INSTITUTIONAL BIOSAFETY COMMITTEE
IBC MEETING MINUTES
December 11, 2025

MEMBERS PRESENT: JoEllyn McMillan - Chair, Pete Iwen – Vice Chair, Jim Kee, Jenna McKenzie, Jim Talmadge, Vinai Thomas, Mimi McCann, Micah Schott, Eric Bradley, and Paul Denton

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

ADMINISTRATIVE STAFF PRESENT: Jackie Hollinger

GUESTS PRESENT: Stephen Asante-Adde

Dr. McMillan opened the meeting at 2:33pm.

A. Review and Acceptance of IBC Minutes

The IBC voted (10 in favor, 0 against, 0 abstention) to accept November 13, 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#:** 25-10-023-ABL1
PI: Fernandez-Pena, Carlos
Title: Neurobiology of anxiety and anxiety disorders
Biohazardous Agents: Adeno-associated viral vector
Applicable NIH Guidelines: III-D-4-a
Summary: In this protocol, the PI will study the neural mechanisms underlying the regulation of anxiety and development of anxiety disorders. AAV constructs will be used to express genes related to anxiety and these constructs will be delivered by stereotaxic injection. Assessment includes imaging, behavioral and biochemical assessments.
Committee Recommendation: Asked to update lab room numbers.

Training: All training is complete and up to date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

F. IBC Change in Protocol

none

G. IBC Continuing Review Active Research

1) **IBC#:** 24-12-043-BL2
PI: Rodenbaugh, Kerry
Title: A Phase 1/2 Open-label, Single-arm, Multicenter Study to Evaluate the Safety and Preliminary Efficacy of Autologous SCG142 T Cell Receptor (TCR) T Cells in Patients with Advanced or Metastatic HPV16- or HPV52-positive Carcinomas
Biohazardous Agents: Human cell line/cells/tissues, lentiviral vector
Applicable NIH Guidelines: III-C-1
Summary: Phase 1/2, open-label, multicenter trial in patients with advanced or metastatic human papillomavirus type 16 (HPV16)- or human papillomavirus type 52 (HPV52)-positive carcinomas who have progressed after at least 1 line of systemic therapy, including but not limited to combination chemotherapy and/or combination chemoimmunotherapy.
Committee Recommendation: Section II.1 - Please add a brief sentence about whether samples are collected from the patient after treatment. If yes, also indicate what samples and where they are processed. Section II - What is the room number for where cryopreservation will occur?
Training: All training is complete and up-to-date.
Motion: Conditionally Approved

2) **IBC#:** 14-11-025-EX
PI: Boesen, Erika
Title: Renal iron handling in health and disease
Biohazardous Agents: Canine cell line / tissues, human cell line/cells/tissues, murine cell line
Applicable NIH Guidelines: Exempt
Summary: Experiments will evaluate uptake of iron or fluorescently-labelled iron transport proteins will be studied with and without co-treatment of the cells with inflammatory cytokines to determine whether inflammatory stimuli increase iron uptake by the cells.
Committee Recommendation: None
Training: Training is completed and up-to-date.
Motion: Approve
Vote Counts: 10-0-0

3) **IBC#:** 17-06-013-BL2
PI: Rucks, Elizabeth
Title: Understanding fundamental host-pathogen interactions through examination of how Chlamydia interact with eukaryotic cells
Biohazardous Agents: *Chlamydia*, *Chlamydia trachomatis*, *Coxiella burnetiid* Nine Mile Phase II (avirulent), *Escherichia coli* K-12, Human cell line, human cell line/cells/tissues, *Pseudomonas aeruginosa,* Wolbachia, *Yersenia pseudotuberculosis*, Plasmid, siRNA

Applicable NIH Guidelines: Exempt
Summary: Change request was for personnel changes only.
Committee Recommendation: None
Training: All training is complete and up-to-date
Motion: Approve
Vote Counts: 10-0-0

4) **IBC#:** 24-04-007-BL2
PI: Kwok, Benjamin
Title: Investigating the roles of microtubule-based kinesin motor proteins in cell division and cancer
Biohazardous Agents: Baculovirus, Lentivirus, not HIV, Plasmid, siRNA small interfering
Applicable NIH Guidelines: III-D-1-a, III-D-2-a
Summary: Project focuses on cancer-centric mechanisms affecting microtubule dynamics via kinesin-family proteins. Standard genetic tools are proposed including plasmid DNA, baculovirus, lentiviral vectors, gene editing, and silencing RNA.
Committee Recommendation: Update room numbers in Section I.4 - if needed.
Training: All training is complete and up-to-date.
Motion: Approve
Vote Counts: 10-0-0

5) **IBC#:** 24-02-005-BL2
PI: Scherger, Sias
Title: Cytomegalovirus (CMV) Vaccine in Orthotopic Liver Transplant Candidates
Biohazardous Agents: Human cell line/cells/tissues, vaccinia viral vector
Applicable NIH Guidelines: III-C-1
Summary: This is a phase 2 study evaluating the safety and efficacy of a cytomegalovirus vaccine in orthotopic liver transplant candidates.
Committee Recommendation: In Section II.1, please delete the sentence "There is no laboratory associated work or research performed with the vaccine" from the first paragraph. Section II.2.C - Please update the sentence "MVA is an attenuated pox virus that is made avirulent through repeated passages[...]".
Training: All training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

6) **IBC#:** 24-11-040-ABL2
PI: Sillman, Brady
Title: Long-acting injectable atovaquone nanoformulation for malaria prophylaxis
Biohazardous Agents: *Plasmodium yoelli* (rodent)
Applicable NIH Guidelines: Exempt
Summary: This is the first continuing review of the study of long-acting injectable atovaquone nanoformulation for malaria prophylaxis..
Committee Recommendation: Update personnel.
Training: Training is complete and up-to-date.
Motion: Approved
Vote Counts: 10-0-0

7) **IBC#:** 17-08-017-BL3-SA
PI: Larson, Marilynn

Title: Characterization of Francisella tularensis and Mammalian Cell Interactome
Biohazardous Agents: *Escherichia coli* K-12, *Francisella tularensis,* Human cell line, Primary Human Cell Line, CRISPR-Cas9, miRNA micro, mRNA, Plasmid, siRNA, siRNA small interfering
Applicable NIH Guidelines: III-D-1-b, III-D-2-a
Summary: The purpose of this study is to better understand the mechanisms used by *Francisella tularensis* that allow this intracellular pathogen to suppress an effective immune response, rapidly replicate to high numbers in the cytosol of infected host cells, and then ultimately induce apoptosis and the release of viable progeny..
Committee Recommendation: None
Training: Training is complete and up-to-date
Motion: Approved.
Vote Counts: 10-0-0

8) **IBC#:** 10-12-024-BL3-SA
PI: Larson, Marilynn
Title: Molecular Genetic, Proteomic, Lipidomic, and Metabolomic Analysis of Select Agents.
Biohazardous Agents: *Bacillus anthracis*, *Botulinum neurotoxin* producing species of *Clostridium*, *Brucella abortus*, *Brucella melitensis*, *Brucella suis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Coxiella burnetii*, *Francisella tularensis*, *Rickettsia prowazekii*, Select agents, diagnostic testing, vaccinia virus, Venezuelan equine encephalomyelitis virus, Western equine encephalomyelitis virus, culture or specimen, *Yersinia pestis*, *Botulinum* neurotoxin greater than 10mg.
Applicable NIH Guidelines: Exempt
Summary: The purpose of this study is to evaluate and optimize current detection methods, and to develop new diagnostics, therapeutics, and vaccines to counter diseases caused by various pathogens and the associated toxins.
Committee Recommendation: none
Training: Training is complete and up-to-date
Motion: Approve
Vote Counts: 10-0-0

9) **IBC#:** 16-01-001-ABL2
PI: Gendelman, Howard
Title: NanoART Manufacture, Delivery and Pharmacokinetics for Optimizing Drug Adherence. Project 3: Nanotherapeutics for Lentivirus Infected Rodents;2. Novel Adjunctive Therapies for NeuroAIDS: Project 3: Animal Models for Preclinical Drug Testing
Biohazardous Agents: Adeno-associated virus, Human cell line/cells/tissues, Human immunodeficiency virus types 1 and 2 (not concentrated), Humanized mouse
Applicable NIH Guidelines: III-D-4-a
Summary: This is a continuing review for a longstanding and productive protocol from the Gendelman lab. This protocol focuses on developing better HIV treatment approaches with an emphasis on long-acting antiretroviral therapies.
Committee Recommendation: Update personnel. Section III.2, HIV, please add new IACUC numbers and relevant procedures (humanized, HIV infected mice). Section III.3, HIV: Please update strains used. Section II.1, a closed IRB protocol is mentioned, please remove this information.
Training: Training is complete and up-to-date.
Motion: Conditionally Approved
Vote Counts: 10-0-0

10) **IBC#:** 04-11-050-BL2
PI: Gendelman, Howard
Title: 1) Propagation and purification of large quantities of HIV-1 2) Neural immunity in HIV dementia 3) Molecular mechanisms of HIV-mediated encephalopathy 4) Training Program in Neurovirology 5) Immunopathogenesis of HIV Neurological Disorders: Project 2: Monocyte Immunity and HIV-1 Induced Dementia
Biohazardous Agents: Human cell line/cells/tissues, human immunodeficiency virus types 1 and 2 (not concentrated)
Applicable NIH Guidelines: Exempt
Summary: This protocol describes the propagation of HIV-1 in cells for preparation of HIV-1 stocks for other studies. The protocol also describes the study of neurotoxic effects of HIV-1 and the immunologic basis of HIV-1 associated dementia using HIV infected human monocyte-derived macrophages and microglial cells.
Committee Recommendation: Update personnel.
Training: Training is complete and up-to-date
Motion: Approve
Vote Counts: 10-0-0

11) **IBC#:** 20-01-003-BL2
PI: Singh, Dhirendra
Title: Role of antioxidant protein Peroxiredoxin (Prdx) 6 in eye lens epithelial cell survival
Biohazardous Agents: Human cell line/cells/tissues, murine primary cells, lentiviral vector
Applicable NIH Guidelines: III-D-1-a
Summary: Replication incompetent Lentiviral and retroviral vectors will be used to deliver small interfering RNA (shRNA) or Lenti ORF into lens epithelial cells (derived from eye lens).
Committee Recommendation: Section II.1 and 2, clarify retroviral vector use in the Description of Work and, if applicable, select an agent to cover this (in Section IIA) and complete all questions for that agent.
Training: PI needs to complete training.
Motion: Conditionally Approved
Vote Counts: 10-0-0

There being no further business, Dr. McMillan adjourned the meeting at 3:16pm

Respectfully Submitted,

JoEllyn McMillan, PhD
Chair, IBC
JM

ADDENDUM
December 11, 2025
IBC REVIEW LETTER/EMAIL TO INVESTIGATORS

IBC #	Date of Letter/Email
25-10-023-ABL1	12-12-2025
24-12-043-BL2	12-12-2025
14-11-025-BL2	12-11-2025
17-06-013-BL2	12-11-2025
24-04-007-BL2	12-11-2025
24-02-005-BL2	12-12-2025
24-11-040-ABL2	12-11-2025
17-08-017-BL3-SA	12-11-2025
10-12-024-BL3-SA	12-11-2025
16-01-001-ABL2	12-12-2025
04-11-050-BL2	12-11-2025
20-01-003-BL2	12-12-2025