Creighton UNIVERSITY

Office of the Provost
Research Compliance

CREIGHTON UNIVERSITY
INSTITUTIONAL BIOSAFETY COMMITTEE

IBC MEETING MINUTES

MEETING LOCATION
Zoom (via Invitation)

MEETING DATE and TIME
08-Aug-2025 at 02:00 PM

Institutional Biosafety Committee
2500 California Plaza
Omaha, NE 68178-0125
T: 402.280.2126 | **E:** IBC@creighton.edu
creighton.edu | **creighton.edu/researchservices**

ATTENDANCE

VOTING MEMBERS PRESENT:	
Michael Belshan, PhD Chair, Scientist (Medical Microbiology & Immunology)	**Aurijit Sarkar, PhD** Member, Scientist (Pharmaceutical Sciences)
Richard Goering, PhD Vice Chair, Scientist (Medical Microbiology & Immunology)	**Charles Brockhouse, PhD** Member, Scientist (Biology)
Stacey Morrow, MS, MT(ASCP) Member, Scientist (Molecular Biology)	**Marisa Zallocchi, PhD** Member, Scientist (Biomedical Sciences)
Nicholas Streck, PhD Member, Scientist (Biomedical Sciences, Virology, & Immunology)	**Graham Cox, PhD** Member, Scientist, Community Representative (Animal Containment Expert)
Rima El-Herte, PhD Member, Scientist (Infectious Disease)	
STAFF MEMBERS PRESENT:	
Teri Prentis, BA *IRB Administrator*	
Stuart Martens, JD *Legal*	
DESIGNATED GUESTS:	
Alessandra Menezes Campos Staffico, PhD (Pharmacy, Occupational Therapy, Physical Therapy) Principal Investigator, EHS-25-0551 *Present 2:15 PM-2:18 PM*	**Justine Renauld, PhD** (Biomedical Sciences) Principal Investigator, EHS-25-0552 *Present 2:21 PM-2:22 PM*

Attended in Person: None – virtual meeting.
Attended via Zoom: All attendees were present via Zoom.

The IBC has 10 voting members. Six members, including at least one community representative, are required to conduct business.

A quorum was met and Dr. Belshan called the meeting to order at 2:13 PM

The Chair asked whether any members of the Committee had a conflict of interest for any item on the meeting agenda. No members reported a conflict of interest.

The Chair asked whether members of the Committee had received all necessary materials to complete their reviews for this meeting. All members confirmed they received all necessary materials to complete their reviews for this meeting.

The IBC Administrator reviewed the CITI training, documentation, and disclosure requirements for members of the IBC. No members present at this meeting had training, documentation, and/or disclosure deficiencies. All present members were therefore eligible to vote.

The Chair will vote only as necessary to maintain quorum or to break a tie in voting.

REVIEW AND APPROVAL OF PREVIOUS MINUTES

The Committee reviewed and approved the **11-Apr-25 IBC Minutes** as written.

Total Vote Count	For	Against	Abstained	Absent	Recused
9	8	0	1	0	0

The Chair, Michael Belshan, abstained.

REVIEW OF PRIOR BUSINESS

None.

POLICY APPROVALS, ANNOUNCEMENTS, EDUCATION

None.

COMMITTEE REVIEW

Submission Number: EHS-25-0551-01

Title: Unraveling Lipoprotein(a) Mechanisms in Anthracycline Cardiotoxicity: Bridging Clinical Observations with Cellular Evidence

Principal Investigator: Alessandra Menezes Campos Staffico

Submission Type: New

Type of Registration: Exempt Recombinant/Synthetic Nucleic Acid Registration

Determination: Approved

Determination Date: 08-Aug-2025

Expiration Date: 08-Aug-2028

Total Vote Count	For	Against	Abstained	Absent	Recused
9	8	0	1	0	0

The Chair, Michael Belshan, abstained.

Agents:	Human induced pluripotent stem cell-derived cardiomyocytes (iPSC-CMs), commercially sourced (FUJIFILM iCell Cardiomyocytes), Risk Group 1, certified free of bloodborne pathogens
Agent Risk Group:	RG-1
NIH Guidelines category of r/s NA research, if applicable:	Section III-F

Summary: The goal of this project is to investigate the role of lipoprotein(a) [Lp(a)] as a mediator of anthracycline-induced cardiotoxicity (AIC) using human induced pluripotent stem cell-derived cardiomyocytes (iPSC-CMs). Anthracyclines, such as doxorubicin, are widely used chemotherapy agents, but their clinical use is limited by the risk of dose-dependent cardiotoxicity. Doxorubicin will be applied directly to iPSC-CMs in vitro to model chemotherapy-induced cardiac injury.

The commercially available iPSC-CMs used in this project are classified as Risk Group 1 (RG-1) and are sourced from a vendor that certifies they are free of bloodborne pathogens. In addition, HepG2 cells (human hepatocellular carcinoma cell line, RG-1, ATCC #HB-8065) may be used for selecting control experiments. All cell lines will be handled in accordance with institutional biosafety protocols.

In this study, iPSC-CMs will be cultured and exposed to physiologically relevant concentrations of Lp(a), doxorubicin, and combinations thereof. The project will assess the direct cellular impact of Lp(a) on doxorubicin-induced injury by measuring cell viability, cytotoxicity, and oxidative stress using enzyme-based assays (MTT, LDH, ROS). To determine the role of LDLR and PlgRKT receptors in mediating Lp(a)-driven AIC, the study will employ siRNA knockdown, antibody blocking, and pharmacological inhibitors – without introducing recombinant DNA constructs into the cells. Receptor expression and function will be measured using ELISA and related assays.

The siRNA used for gene knockdown is synthetic, non-viral, and does not integrate into the genome or result in stable genetic modification. No recombinant DNA constructs or plasmids will be used. All recombinant and synthetic nucleic acid materials are classified as Risk Group 1 and will be handled at Biosafety Level 1 (BSL-1).

All work with iPSC-CMs, HepG2 cells, Lp(a), and doxorubicin will be performed in accordance with institutional biosafety and chemical safety protocols. While the biological work is conducted at BSL-1, doxorubicin is a hazardous cytotoxic drug. Therefore, all handling, application, and disposal of doxorubicin will be performed in a certified Class II biosafety cabinet (BSC) with enhanced chemical safety precautions, including the use of appropriate PPE (double gloves, lab coat/gown, eye protection) and cytotoxic waste disposal procedures. All laboratory personnel will receive standard

biosafety and chemical safety training prior to working with these materials. No special medical surveillance or vaccinations are required for this project.

Waste disposal and emergency procedures are described in the attached laboratory biosafety and exposure protocols. All laboratory waste will be autoclaved or disposed of in accordance with institutional and regulatory requirements. In the event of a spill or exposure, personnel will follow the posted emergency response procedures and notify the Principal Investigator and Environmental Health & Safety.

All procedures and materials described in this project will be registered with and approved by the Creighton University Institutional Biosafety Committee (IBC) prior to initiation. The Principal Investigator, Dr. Alessandra Staffico, will be responsible for ensuring compliance with all biosafety and chemical safety requirements. All procedures comply with NIH Guidelines and institutional biosafety policies. The expected duration of the project is 12 months, with experiments conducted on a rolling basis as cell cultures and reagents become available.

Discussion: Dr. Staffico entered the room to present a short summary of her protocol and address any questions or concerns from the Committee. No concerns were mentioned while Dr. Staffico was in the room. She left the meeting room.

The Chair provided the opportunity for discussion. Marisa Zallocchi mentioned that the safety guidelines for the drug recommend chemical-resistant gloves. Aurijit Sarkar stated that the drug does pass through the skin layers easily, which is why the recommendation is to use thicker gloves, but that this does not pose a biohazard issue. The Chair stated that this concern could be forwarded to EH&S but does not fall under the purview of the IBC.

No other discussion was had. The Committee voted to approve the initial application as submitted.

All required training per institutional policy is complete for all individuals listed on this registration.

Submission Number: EHS-25-0552-01

Title: New Protocol Created for Justine Renauld on 14-Jul-2025 4:57 PM

Principal Investigator: Justine Renauld

Submission Type: New

Type of Registration: Exempt Recombinant/Synthetic Nucleic Acid Registration

Determination: Approved

Determination Date: 08-Aug-2025
Expiration Date: 08-Aug-2028

Total Vote Count	For	Against	Abstained	Absent	Recused
9	8	0	1	0	0

The Chair, Michael Belshan, abstained.

Agents:	N/A
Agent Risk Group:	N/A
NIH Guidelines category of r/s NA research, if applicable:	Section III-F

Summary: These experiments aim to investigate the potential interaction between adrenergic receptors and melatonin receptors in vitro. We will assess receptor localization and activity using confocal microscopy, and evaluate receptor-receptor interactions through immunostaining, proximity ligation assay (PLA), immunoprecipitation, and mass spectrometry (MS/MS). These studies will help elucidate the molecular mechanisms underlying cross-talk between these receptors.

Two main experiments involving plasmid DNA will be performed:

1. **Plasmid Extraction from Bacterial Culture**
   A single colony of transformed *E. coli* will be inoculated into LB medium containing the appropriate antibiotic, as specified by the plasmid manufacturer. After overnight growth, the bacterial culture will be centrifuged, and the pellet will be lysed using a commercially available plasmid extraction kit. The purified plasmid DNA will be collected and stored appropriately for downstream applications.
2. **Plasmid Transfection into Mammalian Cells**
   Purified plasmid DNA will be transfected into cultured mammalian cells using Lipofectamine-based reagents. All transfections will be performed under sterile conditions in a biosafety cabinet. Plasmid DNA will be mixed with Lipofectamine in serum-free medium and applied to cells in culture according to the manufacturer's protocol. After 24–48 hours, cells will be analyzed for transfection efficiency by fluorescence microscopy (e.g., GFP or RFP expression). Following imaging, cells may undergo one of the following downstream applications:
   1. Fixation for immunostaining,
   2. Lysis for immunoprecipitation followed by mass spectrometry (MS/MS) to identify protein interactions or post-translational modifications,
   3. Disposal in accordance with institutional biosafety procedures via designated biohazard waste containers.

Discussion: Dr. Renauld entered the room to present a short summary of her protocol and address any questions or concerns from the Committee. No concerns were mentioned while Dr. Renauld was in the room. She left the meeting room.

The Chair provided the opportunity for discussion. No discussion was had. The Committee voted to approve the initial application as submitted.

All required training per institutional policy is complete for all individuals listed on this registration.

Submission Number: EHS-22-0540-04
Title: 244 Transcription regulation in the inner ear
Principal Investigator: Litao Tao
Submission Type: Modification
Type of Registration: Exempt Recombinant/Synthetic Nucleic Acid Registration
Determination: Tabled
Determination Date: 08-Aug-2025
Expiration Date: N/A

Total Vote Count	For	Against	Abstained	Absent	Recused
9	8	0	1	0	0

The Chair, Michael Belshan, abstained.

Agents:	AAV
Agent Risk Group:	RG-1
NIH Guidelines category of r/s NA research, if applicable:	Section III-D

Summary: Investigation of the transcription regulation in the inner ear will provide valuable information for us to understand the molecular mechanisms specifying cell fates during development and determining the death or survival of cochlear cells upon traumatic challenges. Such understanding will help us find new treatment to prevent sensory hair cell loss or to regenerate sensory hair cells after damage to cure deafness which otherwise is permanent for the rest of life in human and other mammalian animals. Using in vitro assays and in vivo experiments, we are planning to investigate the regulatory roles of enhancers of essential cochlear genes, since enhancers dictate the cell type-specific and developmental stage-specific expression of target genes. Given the technical difficulty to transduce cochlear cells by other viral vectors, we

choose the Adeno-Associated Virus serotypes (Anc80L65, AAV-ie, and AAV-ie-K558R), which has been shown to be highly efficient in transducing sensory hair cells and other cochlear cells in vitro and in vivo (Landegger et al., Nat Biotechnol. 2017; Tan et al., 2019; Tao et al., 2022), to infect cultured cochlear cells in vitro or to transduce inner ear cells in vivo through lateral ventricles of the brain.

Two sets of AAV vectors will be used:

1. AAV vector carrying candidate enhancer and reporter genes for enhancer activity assay.
2. AAV vector with dCAS9-VP64 expression construct and AAV vector with enhancer specific sg-RNA expression construct for epigenetic manipulation of candidate enhancers to stimulate/repress the expression of target genes.

Discussion: Marisa Zallocchi raised the concern that the biosafety level may be incorrect. She mentioned that other universities would consider this type of work to be BSL-2, as there is an introduction of the AAV into human cells regardless of the presence of a helper.

Graham Cox stated that the work being done in a hood would be best practice.

The concern of the work being done in a shared space was discussed. It was determined that there was not enough specification regarding locations of facilities and storage, transport, the equipment being used, and cleaning/decontamination procedures of the equipment.

It was also discussed that the SASP form looked like it needed to be reviewed again by the attending veterinarian.

The Committee voted to table this application and requested that the Principal Investigator upload an updated protocol with the following revisions:

- Clarify the locations of all facilities that will be utilized, including locations of storage.
- Clarify the equipment that will be utilized
- Include a detailed handling protocol including methods of transport between facilities.
- Include a detailed narrative of the protocol of the production of the virus in addition to referencing a commercial kit.
- If working in a common area/shared space, include the following in the protocol:
    - Methodology to notify individuals working in the common area/shared space of the presence of the virus
    - Methodology that will be used to clean/decontaminate shared equipment after work is performed.

All required training per institutional policy is complete for all individuals listed on this registration.

PUBLIC COMMENTS

There were no public comments.

THIS MEETING ADJOURNED AT 2:47 PM

END OF COMMITTEE REVIEW

Next meeting is tentatively scheduled for 12-Sep-2025 at 2 PM.

END REPORT