INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
06-12-25

MEMBERS PRESENT: JoEllyn McMillan - Chair, Pete Iwen – Vice Chair, Jim Kee, Jenna McKenzie, Jim Talmadge, Noel Johnson, Sandipan Brahma, Micah Schott, Jim Talmadge, Vinai Thomas

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

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger

GUESTS PRESENT: Stephen Asante-Adde, Desmond Amponsah

Dr. McMillan opened the meeting at 2:35pm.

A. Review and Acceptance of IBC Minutes

The IBC voted (10 in favor, 0 against, 0 abstention) to accept May 8, 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#:** 25-05-014-BL2
PI: Sharma, Bhavina
Title: A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)
Biohazardous Agents: Human cell line/cells/tissues, lentivirus, not HIV
Applicable NIH Guidelines: III-C-1
Summary: This is a phase 3 clinical trial protocol that will assess the efficacy of an adoptive cellular therapy for refractive unresectable or metastatic cutaneous melanoma. The therapy

is based on the use of [redacted]
Training: All training is complete.
Committee Recommendations: PI was asked to describe how the treatment will be administered (volume, rate, central line, PIV). IBC asked where drug product is thawed and how it is transported from BPF to bedside. Asked to clarify what is involved in processing "location of study center's cell processing laboratory."
Motion: Conditionally Approved
Vote Counts: 10-0-0

F. IBC Change in Protocol

1) **IBC#:** 20-02-010-BL3
PI: Santarpia, Joshua
Title: Environmental Sample Collection and Processing from Nebraska Medicine and other Hospital Environments to Test for SARS-CoV-2 and Other Infectious Diseases
Biohazardous Agents: Mpox clade II, SARS-CoV-2
Applicable NIH Guidelines: Exempt
Summary: This project involves the collection and genomic analysis of surface swabs and aerosol samples in clinical/patient care spaces. The goal is to support the use of appropriate personal protective equipment (PPE) and improve the understanding of the aerosol hazard risk posed by infectious disease. This change request includes updates to personnel and funding, but also the addition of four (4) new RG2 agents, influenza viruses, RSV, measles virus, and environmental bacterial samples.
Training: All training is complete.
Committee Recommendations: The Committee asked for clarification on sampling procedures, if any culture from samples will be conducted, and if the vaccine information for staff is still current.
Motion: Conditionally Approved
Vote Counts: 10-0-0

2) **IBC#:** 22-06-017-ABL2
PI: Michaud, Jason
Title: Investigations of bacterial urinary tract infections
Biohazardous Agents: *Escherichia coli, Proteus mirabilis, Enterococcus* species
Applicable NIH Guidelines: Exempt
Summary: This study uses a mouse model of urinary tract infections (UTI) and bacteria to study the etiology of UTI and develop a novel drug delivery approach to manage such infections. The request for change is to add *Proteus mirabilis* to the protocol.
Training: All training is complete.
Committee Recommendations: The PI was asked to provide additional room information and the requested information for *Enterococcus*.
Motion: Conditionally Approved
Vote Counts: 10-0-0

G. IBC Continuing Review Active Research

1) **IBC#:** 22-05-012-BL2
PI: Fauver, Joseph
Title: Whole Genome Sequencing of Arboviruses
Biohazardous Agents: West Nile virus
Applicable NIH Guidelines: Exempt
Summary: This project looks at the genomic analysis of West Nile Virus (WNV) RNA for transmission dynamics and epidemiology purposes. RNA from WNV positive samples will be given to the Fauver lab for further analysis. No virus is cultured; no genome editing occurs.
Training: All training is complete.
Committee Recommendations: Update protocol to reflect current room use.
Motion: Conditionally Approved
Vote Counts: 10-0-0

2) **IBC#:** 18-10-023-BL2
PI: Vose, Julie
Title: An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)
Biohazardous Agents: Human cell line/cells/tissues, lentiviral vector
Applicable NIH Guidelines: III-C-1
Training: All training is complete.
Summary: This protocol is a Phase I and Phase 2 study that examines the safety, tolerability, activity and pharmacokinetics of the autologous T-cell therapy JCAR017 for treatment of R/R CLL or SLL.
Committee Recommendations: Asked to spell out all abbreviations at first use and provide clarification on IP storage, preparation, and, patient specimen collection and handling.
Motion: Conditionally Approved
Vote Counts: 10-0-0

3) **IBC#:** 23-07-014-BL2
PI: Lunning, Matthew
Title: A Phase 1 Study of FT522 in Combination with Rituximab in Participants with Relapsed/Refractory B-Cell Lymphoma
Biohazardous Agents: Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: This is a Phase 1 study that examines the safety and tolerability of the iPSC engineered T-cell chemotherapeutic agent FT522 for B-cell lymphoma.
Training: All training is complete.
Committee Recommendations: Add local IRB number, define all acronyms at first use, and add location of speciment processing and storage.
Motion: Conditionally Approved
Vote Counts: 10-0-0

4) **IBC#:** 24-08-027-BL2
PI: Guisbert, Eric
Title: Research on stress responses and fertilization using *C. elegans* and cultured cells

Biohazardous Agents: *Caenorhabditis elegans, Escherichia coli* K-12, Human cell line/cells/tissues, *Saccharomyces cerevisiae,* CRISPR-Cas9, Plasmid, siRNA
Applicable NIH Guidelines: III-D-1-a, III-D-2-a
Summary: This project studies heat shock response cellular pathways. *C. elegans* is used as the model system. *E. coli, S. cerevisiae*, plasmids, and human cell cultures are used for genetic expression experiments. Personnel updates are the only changes submitted with this continuing review.
Training: All training is complete.
Committee Recommendations: none
Motion: Approve
Vote Counts: 10-0-0

5) **IBC#:** 21-08-021-BL2
PI: Chaudhari, Sujata
Title: Understanding the molecular mechanisms of insect cuticular chitin maintenance
Biohazardous Agents: Baculovirus, *Escherichia coli* K-12, *Tribolium castaneum*, Plasmid
Applicable NIH Guidelines: III-D-2-a
Summary: This protocol studies the molecular mechanisms of cuticle development in insects using the red flour beetle as the model insect. Down regulation of genes will be conducted using RNAi and a baculovirus expression system. Personnel changes only.
Training: All training is complete.
Committee Recommendations: Add location of freezer storage and incubators for culture maintenance.
Motion: Conditionally approved
Vote Counts: 10-0-0

6) **IBC#:** 22-07-022-BL2
PI: Wiley, Mike
Title: Monkeypox virus sequencing
Biohazardous Agents: Monkeypox (mpox) virus, extracted genomic DNA
Applicable NIH Guidelines: Exempt
Summary: Extracted DNA from samples analyzed by the NPHL that are mpox+ will be provided to the Wiley lab for further genomic analysis. Personnel updates are the only changes included in this continuing review. No culture of the mpox virus will occur.
Training: All training is complete.
Committee Recommendations: none
Motion: Approve
Vote Counts: 10-0-0

7) **IBC#:** 22-05-015-BL2
PI: Wiley, Mike
Title: Nucleic acid extraction of viruses
Biohazardous Agents: Cytomegalovirus, human mastadenovirus, influenza viruses (not highly pathogenic), reovirus, respiratory syncytial virus, Zika virus
Applicable NIH Guidelines: Exempt
Summary: The aim of this work is to determine which nucleic acid extraction kits are most effective at extracting viruses when the virus type is unknown. Personnel changes only.
Training: All training is complete.
Committee Recommendations: none
Motion: Approve
Vote Counts: 10-0-0

8) **IBC#:** 22-08-023-BL2
PI: Cross, Shaun
Title: Evaluation of *Yersinia pestis* Sequencing Methods
Biohazardous Agents: *Yersinia pestis*; *Yersinia pestis,* extracted genomic DNA
Applicable NIH Guidelines: Exempt
Summary: This study looks at validating and implementing next generation sequencing techniques for *Yersinia pestis* surveillance. Various RG1 *Y. pestis* strains genomic DNA samples are obtained from BEI. RG2 *Y. pestis* strains are also used. No changes were submitted with this continuing review.
Training: All training is complete.
Committee Recommendations: none
Motion: Approved
Vote Counts: 10-0-0

There being no further business, Dr. McMillan adjourned the meeting at 3:06pm

Respectfully Submitted,

JoEllyn McMillan, PhD
Chair, IBC
JM

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

IBC #	Date of Letter/Email
25-05-014-BL2	06/12/25
20-02-010-BL3	06/12/25
22-06-017-ABL2	06/12/25
22-05-012-BL2	06/12/25
18-10-023-BL2	06/13/25
23-07-014-BL2	06/13/25
24-08-027-BL2	06/13/25
21-08-021-BL2	06/13/25
22-08-022-BL2	06/13/25
22-05-015-BL2	06/13/25
22-08-023-BL2	06/13/25