR SF

PI: Scott Filler, M.D. iRIS Ref #: 062578

Summary: The lab intends to use CRISPR/Cas9 to construct a pool of human cells, each of which has a deletion of a different gene. They will screen these cells to identify genes whose products are required for fungi to damage these cells. They will also verify these results by using CRISPR/Cas9 to delete specific genes in the human cells.

The lab will also use CRISPR/Cas9 to delete genes in the fungi Candida albicans and Aspergillus fumigatus to identify genes that are required for virulence.

Inserts: Brunello sgRNA library, pFC331, pFC334, pVG2.2hph, p402, pNAT, pV1093, GFP, CFP, BFP, RFP

Vectors: pLenti-Cas9-Blast vector, pLentiGuide-Puro plasmid, psPAX2, pCMV-VSVG, Brunello human whole genome sgRNA library, pLentiCRISPRv2-blast plasmid, pV1039, pFc334, Pfc331

Pathogens: Candida albicans, Aspergillus fumigatus, candidalysin, Candida glabrata, gliotoxin

Risk Assessment: Risk Group 2

Containment: ABSL-2

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

NIH Guidelines Section: III-D

Conflicts: Scott Filler, M.D. was excused from the meeting room during the discussion and vote.

Motion: A motion was made and seconded to APPROVE the BUA.

Vote: For - 6, Opposed - 0, Absent - 0, Abstained - 0, Recused - 1 (S. Filler)

C. Continuing Reviews

IBC #: IBC 22860-01

PI: Achal Singh Achrol, M.D.

iRIS Ref #: 062617

Summary: Research aims to evaluate and optimize the performance of a delivery system for different classes of therapeutics, ranging from small molecules to larger biologics (e.g., adenoviruses). Specifically, the researchers will assess the safety, precision, and distribution characteristics of therapeutics delivered by the system in comparison to traditional methods.

Inserts: eGFP, CMV, HSV-thymidine kinase under transcriptional control of RSV-long terminal repeat

Vectors: pcDNA3.1 + N-eGFP 6.1kb, AAV1-CMV-GFP, AAV9-CMV-GFP, AAV8-CMV-GFP, AAV1-GFP, AAV8-GFP, AAV9-GFP, AdV-CAN0924, AdV-GFP, antisense oligonucleotides

Pathogens: NA

Risk Assessment: Risk Group 1 & Risk Group 2

Containment: ABSL-1 & ABSL-2

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

NIH Guidelines Sections: III-D, III-E

Conflicts: None.

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

• The PI is to ensure all personnel listed are current in their Biosafety Training and update all of the personnel entries in item 4.4 to include the most recent Biosafety Training Date.

2. Section 5.0 - Description of Procedure(s)/Research

- The PI is to explicitly state PPE instead of using phrases like "appropriate PPE" or "full PPE as recommended by the manufacturer" as it is unclear what PPE that is. Since the actual PPE used is stated elsewhere, the BUA should either remove these phrases or refer the reader to the sections where the actual PPE used is listed.
- Emergency Procedures The PI is to confirm that individuals wearing N95 respirators are registered with the Respiratory Protection Program (medical evaluation/clearance and annual fit testing), alternatively, surgical masks are acceptable. The PI is to revise the text if study team will opt to use surgical masks.
- The PI is to revise the research description to clearly indicate from the beginning what are the genes expressed by each vector followed by the details which are already provided.

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- The PI is to clarify to how liquid and solid waste is chemically disinfected. Please refer to the <u>list of EPA-registered disinfectants</u> that are effective at killing adenovirus or consult with TLI EH&S.
- For adenovirus, small volume is different than MOI. The PI is to clearly indicate the specific quantity/concentration.
- It is stated that NIH Guidelines for decontamination the lab will be followed. The PI is to clarify what is meant by this or remove the statement since decontamination is described elsewhere in the BUA.
- The PI is to clarify which emergency procedures are followed in both BioLabs and in the animal facility.
- The PI is to briefly explain the work to be performed at MRL 3rd floor/BioLabs versus the activities conducted in the animal facility.
- The PI is to clarify that AAV vectors inherently carry AAV DNA sequence, for our purposes, this DNA sequence additionally encodes fluorescent report proteins (GFP, mCherry), per email response on 08/12/2025.
- The PI is to clarify that DNA plasmids encode fluorescent reporter proteins (GFP, mCherry). Per PI email response on 8/12/2025 "Currently, our ASOs do not target any genes and are only used to assess delivery efficiency via a fluorescent tag directly on the ASO. DNA plasmids, ASOs, and AAVs are used separately."

3. Section 6.0 - Risk Assessment

• The PI is to clarify: AAV-used at BSL1/ABSL1/Adenovirus-used at BSL2/ABSL2

4. Section 9.0 - Vectors for Recombinant or Synthetic DNA

• Potential Hazards – The PI is to replace "no" risk with "low" risk.

5. Section 10.0 - Encoded Recombinant or Synthetic DNA Sequences

- The use of mCherry as a fluorescent reporter is discussed in several sections of the BUA. If mCherry is being used, the PI is to add it to the eGFP entry (since they both serve the same purpose), or create a new entry for this reporter.
- For entry 1, the PI is to select the option for jellyfish.
- For entry 3, the PI is to briefly explain the reason for including thymine kinase and in which vector it will be used.

6. Section 12.0 - Research with Eukaryotic Hosts (Including Fungi)

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• Following approval of this 3-year renewal, the PI is to submit an IBC Amendment with updates to this section to describe work with eukaryotic cells. The IBC does not intend to hold up the approval of this renewal to review the additional work and therefore requests a separate amendment.

Vote: For - 7, Opposed - 0, Absent - 0, Abstained - 0, Recused - 0

OTHER BUSINESS

a. <u>Safety Committee Report (David Applebaum) Accident/Spills</u> Mr. Applebaum stated no incidents were reported.

b. Lab Coat Update

Mr. Applebaum reported that he conducted an inventory of lab coats and usage across labs and provided this information to TLI Procurement. The team determined that most lab coats should be waterproof, though cloth coats can sometimes be sufficient when immediate protection is needed. Procurement has a list of lab coat types and quantities needed. The IBC will follow up with TLI Procurement for an update on the status of obtaining and distributing the appropriate coats for lab personnel.

- c. EPA's Registered Antimicrobial Products Effective Against Candida auris (List P)

 The Committee discussed EPA disinfectant requirements, agreeing to require products from the EPA list for human materials, especially for organisms like hepatitis B which are resistant to quaternary ammonia compounds. The EPA disinfectant list link will be added to the iRIS Help section for easy access and recommended that custodial staff be trained on proper disinfectant use.
- d. <u>Self-Assessment Tool for Institutional Biosafety Committees and Programs of Oversight of Recombinant or Synthetic Nucleic Acid Research:</u>
 Tabled for the next meeting due to time constraints.

With no further business, the meeting adjourned at 3:59 PM

Respectfully submitted,

- signed by:

Sulf Filler

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Scott Filler, M.D.

Chair, Institutional Biosafety Committee

cc: Research Committee Agenda