INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
July 10, 2025

MEMBERS PRESENT: JoEllyn McMillan - Chair, Pete Iwen – Vice Chair, Jim Kee, Jim Talmadge, Mimi McCann, Noel Johnson, and Paul Denton

NON-VOTING ALTERNATE MEMBERS PRESENT: Mackenzie Conrin, Jared Evans, and Makayla Walker.

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger

GUESTS PRESENT: none

Dr. McMillan opened the meeting at 2:34pm.

A. Review and Acceptance of IBC Minutes

The IBC voted (7 in favor, 0 against, 0 abstention) to accept **June 12, 2025** minutes.

B. Information, Education and Policy Items

C. Special Notification/Review

none

D. Incident and Event Reports Special Notification and/or Review Approved

none

E. IBC Initial Research Proposals and/or Previously Tabled

1) **IBC#:** 25-06-015-BL1
PI: Yeh, Steven
Title: A Multi-Center, Randomized, Double-Masked, Active-Comparator-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Ixoberogene soroparvovec (Ixo-vec) in Participants with Neovascular Age-Related Macular Degeneration (ARTEMIS)
Biohazardous Agents: adeno-associated virus
Applicable NIH Guidelines: III-C-1
Summary: This protocol is a Phase III trial that will assess the efficacy and safety of a gene therapy treatment, Ixoberogene soroparvovec (Ixo-vec), for treatment of age-related macular degeneration. The vector for gene delivery is adeno-associated virus (AAV) based.

Committee Recommendations: IBC recommends selecting “red bin waste” in Section II.3.A. Clarification is needed on Section II.D for the method of storage and location.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 7-0-0

2) **IBC#:** 25-06-016-BL2
PI: Carnes, Eric
Title: Novel Materials to Rapidly Inactivate or Treat Bacteria and Viruses
Biohazardous Agents: *Acinetobacter* not *baumannii*, *Bacillus anthracis*, avirulent, *Bacillus* not *anthracis* or *cereus*, *Bacillus subtilis*, Bacteriophage, *Burkholderia* (not *mallei* or *pseudomallei*), *Escherichia coli*, *Escherichia coli* K-12, *Francisella* not *tularensis*, *Frencisella tularensis* (LVS strain), *Klebsiella pneumoniae*, *Stapyhlococcus* species not *aureus*, Vaccinia virus, avirulent, *Vibrio cholera*, *Yersinia rohdei*
Applicable NIH Guidelines: Exempt
Summary: In this protocol antimicrobial properties of environmental samples will be examined using various bacterial and viral species.
Committee Recommendations: Add Provide additional information on proposed strains, any hazards posed by the proposed modifications or treatments, and rationale for why non-pathogenic surrogates cannot be used.
Training: Two personnel still need to complete their training.
Motion: Conditionally Approved
Vote Counts: 7-0-0

F. IBC Change in Protocol

1) **IBC#:** 23-11-029-ABL2
PI: Viswanathan, Saraswathi
Title: Transfection studies using viral vectors
Biohazardous Agents: Adeno-associated virus, Lentiviral vector
Applicable NIH Guidelines: III-D-1-a
Summary: This protocol will use AAV and lentiviral vectors to over-express or silence signal transduction genes to determine the effect on cellular responses related to obesity and alcohol exposure. Human and rodent primary cells and cell lines will be used to assess the various disease-related cell responses.
Committee Recommendations: Update the title to reflect work captured and lab locations. A BSL2 laboratory inspection will be needed and can be done at the same time as the lab safety audit for 7/24/15. In Section II.2.D, update the language to address the question for ALL cell lines, transfected or otherwise. Section II.1 indicates mouse cells will be cultured, if this is accurate add mouse cells to Section II.2A.
Training: All training is complete and up to date.
Motion: Conditionally Approved
Vote Counts: 7-0-0

2) **IBC#:** 24-07-022-BL1
PI: Broadhurst, Jana
Title: Generation of synthetic control material for molecular infectious disease assays

Biohazardous Agents: *Escherichia coli* K-12, Plasmid
Applicable NIH Guidelines: III-D-2-a
Summary: In this protocol control gene libraries for certain pathogens will be created for use in development and validation of molecular infections disease assays. The change request was to add wording to add control plasmids for developing additional tests.
Committee Recommendations: In Section I.3, there are many duplicated names. Fix to represent the appropriate list. Remove "e.g." to be specific on use of pUC19 and to remove vagueness. Describe, in detail, the assay validation in Section II.1. Please answer how the investigators will use these materials. Is there a list of assays they intend to validate with these plasmids / sequences?
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 7-0-0

3) **IBC#:** 24-04-008-BL2
PI: Sharma, Bhavina
Title: A Phase 1, Open-Label, Multicenter, Dose Escalation and Expansion Study of KB707 in Subjects with Locally Advanced or Metastatic Solid Tumor Malignancies
Biohazardous Agents: Herpes virus vector, Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: This is a clinical trial to assess the safety and tolerability of the investigative drug KB707, a herpes simplex-1-based vector delivery system for IL-2 and IL-12 for tumor control. Change request was for personnel changes and to add two new cohorts to the stated study groups.
Committee Recommendations: Attach the NM policy as described in Section II.1. In Section II.2.C, following the statement "the sponsor's proprietary complementing cell line for propagation was adapted from a parent VERO line": describe this cell line. Such as [redacted] In Section II.5, please add a statement that personnel involved in shipping have been trained on institutional procedures and requirements.
Training: All training is completed and up to date.
Motion: Conditionally approved
Vote Counts: 7-0-0

G. IBC Continuing Review Active Research

1) IBC#: 24-07-024-BL2
PI: Davis, Paul
Title: Exploring Anti-Inflammatory Tissue Sparing in Brain Organoid Models of Toxoplasma gondii Infection
Biohazardous Agents: Human cell line/cells/tissues, primary human cell line, *Toxoplasma gondii*
Applicable NIH Guidelines: Exempt
Summary: In this protocol human brain organoids will be exposed to *Toxoplasma gondii* for the purpose of developing a model of *T. gondii* infection in the CNS. The aim of this new submission is "to model the infection of central nervous system tissue by Toxoplasma gondii".
Committee Recommendations: BSL2 laboratory inspection required.
Training: All training is completed and up to date.

Motion: Approve
Vote Counts: 7-0-0

2) **IBC#:** 23-08-023-BL2
PI: Lunning, Matthew
Title: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Axicabtagene Ciloleucel
Biohazardous Agents: Human cell line/cells/tissues, Retroviral vector
Applicable NIH Guidelines: III-C-1
Summary: This is a clinical trial study to assess the efficacy of the CAR-T cell therapy Axicabtagene ciloleucel for B-cell malignancies using out-of-specification cells.
Committee Recommendations: Add RG2/BSL-2 practices to II.4 safety practices.
Training: All training is completed and up to date.
Motion: Approve
Vote Counts: 7-0-0

3) **IBC#:** 23-08-024-BL2
PI: Lunning, Matthew
Title: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Brexucabtagene Autoleucel
Biohazardous Agents: Human cell line/cells/tissues, retroviral vector
Applicable NIH Guidelines: III-C-1
Summary: Axicabtagene ciloleucel and brexucabtagene autoleucel are autologous treatments in which the subjects own T cells, obtained by leukapheresis, are genetically engineered ex vivo, by retroviral transduction of a construct encoding an anti-CD19 chimeric antigen receptor (CAR), to target CD19 expression on B-cell malignancies.
Committee Recommendations: In Section II.1, description of work, discuss the retrovirus and patient samples collected post-administration of the therapy. The IB indicates that the retrovirus is replication competent, this should be described here as well. Address the following questions: what happens if personnel administering the product are exposed? Does the subject shed viral particles? Are any samples collected from the subjects after the therapy is administered? What does RCR monitoring look like (samples? timeline?). What are the release criteria? Does this include any testing to ensure there is no remaining virus in the product? In Section II.2.C, make note that the retrovirus is replication competent. In Section II.3.A, select 10% bleach or 'other' for liquid and surface decontamination. Also select RG2/BSL2 practices in Section II.4. Also describe the processes for handling left-over product and sharps used to administer product.
Training: All training is completed and up to date.
Motion: Conditionally approved
Vote Counts: 7-0-0

4) **IBC#:** 24-08-025-BL2
PI: Krishnan, Mridula
Title: A PHASE II, OPEN-LABEL, MULTICENTER, RANDOMIZED STUDY OF THE EFFICACY AND SAFETY OF ADJUVANT AUTOGENE CEVUMERAN PLUS ATEZOLIZUMAB AND mFOLFIRINOX VERSUS mFOLFIRINOX ALONE IN PATIENTS WITH RESECTED PANCREATIC DUCTAL ADENOCARCINOMA
Biohazardous Agents: Human cell line/cells/tissues, mRNA
Applicable NIH Guidelines: III-C-1

Summary: This protocol describes a Phase II study to assess the safety and efficacy of the autogene mRNA vaccine cevumeran for treatment of PDAC (pancreatic ductal adenocarcinoma) in combination with atezolizumab and mFOLFIRINOX.
Committee Recommendations: Section II.1: Define abbreviations such as PDAC and IMPs at first use. Section II.1: Add to what document the references to Section 3.1.3.1, 4.3.2.1, 4.3.2.3, etc refer to. Section II.1: Citations are provided in the description of the investigational product autogene cevumeran that are not included in the literature cited section. Section II.5: Describe shipment of blood and tumor tissue to sponsor, as well as unused IP for disposal, which is an international shipment. Change the answer to "Yes" to the question of whether the biologicals or data will be shipped to a foreign national or entity. Section II.3.A add red bin waste. In addition, add what surface disinfectants will be used at the time of administration.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 7-0-0

5) **IBC#:** 20-08-041-BL3
PI: Santarpia, Joshua
Title: Investigation of Novel Materials to Rapidly Inactivate SARS-CoV-2 Virus
Biohazardous Agents: SARS-CoV-2, Vero cells (African Green Monkey kidney), CRISPR-Cas9, Plasmid
Applicable NIH Guidelines: exempt
Summary: This study will assess the activity of surface coatings, filters or fabrics, and biological methods for tissue culture as inhibitors of SARS-CoV-2 viral replications.
Committee Recommendations: Contact Biosafety Officer to discuss a possible downgrade in containment and to schedule a laboratory inspection.
Training: One person needs to complete training.
Motion: Approve
Vote Counts: 7-0-0

6) **IBC#:** 20-08-040-BL2
PI: Lunning, Matthew
Title: Expanded Access Protocol (EAP) for Patients Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release
Biohazardous Agents: Human cell line/cells/tissues, lentiviral vector
Applicable NIH Guidelines: III-C-1
Summary: For non-Hodgkin lymphomas, CAR-T therapy, autologous product. Samples are sent to the manufacturer for modification with a replication incompetent lentivirus to express truncated human epidermal growth factor receptor (EGFRt) protein along with CD19-specific CAR as cell surface proteins. This product, JCAR017 (also known as lisocabtagene maraleucel), has been used in several clinical trials thus far and this study is essentially and extension of those to see how effective the treatment is over 3 months.
Committee Recommendations: None
Training: All training is completed and up to date.
Motion: Approve
Vote Counts: 7-0-0

7) **IBC#:** 21-09-025-BL2
PI: Brinkworth, Amanda
Title: Bacterial transmission from a tick vector into in vitro generated human skin rafts

Biohazardous Agents: *Borrelia burgdorferi,* Human cell line/cells/tissues, murine cell line, porcine cells/tissues, tick
Applicable NIH Guidelines: Exempt
Summary: This protocol studies the use of human skin rafts as a model for assessing the feeding patterns of ticks infected with Borrelia burgdorferi and changes in skin and tick transcriptomes related to tick feeding.
Committee Recommendations: Schedule a BSL2 laboratory inspection. Section I.4, update laboratory rooms.
Training: All training is completed and up to date.
Motion: Conditionally approved
Vote Counts: 7-0-0

There being no further business, Dr. McMillan adjourned the meeting at 3:45pm

Respectfully Submitted,

[redacted]

JoEllyn McMillan, PhD
Chair, IBC
JM

ADDENDUM
July 12, 2025
IBC REVIEW LETTER/EMAIL TO INVESTIGATORS

IBC #	Date of Letter/Email
25-06-015-Pending	07/11/25
25-06-016-Pending	07/11/25
23-11-029-ABL2	07/11/25
24-07-022-BL1	07/11/25
24-04-008-BL2	07/11/25
24-07-024-BL2	07/10/25
23-08-023-BL2	07/10/25
23-08-024-BL2	07/11/25
24-08-025-BL2	07/11/25
20-08-041-BL3	07/10/25
20-08-040-BL2	07/10/25
21-09-025-BL2	07/11/25