University of Nebraska Medical Center
BREAKTHROUGHS FOR LIFE.

INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
March 12, 2026

MEMBERS PRESENT: JoEllyn McMillan - Chair, Jim Kee, Jenna McKenzie, Jim Talmadge, Mimi McCann, Noel Johnson, Ryan Duden, Micah Schott, Eric Bradley, Vinai Thomas, and Paul Denton

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

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger

GUESTS PRESENT: Stephen Asante-Adde and Rebecca Cash (Boystown)

Dr. McMillan opened the meeting at 2:31pm.

A. Review and Acceptance of IBC Minutes

The IBC voted (11 in favor, 0 against, 0 abstention) to accept February 12, 2026 minutes.

B. Information, Education and Policy Items

Minutes: Legal representative will review, only as needed.

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#:** 26-02-004-Pending
PI: Lunning, Matthew
Title: A Phase 3 Randomized Controlled Trial of LYL314, a Dual-targeting CD19/CD20 Car T-Cell Product Candidate Versus Investigator's Choice of CD19 Car T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-line Setting
Biohazardous Agents: Lentiviral vector
Applicable NIH Guidelines: III-C-1

Summary: This is a Phase 3 randomized controlled trial that compares the efficacy and safety of LYL314, a dual-targeting CD19/CD20 CAR T-cell product candidate, versus currently approved CD19 CAR T-cell therapies in patients with aggressive relapsed or refractory large B-cell lymphoma. Patient's T-cells are modified using a lentiviral expression vector to express both CD19 and CD20.
Committee Recommendation: The description of the product should be explained more clearly to avoid any confusion if viewed by a non-expert.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 11-0-0

2) **IBC#:** 26-02-005-Pending
PI: Broadhurst, Jana
Title: Developing MALDI Malaria custom library
Biohazardous Agents: *Plasmodium falciparum* (Malaria)
Applicable NIH Guidelines: Exempt
Summary: The goal of these studies is to construct a proteomics library using MALDI-TOF to distinguish between malaria positive and malaria negative blood samples. Blood and red blood cells infected with *Plasmodium falciparum* will be obtained from Dr. Caroline Ng's laboratory for these studies.
Committee Recommendation: Asked to provide internal transport details in the "additional safety practices" in Section II.4
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

3) **IBC#:** 26-02-006-Pending
PI: Devetten, Marcel
Title: A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogenic CRISPR-Cas9-Engineered T-Cells (CTX112) in Adult Participants With Relapsed/Refractory Hematologic Autoimmune Disease.
Biohazardous Agents: Adeno-associated virus, Human cell line/cells/tissues, CRISPR-Cas9
Applicable NIH Guidelines: III-C-1
Summary: This protocol describes a Phase 1/2 clinical trial to determine the safety and preliminary efficacy of CTX112 in adults with relapsed/refractory (r/r) primary immune thrombocytopenia and r/r primary warm autoimmune hemolytic anemia. The treatment CTX112 is a cluster of differentiation (CD) 19–directed chimeric antigen receptor (CAR) T cell immunotherapy composed of allogeneic T cells that are genetically modified ex vivo using CRISPR-Cas9.
Committee Recommendation: Update with new IRB number that is no longer pending. Define IBB (location for processing samples).
Training: One individual needs to complete training.
Motion: Conditionally Approved
Vote Counts: 11-0-0

F. IBC Change in Protocol

4) **IBC#:** 10-09-025-ABL2
PI: Davis, Paul

Title: In vitro and in vivo evaluation of novel anti-parasitic compounds investigating Novel Chemotherapeutics Against the Parasite *Toxoplasma gondii* Exploring the Antimicrobial Potential of Novel Neutrophil-enhancing Compounds [redacted]
Biohazardous Agents: *Escherichia coli* K-12, Human cell line/cells/tissues, Leishmania species, Murine cell line, *Naegleria fowleri*, *Naegleria lovaniensis*, Primary human cell line, *Toxoplasma gondii*, Plasmid
Applicable NIH Guidelines: Exempt
Summary: This is a change request for a long-standing protocol from the Paul Davis Lab at UNO. This first change is to add a series of *Naegleria* species (RG1) that can be tested under this protocol. The second is a proposal to use random mutagenesis (e.g., ENU) strategies to identify temperature sensitive *Naegleria fowleri* (RG2) that exhibit restricted growth at temperatures above 33C. The third is to inoculate any of various immunodeficient strains of mice with the different *Naegleria* species to develop a novel in vivo mouse model of *Naegleria* infection. Minor changes included an additional cell line (CHO), additional PPE, changes from UNO IACUC protocol numbers to the UNO numbers, and inclusion of a note that mice will be anesthetized before injection of *Naegleria* to mitigate the potential of auto-injection during that process.
Committee Recommendation: Section II: The additional protection measures described when lab workers are culturing naegleria fowleri are appropriate. However, asked to clarify that the face masks referenced are N95 respirators, and what type of puncture-resistant gloves will be utilized
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

G. IBC Continuing Review Active Research

5) **IBC#:** 09-06-018-ABL2
PI: Buch, Shilpa
Title: HIV pathogenesis and drugs of abuse
Biohazardous Agents: Adeno-associated virus, EcoHIV, Human cell line/cells/tissues, Human immunodeficiency virus types 1 and 2 (not concentrated), Lentivirus, not HIV, Simian immunodeficiency virus
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This protocol describes studies to investigate the mechanisms of neurodegeneration and neuroinflammation caused by HIV infection. Recombinant DNA (antisense DNA) will be explored for it's therapeutic effects in protecting against neuronal loss and damage. The interactions from drugs of abuse in HIV-induced neuronal damage will also be investigated. Change request was for personnel changes only.
Committee Recommendation: Asked to provide more information regarding location of specific studies and where cells are stored. In Section III, asked to update with new IACUC numbers and information from those protocols.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

6) **IBC#:** 13-06-013-ABL2
PI: Mahato, Ram
Title: Small Molecule and siRNA Delivery for Treating Cancers

Biohazardous Agents: Human cell line/cells/tissues, Murine cell line, lentiviral vector
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This protocol evaluates several therapeutic strategies for three cancer types (HCC, MB, and AML) as well as liver fibrosis using mouse models. The approaches utilize cancer cell lines expressing reporter genes through lentiviral transduction for vivo imaging. They also include delivery of siRNA, shRNA, miRNA, and recombinant AAV vectors, as well as small-molecule inhibitors encapsulated within lipid nanoparticles to target these diseases. Change request was to add new cell lines, AAVs and RNAs that were on a re-written IACUC protocol.
Committee Recommendation: Update personnel. Update Section II.2.B with cells mentioned in associated IACUC protocols. Add new IACUC protocols.
Training: All training is complete and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

7) **IBC#:** 12-11-017-ABL3
PI: Narayanasamy, Prabagaran
Title: Drug discovery and long acting nanoformulations for bacteria and viral infections
Biohazardous Agents: *Acinetobacter baunmanni*, *Chlamydia trachomatis*, *Clostridium* species (not *botulinum*), Human cell line/cells/tissues, Human coronavirus NL63, Human immunodeficiency virus types 1 and 2 (not concentrated), *Klebsiella pneumoniae*, *Mycobacterium* (other than tuberculosis complex), *Mycobacterium tuberculosis*, *Mycobacterium tuberculosis* attenuated strain, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa*, *Sphingopyxis macrogoltabida*, *Staphylococcus aureus* (not vancomycin-resistant)
Applicable NIH Guidelines: Exempt
Summary: This protocol describes studies to determine the effect of newly synthesized compounds and nanoparticles in virus, bacteria and HIV-TB infected macrophages.
Committee Recommendation: Requested to schedule a lab inspection, update animal use description and IACUC protocols. Remove all BL3 and RG3 information from protocol so it may be downgraded to ABL2.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

8) **IBC#:** 25-03-010-BL2
PI: Vose, Julie
Title: A Phase 2, Open-Label, Multicenter Study of MB-105 in Patients with CD5 Positive (CD5+) Relapsed/Refractory T-Cell Lymphoma (r/r TCL)
Biohazardous Agents: Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: The protocol involves the use of MB-105, a CAR-T cell therapy utilizing autologous T cells that are genetically modified to target $CD5^{+}$ T-cell lymphoma.
Committee Recommendation: None
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 11-0-0

9) **IBC#:** 19-10-025-ABL2
PI: Bi, Andy
Title: Targeting oncogenic pathways in hematological malignancies

Biohazardous Agents: *Escherichia coli* K-12, Human cell line/cells/tissues, CRISPR-Cas9, Lentiviral vector, Lentiviral vector (feline immunodeficiency virus), Plasmid, Retroviral vector, shRNA short hairpin
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This protocol aims to study the genes involved in human hematological malignances. Various knock-in, knock-out and knock-down methods are used.
Committee Recommendation: Resolve the discrepancy between the IACUC and IRB numbers linked to this IBC. Update IACUC numbers and indicate in the description of work what cells are used on what IACUC protocols. Chage from ABSL2 to ABSL1 in Section III.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

10) **IBC#:** 17-10-021-BL2
PI: Byrareddy, Siddappa
Title: Vedolizumab treatment in Antiretroviral drug treated chronic HIV infection
Biohazardous Agents: Human cell line/cells/tissues, Human immunodeficiency virus types 1 and 2 (not concentrated), Human stool
Applicable NIH Guidelines: Exempt
Summary: This protocol evaluates biological materials from de-identified, HIV-infected patients including blood, plasma, feces, saliva, and gut biopsies. Viral load is analyzed using PCR, and DNA is isolated from fecal samples for microbiome sequencing at an off-site commercial facility. The overall goal is to evaluate whether the drug Vedolizumab (commonly used to treat ulcerative colitis and Crohn's disease), is safe and effective for patients infected with HIV.
Committee Recommendation: Asked to clarify: are HIV-infected samples only handled within the biological safety cabinet? Indicate in which lab the HIV work will be done
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 11-0-0

There being no further business, Dr. McMillan adjourned the meeting at 3:10pm

Respectfully Submitted,

[redacted]

JoEllyn McMillan, PhD
Chair, IBC
JM

ADDENDUM
March 12, 2026
IBC REVIEW LETTER/EMAIL TO INVESTIGATORS

IBC #	Date of Letter/Email
26-02-004-Pending	03/16/2026
26-02-005-Pending	03/16/2026
26-02-006-Pending	03/16/2026
10-09-025-ABL2	03/13/2026
09-06-018-ABL2	03/13/2026
13-06-013-ABL2	03/16/2026
12-11-017-ABL3	03/13/2026
25-03-010-BL2	03/13/2026
19-10-025-ABL2	03/16/2026
17-10-021-BL2	03/13/2026