INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
October 9, 2025

MEMBERS PRESENT: JoEllyn McMillan - Chair, Pete Iwen – Vice Chair, Jim Kee, Jenna McKenzie, Micah Schott, Eric Bradley, Jared Evans, Noel Johnson, and Paul Denton

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

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger

GUESTS PRESENT: Stephen Asante-Adde

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

A. Review and Acceptance of IBC Minutes

The IBC voted (9 in favor, 0 against, 0 abstention) to accept September 11, 2025 minutes.

B. Information, Education and Policy Items

None

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#:** 25-09-019-BL2
PI: Lunning, Matthew
Title: A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, a CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy in Participants With Aggressive B-Cell Non-Hodgkin Lymphoma
Biohazardous Agents: Human cell line/cells/tissues, lentiviral vector

Applicable NIH Guidelines: III-C-1
Summary: This is a Phase 1/2 trial to study the therapeutic efficacy of the CAR-T cell therapy LYL314 for non-responsive B-cell lymphomas. This study uses a lentiviral vector system to express in a patient's T-cells a chimeric antigen receptor designed to recognize CD19 and CD20.
Committee Recommendation: Approve
Training: All training is complete and up-to-date.
Motion: Approved
Vote Counts: 9-0-0

2) **IBC#:** 25-09-020-BL2
PI: Ganti, Apar
Title: A Phase II Randomized Study of Safety and Efficacy of a Multiple Antigen Vaccine(STEMVAC) in Non-Small-Cell Lung Cancer Patients (CVI Protocol 151)
Biohazardous Agents: Human cell line/cells/tissues, Plasmid
Applicable NIH Guidelines: III-C-1
Summary: This is a randomized Phase II study in patients with advanced NSCLC who have completed induction therapy without progression and have measurable disease. The IP is a circular DNA plasmid encoding a fusion protein of regions of interest from the five cancer proteins under the control of the CMV promoter. The pUMVC3 plasmid was used to create the IP.
Committee Recommendation: Make one small change to a typo that can be done administratively.
Training: All training is complete and up-to-date.
Motion: Approved
Vote Counts: 9-0-0

3) **IBC#:** 25-09-021-BL2
PI: Gundabolu, Krishna
Title: Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia
Biohazardous Agents: Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: This is an Expanded Access Program trial for Out-of-specification Obecabtagene Autoleucel (obe-cel) in adults with acute lymphoblastic leukemia. The treatment agent is an autologus CAR T-cell therapy.
Committee Recommendation: Section II.1: Add a statement identifying where the transduction takes place. Section II.1: Add a statement describing when and where blood collection and processing will occur. Section II.5: International shipment marked. Identify what is being shipped and that personnel are trained.
Training: All training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 9-0-0

4) **IBC#:** 25-09-022-ABL2
PI: Mammen, Joshua
Title: Development and Application of a Porcine Model of Pancreatic Cancer
Biohazardous Agents: Adenovirus, Porcine cells/tissues
Applicable NIH Guidelines: III-D-1-a, III-D-4-a

Summary: this protocoluses porcine models in pancreatic cancer to develop and assess pancreatic cancer therapeutics and devices. This is a new protocol developed at the request of the IBC from an existing protocol.
Committee Recommendation: Asked to schedule a laboratory inspection and update the IACUC number in Section 1.6.
Training: Two personnel on the protocol need to complete training.
Motion: Conditionally Approved
Vote Counts: 9-0-0

F. IBC Change in Protocol

5) **IBC#:** 08-11-027-ABL2
PI: Wang, Guanshun
Title: Development of Antimicrobial Peptides into Novel Antibacterial Agents
Biohazardous Agents: *Acinetobacter baumannii*, *Bacillus subtilis, Candida albicans, Candida auris, Candida glabrata, Candida tropicalis, Enterobacter cloacae, Enterococcus species, Escherichia coli, Escherichia coli* K-12, *Francisella tularensis* (LVS strain), *Klebsiella pneumoniae*, *Pseudomonas aeruginosa, Staphylococcus aureus,* methicillin-resistant, *Staphylococcus* species, not aureus, *Streptococcus pneumoniae*, *Zygosaccharomyces bailii*
Applicable NIH Guidelines: Exempt
Summary: Adding *Candida auris* to their protocol.
Committee Recommendation: No changes needed. Approve.
Training: One more personnel need to complete training.
Motion: Approve (pending training completion)
Vote Counts: 9-0-0

G. IBC Continuing Review Active Research

6) **IBC#:** 21-03-007-BL3-SA
PI: Gilk, Stacey
Title: Identification and characterization of virulence factors for *Coxiella burnetii*
Biohazardous Agents: *Coxiella burnetii,* CRISPR System Lentivirus-based, *Escherichia coli* K-12, Human cell line/cells/tissues, Vero cells (African Green Monkey kidney), CRISPR-Cas9, Plasmid, shRNA short hairpin, siRNA, siRNA small interfering
Applicable NIH Guidelines: III-D-2-a
Summary: In this protocol, virulence mechanisms for *Coxiella burnetii* will be identified and characterized. Focus is on the lipid and lipid-signaling pathways. Virulence factors will be characterized from *C. burnetti* strains isolated from the environment and acute or chronic patients. Modifications have been evaluated for gain-of-function concerns.
Committee Recommendation: No changes needed, select agent approvals are up-to-date.
Training: All training is complete and up-to-date.
Motion: Approve
Vote Counts: 9-0-0

7) **IBC#:** 24-10-031-BL2
PI: Lunning, Matthew

Title: A PHASE 1, MULTICENTER, OPEN-LABEL STUDY OF UB-VV111 IN COMBINATION WITH RAPAMYCIN IN RELAPSED OR REFRACTORY (R/R) CD19+ B-CELL MALIGNANCIES
Biohazardous Agents: Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: This is a Phase 1 clinical trial to determine the safety and efficacy of the investigational treatment UB-VV111 in combination with or without rapamycin for B-cell lymphoma and lymphocytic leukemias.
Committee Recommendation: In section I, Is ESH 10014 still in use? If yes, add it to Section I.4. If not, update Section I.4 and Section II.5 with current information. In section V, update the answer for Section V.1 to 'none of the above'
Training: All training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 9-0-0

8) **IBC#:** 19-02-006-ABL2
PI: Fisher, Kurt
Title: Assessment of cell signaling and transcriptional regulation
Biohazardous Agents: Human cell line/cells/tissues, CRISPR-Cas9, Lentiviral Vector, miRNA micro, Retroviral vector, shRNA short hairpin, siRNA.
Applicable NIH Guidelines: III-D-2-a, III-D-4-a
Summary: The work in this protocol involves investigation of the role of proteins and other signaling molecules in cancer and normal cell growth.
Committee Recommendation: Schedule their BSL-2 laboratory inspection. In section I, Dr. Fisher is the only person on this IBC that is also listed on the associated IACUC protocol. If anyone else is working with these vectors or modified human cells, please add them to this IBC protocol.
Training: All training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 9-0-0

9) **IBC#:** 19-03-008-BL2
PI: Vose, Julie
Title: Managed Access Program (MAP) Cohort Treatment Plan CCTL019B2003I to provide access for patients with out of specification leukapheresis product and/or out of specification manufactured tisagenlecleucel (CTL019; Kymriah®)
Biohazardous Agents: Human cell line/cells/tissues, Lentiviral vector
Applicable NIH Guidelines: III-C-1
Summary: Only personnel updates are requested; no changes have been made to the protocol itself. This protocol allows physicians to request compassionate-use access to the CAR-T therapy tisagenlecleucel (Kymriah) for patients who may otherwise fall outside the standard inclusion criteria.
Committee Recommendation: In section I, ss ESH 10014 still in use? If yes, no action. If not, please update Section I.4. In section II.1, add a sentence that indicates where and when the lentiviral vectors are introduced.
Training: All training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 9-0-0

10) **IBC#:** 02-11-029-BL3-SA
PI: McCutchen, Emily

Title: CDC-LRN-B Diagnostic Testing for Variola virus: Real-time PCR
Biohazardous Agents: Select agents, diagnostic testing
Applicable NIH Guidelines: exempt
Summary: This is a select agent protocol for the NPHL to provide Variola virus testing. DNA is extracted from samples sent to the NPHL. The CDC Laboratory Response Network protocol is used to test for orthopoxvirus using RT-PCR.
Committee Recommendation: Indicate all personnel who have been trained for shipping.
Training: All training is complete and up-to-date.
Motion: Approved
Vote Counts: 8-0-1

There being no further business, Dr. McMillan adjourned the meeting at 3:15pm

Respectfully Submitted,

[redacted]

JoEllyn McMillan, PhD
Chair, IBC
JM

ADDENDUM
October 9, 2025
IBC REVIEW LETTER/EMAIL TO INVESTIGATORS

IBC #	Date of Letter/Email
25-09-19-BL2	10-09-2025
25-09-20-BL2	10-15-2025
25-09-21-BL2	10-09-2025
25-09-22-ABL2	10-09-2025
08-11-027-ABL2	10-10-2025
21-03-007-BL3-SA	10-10-2025
24-10-031-BL2	10-10-2025
19-02-006-ABL2	10-10-2025
19-03-008-BL2	10-10-2025
02-11-029-BL3-SA	10-10-2025