

**Lundquist Institute for Biomedical Innovation
at Harbor-UCLA Medical Center****Institutional Biosafety Committee
Meeting Minutes
12/09/2025
Zoom Virtual Conference**

MEMBERS PRESENT	MEMBERS ABSENT
David Applebaum, M.S. Helen Chun, Ph.D. Rami Doueiri, Ph.D. Scott Filler, M.D. Adrienne Zweifel, Ph.D.	Fawzia Bardag-Gorce, Ph.D. Fang Wang, Ph.D.
STAFF PRESENT	STAFF ABSENT
Rosa Harmon, CPIA Annie Hilo	Elizabeth Burrola, CIP Rosemary Madnick, MBA

1. CALL TO ORDER

The meeting was called to order by Scott Filler, M.D. at 3:00 PM.

2. MEETING MINUTES

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

A motion was made and seconded to APPROVE the minutes.

Vote: For - 5, Opposed - 0, Absent – 0, Abstained - 0, Recused – 0

3. BUA REVIEW**a. Initial Reviews**

IBC #: IBC 2025-33798-01

PI: Michelle Matter, Ph.D.

iRIS Ref #: 063310

Summary: Postpartum cardiomyopathy (PPCM) is of unknown etiology and remains a major cause of maternal morbidity in the U.S. Therefore, identifying cardioprotective pathways that attenuate PPCM is clinically relevant. Female mice lacking the protein PTRH2 (also called Bit1, Bit-1) only in the heart exhibit PPCM and die due to heart failure. We will determine if PTRH2 is a viable therapeutic target for PPCM.

Inserts: Ptrh2, Ptrh2 shRNA, MyH7, Trabid, RRas, DOCK1, PGL4.19 (Luc2CP/Neo), PLKO.1, PCL-Neo, pcDNA3.1-Zeo, PVLX-Puro, PLKo1 Puro

Vectors: MISSION® pLKO.1-puro vector expression vector, pLVX-Puro, pcDNA3.1-Zeo, pCMV delta R8.2, pCI-Neo, pGL4.19[luc2CP/Neo], pVSV-G envelop vector

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

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

- Lay Description - Based on what is currently written, it is not clear why mice are being referenced in this section. The PI is to move the sentence "We will use primary mouse cardiomyocytes that we isolate from our heart specific PTRH2 null mice" to this section. For introduction to problem & area of study --> We will determine if PTRH2 is a viable therapeutic target for PPCM by [Introduce materials and procedures used]--> The PI is to indicate what would be next for the field of study if successful.
- Overall Goal - the PI is to
 - Provide a brief summary of the overall goal of the project. Recommend copying the general overview from the "Lay Description" and adding a 1-2 sentence introduction of what PTRH2 and the other constructs of interest used in this work do. Also recommend moving the sentence "The purpose is to determine how the modulation of our genes-of-interest regulates cell survival" here.
 - Remove the sentence "We will use primary mouse cardiomyocytes that we isolate from our heart specific PTRH2 null mice. Cells will be isolated and then examined by immunohistochemistry, Western blotting and Elisa to determine protein-protein interactions, Ptrh2 protein localization and function." since these mice are exempt from the NIH Guidelines section.
 - Move the procedures discussion if those will be used with genetically modified cell lines.
 - Explain what the iPSCs are for.

- Clarify if the mouse cardiomyocytes be genetically modified as well? If so, recommend generalizing the sentence "We will also overexpress and knockdown PTRH2 in human cell lines including fibroblasts and HEK293 cells to examine its signaling pathway." to include "human and murine cell lines" if this is accurate.
- Experimental Procedures -
 - Since the E.coli DH5-alpha host-vector work is exempt, it is unnecessary to provide such extensive detail about how the transformation is performed. The PI is to remove those details and revise the text to state that lentiviruses are risk group 2 pathogens and not risk group 3.
 - The PI is to revise this section to limit the work to:
 - Transfection of Mammalian Cell Lines,
 - Packaging of Lentivirus using Human Cell Lines,
 - Transduction of Mammalian Cell Lines,
 - Cell Culture of Genetically Modified Cell Lines,
 - Analysis of Genetically Modified Cultured Cells Lines-what hazardous procedures are involved with the downstream assays being performed (Cell viability (XTT assay), cell survival assay, immunostaining, etc.
- Containment Conditions – The PI is to confirm that goggles will be used when working in the BSC. If not, the PI is to discuss for which procedures they will be used.
- Containment Conditions - For cell culture decontamination, the PI is to explicitly state that cell culture media will be bleached (10% final concentration for 30 minutes). Only cell culture waste from murine cell culture can be autoclaved. The PI is to explicitly state the parameters of the autoclave cycle used and how the lab will ensure that the autoclave run was completed successfully.

NOTE: According to the California Medical Waste Management Act, liquid waste from any and all Risk Group 2 materials must be bleached, not autoclaved in lab). Solid waste from solid waste must be discarded via the medical waste stream. TLI does not have a CDPH-registered autoclave for this purpose on site.

- Emergency procedures – The PI is to update the sentence "Spills involving recombinant DNA and/or infectious cultures, will be reported immediately to the Tulane Biosafety Office" with the new institution - The Lundquist Institute.

2. Section 6.0 - Risk Assessment

- Describe the specific procedures – The PI is to acknowledge that lab strains of E.coli will be used for the transformation.

- Identify all equipment - Section 5.0 referenced a microscope, the PI is to include that in this section.
- List any vaccinations – The PI is to add Hepatitis B vaccination series since this work involves human materials.

3. Section 6.2 - Applicable Sections of the NIH Guidelines

- The PI is to select the III-F box for the use of E.coli K-12 host/vector system if relevant for cloning purposes.

Based on the current representation of the use of plasmids in E.coli DH5-alpha, use of the host and the plasmids used therein are exempt from NIH Guidelines and IBC review.

4. Section 9.0 - Vectors for Recombinant or Synthetic DNA

- The PI is to add an additional entry for the packaged lentiviral vector.
- Describe potential hazards – The PI is to replace what currently written with:
 - by which hosts the promoters are recognized,
 - by which hosts the origins of replication are recognized, and
 - explicitly state the selection markers present on the plasmids do not provide resistance to clinically relevant antibiotics. If the markers are not antibiotics, the PI is to discuss whether hazards are present for the whatever marker is being used. Several parts of the "Assessment of the Hazardous Potential" from Section 5.0 can be moved here.

5. Section 10.0 - Encoded Recombinant or Synthetic DNA Sequences

- The PI is to change the response to this question from no to yes, then complete an entry for all genes/constructs being expressed:
 - ptrH2 gene (for overexpression),
 - ptrH2 shRNA (for knock-down,
 - one entry for the proteins expressed from the lenti packaging plasmids.
- Section 5.0 (Experimental Procedures) section referenced: Human peptidyl tRNA hydrolase (PTRH2), Myh7, and Trabid cDNAs, the promoter regions, and RRAs, as well as Dock family member shRNAs
- Referring to the pGL4.19[luc2CP/Neo] vector from Section 9.0 - If luciferase will be delivered to the cells from the packaged lentiviral vector, the PI is to include the gene in this section.

- Describe potential hazards – The PI is to discuss the potential hazards. Certain parts of Section 5.0 can be moved here.

6. Section 11.0 Research With Whole Plants or Animals as Hosts

- The PI is to revise item 11.1 from "Yes" to "No", as the work with mice described in the BUA is exempt.

The PI is to complete the Stem Cell Intake Form that has been sent via email. The details to be collected in the form will assist the IBC in assessing whether the project requires SCRO (Stem Cell Research Oversight) review and approval.

Vote: For - 5, Opposed - 0, Absent - 0, Abstained – 0, Recused – 0

b. Continuations

IBC #: IBC-U-CDU 22948-01

PI: Shehla Pervin, Ph.D.

iRIS Ref #: 063242

Summary:

Protocol #22948: Study team will knock down SOD (shRNA) in MDA-MB-231 breast cancer cell line (expresses stable SOD) before implanting in mice exposed to E-Cig. MDA-MB-231 cells treated with scrambled ShRNA will be used as control. Xenograft growth will be monitored from SOD ShRNA and scrambled ShRNA treated cells in mice following E-Cig exposure. RNA sequencing and computational analysis will be performed to determine differences in chemokine and immune gene signatures, which will be validated by qPCR and immunoblot analysis.

Protocol #22453: Study team will knock down tyrosine hydroxylase and psoriasin with shRNA in breast cancer cell line HCC70 before implanting in nude mice.

Inserts: NA

Vectors: NA

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-F (Exempt)

Conflicts: NA

Motion: A motion was made and seconded to REQUIRE MODIFICATIONS TO SECURE APPROVAL of the BUA. (Modifications not listed due to clarification provided by PI following the meeting. See below.)

After the meeting, the primary reviewer met with the PI, who confirmed that the work proposed requires shRNA oligos during the electroporation process rather than plasmids, which had been the primary focus of the full board discussion. Based on this clarification, both the primary reviewer and the Biosafety Officer determined that the work is **EXEMPT**.

The PI is required to submit an amendment if any portion of the experimental procedures changes. Administrative clarifications will be made on behalf of the PI by the ORC.

Vote: For - 5, Opposed - 0, Absent - 0, Abstained – 0, Recused – 0

IBC #: IBC 2025-U-F-PU

PI: Priya Uppuluri, Ph.D.

iRIS Ref #: 063143

Summary: Mice will be infected with fungal pathogens using different routes of inoculation for evaluating virulence or response to drugs.

Inserts: Nourseothricin N-acetyl transferase (NAT)

Vectors: NA

Pathogens: *Aspergillus fumigatus*, *Rhizopus delemar*, *Candida: albicans, auris, glabrata, tropicalis, krusieci*, *Trichophyton mentagrophytes*

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-F (Exempt)

Conflicts: NA

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

Vote: For - 5, Opposed - 0, Absent - 0, Abstained – 0, Recused – 0

4. Information Only

- a. **BUA Determined to be Exempt (Reviewed/Approved by BSO or Designated Member Review)**

IBC #: IBC 2025-22884-01

PI: Ashraf Ibrahim, Ph.D.

iRIS Ref #: 062758

5. Other Business

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

- b. New BUA:
Members were reminded to review/test the new BUA and provide comments by December 22, 2025.

The Committee discussed revisions to the new BUA form, focusing on improving language around eukaryotic cells and hazardous materials. They agreed to change "host cells" to "strains for recombinant work" and "describe the hazards" to "describe the risks associated with hazardous materials." Dr. Zweifel suggested creating a table with pre-defined waste management options to reduce confusion.

- c. Language regarding animals in IBC Meeting Minutes
The Committee reviewed IBC meeting minutes language regarding animals and decided to use "experimental models" for species above rodents.
- d. Self-Assessment Tool - Physical Containment – Laboratory Environment section
Tabled for the next meeting due to time constraints.

With no further business, the meeting adjourned at 4:14 PM

Respectfully submitted,

Signed by:

Scott Filler

19F1076B3027451
Scott Filler, M.D.

Chair, Institutional Biosafety Committee

cc: Research Committee Agenda