University of Nebraska Medical Center
BREAKTHROUGHS FOR LIFE.

INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
May 14, 2026

MEMBERS PRESENT: JoEllyn McMillan - Chair, Pete Iwen – Vice Chair, Jenna McKenzie, Jim Talmadge, Jared Evans, Ryan Duden, Eric Bradley, Ron Bartlett, Mimi McCann, and Paul Denton

NON-VOTING ALTERNATE MEMBERS PRESENT: Makayla Walker.

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger and Sue Logsdon

GUESTS PRESENT: Stephen Asante-Adde

Dr. McMillan opened the meeting at 2:32pm

A. Review and Acceptance of IBC Minutes

The IBC voted (10 in favor, 0 against, 0 abstention) to accept April 9, 2026 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#:** 26-04-008-Pending
PI: Medlin, Jennifer
Title: A Phase 2, Open-Label, Single-Arm Trial of FT819 in Participants with Refractory Moderate-to-Severe Systemic Lupus Erythematosus with Lupus Nephritis (FT819-201)
Biohazardous Agents: Human cell line/cells/tissues
Applicable NIH Guidelines: III-C-1
Summary: This protocol describes a multicenter, phase 2 trial to evaluate the efficacy and safety of an allogenic T cell therapy ([redacted]) in patients with moderate to severe systemic lupus erythematosus (SLE) refractory to at least 2 immunosuppressive therapies. [redacted] comprises allogeneic T cells, derived from a clonal T-cell receptor (TCR) knockout human

induced pluripotent stem cell (iPSC) line, that expresses a CD19-targeted chimeric antigen receptor (CAR) regulated by the TCR a constant (TRAC) locus.
Committee Recommendation: Add the name of IP to the last paragraph of the description of work. Asked how transport of [redacted] from BPF to patient room will occur. State how mycoplasma, viral, and bacterial infection will be documented. If samples are collected and manipulated by study staff, add room numbers.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

2) **IBC#:** 26-04-009-Pending
PI: Martin, Thomas
Title: Molecular Regulation of Physiologic and Pathological Cardiac Remodeling
Biohazardous Agents: Adeno-associated virus, Adenoviral vectors, *Escherichia coli* K-12, Human cell line/cells/tissues, Murine cell line, Nonhuman Primate Cells (Cos-7 African Green Monkey), Plasmid, siRNA
Applicable NIH Guidelines: III-D-1-A, III-D-3-A, II-D-4-A
Summary: This protocol describes studies to investigate the molecular mechanisms underlying cardiac remodeling. AAV, AV, siRNA and plasmids are used to modulate genes and proteins that can regulate this remodeling. Studies are conducted in human, monkey and mouse cells and in mice in vivo.
Committee Recommendation: Schedule a laboratory inspection. Add sources of cell lines/tissues. Provide a description of the genes targeted or expressed by siRNA/viral vectors. Select red bin waste in Section III.2. Update IACUC numbers. Select “other” in III.5 and note the use of tail vein injection.
Training: All training is completed and up to date.
Motion: Tabled
Vote Counts: 10-0-0

F. IBC Change in Protocol

***The four change requests listed below underwent expedited review by IBC members prior to the meeting and were subsequently presented to the full committee for final approval.

3) **IBC#:** 22-02-005-BL3
PI: Santarpia, Joshua
Title: Protocol for Conducting Research with Hazardous Biological Aerosols
Biohazardous Agents: Hantavirus, Andes Strain, Hantavirus, Sin Nombre Virus, Human cell line/cells/tissues, SARS-CoV-2, Vero cells (African Green Monkey kidney)
Applicable NIH Guidelines: Exempt
Summary: This protocol studies the generation, measurement, inactivation and effectiveness of PPE for bioaerosols. SARS-Cov-2, Hantavirus (Sin Nombre and Andes strains) are used. The change request was to add culture of hantavirus Andes strain from environmental samples and stocks.
Committee Recommendation: None
Training: One individual needs to complete training.
Motion: Approved
Vote Counts: 10-0-0

4) **IBC#:** 20-02-010-BL2

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: Environmental, multiple bacteria, Hantavirus, Andes Strain, Influenza viruses (not highly pathogenic), Measles virus, Mpox clade II, Respiratory syncytial virus, SARS-CoV-2.
Applicable NIH Guidelines: Exempt
Summary: This protocol describes the collection of environmental samples from patient care rooms. Specific focus is on patients with SARS-Cov2, monkey pox and hantavirus (Andes strain). The change request was to add sampling for hantavirus Andes strain. No culture. Environmental samples collected and cultured covered by protocol 22-03-05 performed in the BSL-3. BSL-3 practices are used.
Committee Recommendation: None
Training: One individual needs to complete training.
Motion: Approved
Vote Counts: 10-0-0

5) **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: This protocol describes studies to create libraries of synthetic control material for pathogen detection to be used in molecular infectious disease assays. Sequences homologous to a single gene region from each pathogen will be identified and synthetic double stranded DNA material created using IDT gBlocks. The change request was for addition of the NP (S segment) from hantavirus Andes strain. No whole genomes or extracted RNA from virus are used. The assays are plasmid based only.
Committee Recommendation: None
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

6) **IBC#:** 20-03-018-BL2
PI: Broadhurst, Jana
Title: Pathogen testing, specimen repository and clinical trials processing and shipping.
Biohazardous Agents: Hantavirus, Andes Strain, Human cell line/cells/tissues, Influenza viruses (not highly pathogenic), Respiratory syncytial virus, SARS-CoV-2, SARS-CoV-2 (clinical specimen)
Applicable NIH Guidelines: Exempt
Summary: This protocol involves testing of pathogens, repository of specimens collected in clinical research protocols and shipping of specimens to return unused samples to the originating research PI. The requested change was to add hantavirus Andes strain for diagnostic test development. Studies are carried out in a BSL-2 lab using BSL-3 practices.
Committee Recommendation: None
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

G. IBC Continuing Review Active Research

7) **IBC#:** 13-09-020-ABL2
PI: Davis, John
Title: Signaling spectroscopy of microbial pathogens
Biohazardous Agents: Adenoviral vectors, Bovine cells / tissues, Human cell line/cells/tissues, Macaque NHP cells / tissue, Murine cell line, Murine Primary Cells, Lentiviral Vector, Oncogene, siRNA
Applicable NIH Guidelines: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a
Summary: this protocol describes studies to identify intracellular signaling mechanisms that regulate normal and pathological ovarian function. Adeno- and lentiviral constructs are used to express/inhibit pathways in ovarian and uterine cells from several species.
Committee Recommendation: Schedule a laboratory inspection. Ensure that all personnel complete NHP-B virus safety training in Canvas. Provide information on the source of macaque tissue. Update IACUC numbers. Update the description of use for modification of murine cells if adenoviral vectors will also be used.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

8) **IBC#:** 23-02-005-BL2
PI: Svechkarev, Denis
Title: Molecular spectroscopy of microbial pathogens
Biohazardous Agents: *Acinetobacter baumannii*, *Bacillus subtillis*, Bacteriophage, *Citrobacter* species, *Enterobacter cloacae, Enterobacter* species, *Enterococcus* species, *Escherichia coli*, *Escherichia coli* K-12, *Klebsiella pneumonia*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* (not vancomycin-resistant), *Staphylococcus aureus*, methicillin-resistant, *Staphylococcus aureus* (methicillin-susceptible), *Staphylococcus* species not aureus, *Streptococcus pneumoniae*
Applicable NIH Guidelines: Exempt
Summary: The focus of this project is the development of fluorescent signatures in bacteria and viruses together to recognize pathogens using molecular spectroscopy. The most notable change is the plan to grow bacterial cultures at UNO instead of transferring them from UNMC. New bacterial species in the request for change include: S. *aureus*- UAMS-1, Newman, SA564 (MSSA), JE2, COL, MW2 (MRSA); *E. coli*- K-12, DH5α B. subtilis- 168; S. epidermidis - 1457.
Committee Recommendation: Update personnel list. Add the laboratory where culturing will take place. Expand on what manipulations of the bacteriophages will take place. Update all laboratory locations in Section I.4.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

9) **IBC#:** 04-12-053-BL2
PI: Caplan, Steven
Title: 1) Adenoviral and Lentiviral transfection of endocytic recycling regulatory proteins; 2) Sorting of HeLa cells by flow cytometry; 3) Molecular mechanisms controlling endocytic recycling; 4) Mechanisms and function of endosome-derived tubular carriers; 5) Vesicular transport mechanisms in centrosome regulation; 6) Mechanism and efficacy of Brentuximab Vedotin for Anaplastic large T Cell Lymphoma; 7) Role of Endocytic Regulatory Proteins in

Mitochondrial Fission and Parkinson's Disease 8) Mechanisms of Primary Ciliogenesis: a Novel Approach to Cancer Biology
Biohazardous Agents: Adenoviral vectors, Epstein Barr virus, Human cell line/cells/tissues, Lentiviral Vector
Applicable NIH Guidelines: III-D-1-a, III-D-3-a
Summary: This protocol describes studies to investigate the molecular mechanisms involved in endocytic and membrane trafficking. A variety of human and mouse cell lines are used for these studies. Adenoviral and lentiviral expression systems are used to express proteins of interest for membrane trafficking.
Committee Recommendation: Schedule a laboratory inspection. Remove Epstein Barr virus as a hazard unless working with EBV stocks. Section II.2C, clarify expressed or targeted genes with viral vectors.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

10) **IBC#:** 18-10-023-BL2
PI: Vose, Julie
Title: An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of [redacted] in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Biohazardous Agents: Human cell line/cells/tissues, Lentiviral Vector
Applicable NIH Guidelines: III-C-1
Summary: This is a continuing review of a CAR T cell therapy protocol using genetically modified autologous T cells in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). The study uses a replication incompetent lentiviral vector that is tested for replication competency before shipment to UNMC. The proposed changes to the protocol involve a new contact person.
Committee Recommendation: None
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

11) **IBC#:** 16-12-028-ABL2
PI: Hollingsworth, Michael
Title: Establishment of Patient Derived Models in Immunodeficient Mice
Biohazardous Agents: Human cell line/cells/tissues, Lentiviral Vector
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This protocol uses fresh human tissues to develop patient-derived xenografts, cell lines, and organoids for cancer research. Lentiviral fluorescent labeling will be used to track and study tumor cells and their interactions within the tumor microenvironment.
Committee Recommendation: Update Section I.4 for active or inactive lab locations. Update personnel.
Training: Human cell line/cells/tissues
Motion: Approved
Vote Counts: 10-0-0

12) **IBC#:** 20-02-011-ABL2
PI: Ray, Sutapa
Title: Generation of firefly luciferase reporter cell lines using lentiviral system

Biohazardous Agents: Human cell line/cells/tissues, Lentiviral Vector
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This study uses human cells and lentiviral vectors to create luciferase expressing tumor cells for tracking tumor development *in vivo*.
Committee Recommendation: Update personnel.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

13) **IBC#:** 13-02-006-ABL2
PI: Teoh-Fitzgerald, Melissa
Title: 1) Extracellular redox signaling in tumor-fibroblast interaction 2) Oxidative regulation of C-Met in breast cancer; 3) Nox4 as a Therapeutic Target in Breast Cancer
Biohazardous Agents: Adenoviral vectors, *Escherichia coli* K-12, Human cell line/cells/tissues, Murine cell line, Retrovirus, Murine Moloney Leukemia, Lentiviral Vector, Plasmid, shRNA short hairpin, siRNA
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This study examines the role and regulation of extracellular superoxide dismutase (EcSOD) in the promotion of mammary tumor interactions with fibroblasts. EcSOD will be regulated in mouse and human cells using adenoviral vector, lentiviral vector and retroviral vector expression systems as well as shRNA, siRNA regulation. Mouse and human cells modified for EcSOD expression will be injected into mice for tumor growth and metastasis studies.
Committee Recommendation: Schedule a lab inspection before the end of the year.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

14) **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 [redacted] versus investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma ([redacted]
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 T cell receptor-engineered autologous T-cells directed against tumor-specific HLA-presented peptides. Autologous T-cells are modified to express the modified T-cell receptor using a third-generation lentiviral vector.
Committee Recommendation: None
Training: All training is completed and up to date
Motion: Approved
Vote Counts: 10-0-0

15) **IBC#:** 12-05-007-BL2
PI: Dudley, Andrew
Title: Research in musculoskeletal development and regeneration

Biohazardous Agents: Adeno-associated virus, Adenoviral vectors, Adenovirus, Human cell line/cells/tissues, CRISPR-Cas9, Lentiviral Vector, Lentiviral Vector – feline immunodeficiency virus, Plasmid, Retroviral vector, shRNA short hairpin, siRNA
Applicable NIH Guidelines: III-D-1-a
Summary: This protocol studies musculoskeletal development and regeneration, particularly bone and cartilage, using chick embryo and cell culture models. Researchers use recombinant DNA techniques and viral vectors to manipulate gene expression and analyze the effects through imaging, histological, and biochemical methods.
Committee Recommendation: Schedule a lab inspection.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

16) **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: The work is focused on understanding the cellular stress response pathway known as the "heat shock response" (HSR). Most of the work is done using *C. elegans* or human cell lines (e.g. HEK 293T and HeLa). Plasmid-based cloning is used to produce recombinant DNA for genetic expression experiments or to make reporter constructs such as GFP. There are no changes proposed.
Committee Recommendation: Update lab rooms once UNO renovations have been completed.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

17) **IBC#:** 18-09-020-ABL2
PI: Zucker, Irving
Title: Viral gene transfer for studying sympathetic function in cardiovascular disease in mice
Biohazardous Agents: Herpes virus vector, Lentiviral Vector
Applicable NIH Guidelines: III-D-4-a
Summary: The purpose of the study is to resume work to determine if selective knockdown and overexpression of Nrf2 in the stellate ganglion alters cardiac sympathetic tone in normal and CHF animals by altering ganglionic neuronal excitability.
Committee Recommendation: Update IACUC numbers and schedule a lab inspection.
Training: All training is completed and up to date.
Motion: Approved
Vote Counts: 10-0-0

18) **IBC#:** 16-06-017-ABL2
PI: Ghosal, Gargi
Title: DNA replication stress response in cancer and premature aging
Biohazardous Agents: *Escherichia coli*, Human cell line/cells/tissues, Lentiviral Vector
Applicable NIH Guidelines: III-D-1-a, III-D-3-a, III-D-4-a
Summary: This protocol describes studies to investigate the role of replication stress response in mediating cancer and premature aging. Various proteins involved in DNA replication and damage response are expressed in human cell lines using a lentiviral

expression system. shRNA will be generated against various of these genes using a lentiviral expression system. Modified human cells will be used in mice.
Committee Recommendation: Ensure that all personnel handling cells/tissues on the associated IACUC protocols are listed on this IBC protocol. Add a description for decontamination and disposal of human cell culture plates and other plastics used in cell culture.
Training: All training is completed and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

19) **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 globuli*, *Bacillus* not *anthracis* or *cereus*, *Bacillus subtilis*, Bacteriophage, *Escherichia coli* K-12, *Francisella tularensis* (LVS strain), *Klebsiella pneumoniae*, *Staphylococcus aureus* (not vancomycin-resistant), *Staphylococcus* species not aureus, *Vibrio cholera*, *Yersinia pestis*, *Yersinia rohdei*
Applicable NIH Guidelines: Exempt
Summary: This protocol describes studies to identify environmental sample extracts that have antibacterial properties. Bacteriophages are of particular interest. Several bacterial strains will be used for determining antibacterial activities of isolated bacteriophages and environmental sample extracts.
Committee Recommendation: Change title to "Treat Bacteria WITH Viruses". Schedule a laboratory inspection after June 1st.
Training: One individual needs to complete training.
Motion: Approved
Vote Counts: 10-0-0

There being no further business, Dr. McMillan adjourned the meeting at 3:38pm

Respectfully Submitted,

[redacted]

JoEllyn McMillan, PhD
Chair, IBC
JM

ADDENDUM
May 14, 2026
IBC REVIEW LETTER/EMAIL TO INVESTIGATORS

IBC #	Date of Letter/Email
26-04-008-Pending	05-18-2026
26-04-009-Pending	05-20-2026
22-02-005-BL3	05-11-2026
20-02-010-BL2	05-11-2026
24-07-022-BL1	05-12-2026
20-03-018-BL2	05-11-2026
13-09-020-ABL2	05-20-2026
23-02-005-BL2	05-15-2026
04-12-053-BL2	05-20-2026
18-10-023-BL2	05-15-2026
16-12-028-ABL2	05-15-2026
20-02-011-ABL2	05-15-2026
13-02-006-ABL2	05-15-2026
25-05-014-BL2	05-15-2026
12-05-007-BL2	05-15-2026
24-08-027-BL2	05-15-2026
18-09-020-ABL2	05-15-2026
16-06-017-ABL2	05-15-2026
25-06-016-BL2	05-15-2026