



Minutes

MCW Institutional Biosafety Committee

Institutional Biosafety Committee

9/9/2025

1:00 pm

Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:01 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 12 voting members present. A quorum was maintained for the entire meeting.

Confidentiality: The Chair reminded the committee that while the meeting is open to the public, the information discussed during the meeting should be treated as confidential.

Conflict of Interest: The Chair asked the committee if any members needed to declare a conflict of interest with respect to any matter on the agenda. The Chair notified committee members that if they had a conflict of interest, they must leave the room during the final discussion and voting on that IBC submission.

2 Attendees

Committee Members Present

Lewis Bowen III (Finance and Administration)	Biological Safety Officer
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert
Benjamin Gantner (Medicine)	Chair
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert
Anna Huppler (Pediatrics)	R/SNA Technology Expert
Eric Jensen (Research Office)	Animal Containment Expert
Tyce Kearl (Medicine)	R/SNA Technology Expert
	HGT Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member

Committee Members Absent

Kenneth Allen (Research Office)

Alternate Animal Containment
Expert, Non-Voting

James Case (Non-MCW)

Non-Affiliated Member

Matthew Surdel (Medicine)

R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

8/12/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12

4 New Business

1. IBC Oversight Considerations: Human Source Material

The Chair reminded the Institutional Biosafety Committee (IBC) that IBC approval is currently required for processing of human source material for research purposes regardless of whether that material is recombinant. However, work with human source material also requires approval through the Institutional Review Board (IRB); the IRB submission captures whether study staff will be handling these materials and if they have completed bloodborne pathogens training. He asked the Committee to consider whether requiring an IBC Application for studies that are only processing non-recombinant human source material increased safety or caused duplicative work for Principal Investigators (PIs) and study staff. The Chair noted that these IBC Applications are not reviewed by the full committee, as they do not fall under Sections IIIA-IIIID of the *National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, or include select agents or Risk Group 2 or higher microorganisms. Several IBC members agreed that requiring IBC Applications for such work is duplicative and they supported removing this requirement. The Biosafety Office voiced a concern that if IBC Applications are not required for this work and the samples are shipped, the shipping training of individuals performing shipping would be difficult to verify. After discussion, the Chair asked the Biosafety Officer to reach out to the IRB Office and others in the Environmental Health and Safety Office to determine if either Office has a way to track shipping training. The BSO will bring this information back to a later meeting for further discussion.

2. Administrative Report

The Chair asked the Committee Members to review the Administrative Report and then invited discussion. No concerns were raised.

3. Exempt Rodent Report

The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20240060_AME01 Pre-clinical Study of CAR-T Cells

Principal Investigator:	Fumou Sun
Motion:	Decision Pending Changes
Yes Votes:	12
No Votes:	0

5 Application Reviews

Abstained: 0
Recused: 0
Total Votes: 12

NIH Guidelines: Section III-D-1, Section III-D-2, Section III-D-3, Section III-D-4, Section III-E, Section III-F-8 (C-I)

Biosafety Level(s): BSL1, BSL2, BSL2+

Deliberations: The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Principal Investigator (PI) proposes to add new tumor cell lines including mouse multiple myeloma cell lines and human breast cancer cell lines. Overall, the project focuses on pre-clinical studies of chimeric antigen receptor (CAR)-T cells for the treatment of malignancy. The use of 3rd generation lentiviral transduction to express surface proteins will be expanded to these added cell lines, including BCMA or CD24 expression in mouse myeloma cell lines and ROR1 expression in human breast cancer cell lines. Both new cell types will be administered to mice, similar to the procedures previously done with human myeloma and leukemia cell lines. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers requested a few clarifications, including whether viral vectors will be transported onsite, which viral vectors will be handled at biological safety level (BSL)2+, and what mitigation strategies will be used for work with viral vectors. The Animal Containment Expert (ACE) and Biological Safety Officer (BSO) had no additional concerns. After discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20230065_AME05 Cancer therapeutics and drug resistance

Principal Investigator: Todd Miller
Motion: Decision Pending Changes
Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12

NIH Guidelines: Section III-D-1, Section III-D-2, Section III-D-3, Section III-D-4, Section III-F-8 (C-I)

Biosafety Level(s): BSL1, BSL2, BSL2+

Deliberations: The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Principal Investigator (PI) wishes to add murine-derived cancer cell lines for implantation into immunocompetent recipient mice. The PI plans to generate cell lines that stably express fluorescent reporters prior to transplantation. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The Reviewers requested the PI confirm whether cells lines will be transported onsite, clarify whether tissues will be collected from mice that have been administered human and/or murine tumors, and confirm if microorganisms will be used in the production of lentiviral vectors. The Biological Safety Officer (BSO) stated that a study team member needs to renew their bloodborne pathogens training. The Animal Containment Expert (ACE) had no additional concerns. After discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20250005_AME01 Leone- Viruses In Vivo

5**Application Reviews**

Principal Investigator: Gustavo Leone
Motion: Decision Pending Changes
Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12
NIH Guidelines: Section III-D-4
Biosafety Level(s): BSL1, BSL2

Deliberations:

The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application and the Secondary Reviewer elaborated on the study. The Principal Investigator (PI) is adding the transplant of cells from genetically engineered mice. Cells will be derived from mice with pancreatic tumors (which were induced by genetic engineering) and injected into the pancreases of different genetically engineered mice (with mutations in stromal cells). The goal is to understand the effects of modified stroma on tumor progression. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI clarify if microorganisms will be used to amplify plasmids and to confirm that no shedding of cell lines is expected after administration to mice. The Animal Containment Expert (ACE) and Biological Safety Officer (BSO) had no additional concerns. Upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20131212_REN04 [PPG Planning Grant for Comprehensive Mechanistic Studies](#)

Principal Investigator: Balaraman Kalyanaraman
Motion: Decision Pending Changes
Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12
NIH Guidelines: Section III-D-4, Section III-F-1, Section III-F-8 (C-1)
Biosafety Level(s): BSL1, BSL2

5 Application Reviews

Deliberations:

The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer went on to explain the study. The Principal Investigator (PI) studies the metastatic potential of cancer through the implantation of mouse and human cancer cells in a mouse model. Cells are propagated in culture and examined in vitro in response to various mitochondrial targeted compounds. Tumors that are grown and harvested from mice are considered in a similar manner. Understanding the mechanisms of invasion and migration can help design/develop therapeutic combinations. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers requested a few changes, including that the PI provide a description of the clinical specimens that will be used, clarify where biological safety cabinets (BSCs) will be used, and confirm the route of onsite transport for human and animal cells used to inoculate mice. The Animal Containment Expert (ACE) stated that the PI needs to clarify where inoculation of mouse and human cells will occur. The Biological Safety Officer (BSO) requested that the PI clarify where his research lab space is located. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20160041_REN03 [Small GTPases in Cancer](#)

Principal Investigator: Carol Williams
Motion: Decision Pending Changes
Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12
NIH Guidelines: Section III-D-4, Section III-E, Section III-F-8 (C-I)
Biosafety Level(s): BSL1, BSL2

Deliberations:

The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to elaborate on the study. The Principal Investigator (PI) studies small GTPases in cancer. The PI administers antisense oligonucleotides which target SmgGDS (a protein which is overexpressed in certain cancers) to cultured cancer cells, mice with xenografted human cancer cells, or transgenic mice expressing oncogenes. Cells and mouse tissues will be collected for immunoblotting and immunohistochemistry. In addition, the interaction of G protein-coupled receptors and SmgGDS will be investigated in human cancer cells. The application uses recombinant DNA (rDNA) (antisense oligonucleotides from a vendor), human source materials (human breast, pancreatic, and lung cancer cell lines), and animal materials (human xenograft tumors collected from mice, murine mammary tumor tissue, and the 4T1 mouse mammary cancer cell line). The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are adequate. The Reviewers requested a few changes, including confirming the animal biological safety level (ABSL) of the mouse mammary cancer cell line after the period of shedding and clarifying the transport routes for ABSL1 and Biocontainment facilities. They also noted the PI needs to renew her bloodborne pathogens training. The Animal Containment Expert (ACE) and the Biological Safety Officer (BSO) had no additional comments. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20190048_REN02 [Signaling mechanisms in cardiac tissue](#)

Principal Investigator: Joy Lincoln
Motion: Decision Pending Changes

5 Application Reviews

Yes Votes: 12
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 12

NIH Guidelines: Section III-D-1, Section III-D-2, Section III-E, Section III-F-1, Section III-F-8 (C-I), Section III-F-8 (C-II)

Biosafety Level(s): BSL1, BSL2, BSL2+

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Principal Investigator's (PI's) goal is to define processes that regulate normal heart valve development and maintenance, and determine how those processes go awry in disease. They utilize human and mouse cell lines; primary tissues from pigs, sheep, and rats; induced pluripotent stem cells (iPSCs) from healthy donors or donors with heart disease; as well as mouse models that may receive diphtheria toxin. Cells may be manipulated with adenovirus and/or transfection with lipofectamine to express reporters or overexpress genes of interest. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI clarify if rat tissues will be used in this study, include a description of the preparation of diphtheria toxin, and confirm the onsite transport routes for biological materials. The Animal Containment Expert (ACE) and Biological Safety Officer (BSO) had no additional concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20160053_REN03 Rodent heart regeneration and repair

Principal Investigator: Caitlin O'Meara

Motion: Decision Pending Changes

Yes Votes: 12

No Votes: 0

Abstained: 0

Recused: 0

Total Votes: 12

NIH Guidelines: Section III-D-1, Section III-D-4, Section III-E, Section III-F-1, Section III-F-8 (C-I), Section III-F-8 (C-II)

Biosafety Level(s): BSL1, BSL2

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Secondary Reviewer went on to describe the study. The Principal Investigator's (PI's) goal is to identify pro-reparative cell types and pathways as candidate therapeutics to help treat humans following cardiac injury. To this end, the PI uses a combination of synthetic RNA, adeno-associated virus (AAV), adenovirus, and lentivirus both in vivo and in vitro. The targeted genes do not have oncogenic potential. The PI's lab uses animal models and cell culture (human and animal cells). The lab also administers diphtheria toxin to animals to induce expression in vivo. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Secondary Reviewer stated that the risk assessment and mitigation strategies are appropriate. The Reviewers requested several minor changes, including that the PI clarify where biological safety level (BSL)2 agents will be administered to animals, if microorganisms will be used for cloning or protein production, and what animal cell types will be used in this study. The Animal Containment Expert (ACE) had no additional comments. The Biological Safety Officer (BSO) requested that the PI clarify how long animal primary cells will be cultured with BSL2 precautions. After discussion, upon a motion duly made by the Secondary

5**Application Reviews**

Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20220074_REN01 AAV Stress Exposure Induced Excitatory Plasticity in the Pentapartite Synapse

Principal Investigator: Constanza Garcia Keller

Motion: Decision Pending Changes

Yes Votes: 12

No Votes: 0

Abstained: 0

Recused: 0

Total Votes: 12

NIH Guidelines: Section III-D-4, Section III-E-1, Section III-F-1, Section III-F-8 (C-1)

Biosafety Level(s): BSL1

Deliberations:

The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application. The Primary Reviewer went on to describe the study, in which the Principal Investigator (PI) will continue to study the conditioned stress response of mice and rats, particularly investigating the dopamine receptors in neurons of the nucleus accumbens (NA) core. After behavioral experiments, tissue will be processed for neuronal morphology studies. Blood, brain, and spine morphology studies will be completed and utilize both Glial Fibrillary Acidic Protein (GFAP)-mCherry virus to express GFAP as well as morpholino oligomers to knockdown gene expression of B1, B3 integrins and CSF1R. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers agreed that the risk assessment and mitigation strategies are appropriate. The Reviewers requested a few changes, including that the PI clarify with what vector GFAP-mCherry will be administered, confirm the products that will be collected from animal models after administration of recombinant material, and clarify whether shedding of virus or morpholinos is expected from animals. The Animal Containment Expert (ACE) and the Biological Safety Officer (BSO) had no additional concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

6**Adjournment**

There being no further business, the meeting was adjourned at 2:49 pm. The next regularly scheduled meeting will be held on Tuesday, October 14, 2025 at 1:00 pm in Zoom.