Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
5/12/2026
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:03 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 10 voting members present. A quorum was maintained for the entire meeting.

Confidentiality: The Chair reminded the committee that while redacted meeting minutes will be made public, the information discussed should be considered confidential to protect the identity of individuals and the competitiveness of proprietary or technical information.

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 (Campus Operations)	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
Matthew Surdel (Medicine)	R/SNA Technology Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting

Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

04/14/2026 (Zoom)

Motion:	Minutes Approved
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10

4 New Business

1. Determining Cell Product Thaw Locations for IBC Applications

   The Chair notified the Institutional Biosafety Committee (IBC) of guidance provided by the Office of Clinical Research and Innovative Care Compliance (OCRICC) to clinical study teams regarding the appropriate cell product thaw locations that should be included in IBC Applications. When an infusion must be started within 30 min or less from thaw completion, the product should be thawed at bedside. When an infusion is allowed to start after 30 minutes from thaw completion, the product should be thawed at beside or Cell Processing Lab (CPL). When there are multiple thaws/deliveries, the product may be thawed at beside or Cell Processing Lab (CPL). When an infusion can start after 30 minutes from completion of thaw OR if there are multiple thaws, the recommendation is to list both thaw locations. This approach provides the CPL flexibility to do their work without having to submit future amendments. If study staff do not have sufficient information from the sponsor at the time of submission of an IBC application, they have been instructed to list both locations for possible thaw. The Chair asked if there were any questions or concerns. There being none, he moved to the next agenda item.

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

IBC20260015 UTI and Sensory neurons

Principal Investigator:	Aaron Mickle
Motion:	Tabled
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10

NIH Guidelines:

5 Application Reviews

Biosafety Level(s): BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Secondary Reviewer went on to describe the study. The Principal Investigator (PI) will study urinary tract infections (UTI) and sensory neurons in the bladder. Various pathogenic bacteria will be administered to rats to mimic human disease. The application does not list recombinant or human source materials, and there is no indication that biological materials will be shipped. The Primary and Secondary Reviewers requested that the PI clarify whether bacteria will be cultured in the lab, if animal tissues will be collected after administration of bacteria, and whether human source materials will be used in this study. The Reviewers also requested that any materials added to the application be included in the risk assessment and mitigation strategies. The Animal Containment Expert (ACE) stated the period of infectivity for animals administered these bacteria is the lifetime of the animal and asked the PI to update the application to reflect this. The Biological Safety Officer (BSO) had no additional comments. After discussion, upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to table this application.

IBC20250055 Study of Ocular Surface, Lysosomal Storage and Ophthalmic Disorders

Principal Investigator:	Vinay Aakalu
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-1, Section III-E, Section III-F-8 (C-I), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Secondary Reviewer went on to explain the study. The Principal Investigator (PI) examines the role of Histatin peptides in promoting antimicrobial and innate immune system function, and broadly in wound healing. To study this class of peptides, the lab uses a range of human and mouse cell lines or primary cells (HEK293, human corneal epithelium, THP1, murine monocytes, etc). They've previously identified potential receptors and plan to use transient overexpression systems to determine responsiveness to histidine peptides. The PI plans to knockdown genes using small interfering RNA (siRNA) or short hairpin RNA (shRNA) or modulating genes using CRISPR/dCas9 delivered via lentivirus in the future. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI clarify if biological materials will be shipped offsite, and if so, that the lab member with shipping listed as a responsibility complete the appropriate shipping training. The Reviewers also requested that the PI confirm whether plasmids will be expanded in the lab and include entries for the different types of recombinant DNA (rDNA) that will be used in the study. The Biological Safety Officer (BSO) stated the PI will need to confirm the engineering controls and protective equipment that will be used in this study. After discussion, upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20210040_AME03 Mechanisms of heart disease and regeneration

Principal Investigator:	Lu Han
Motion:	Decision Pending Changes
Yes Votes:	10

5 Application Reviews

No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-1, Section III-D-2, Section III-D-3, 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 amendment of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. The Principal Investigator (PI) would like to include human induced pluripotent stem cells (iPSC)-derived organoids for transplantation in mice to study how heart muscle cells proliferate and differentiate to support heart regeneration. The protocol uses viral vectors (adenovirus and adeno-associated virus (AAV) used both in vitro and in vivo; lentivirus (in vitro only); plasmid DNA/ small interfering RNA (siRNA), and clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 to manipulate candidate genes in rodent primary cells and human cell lines. The study also uses HEK293T for reporter assays and frozen human heart tissue from tissue banks for histology. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The Reviewers requests a few changes, including that the PI clarify whether plasmids will be amplified in the lab using microorganisms, whether human tissue will be transported onsite, and whether liquid waste will be produced while processing rodent tissues. The Animal Containment Expert (ACE) had no additional comments. The Biological Safety Officer (BSO) noted that a plasmid was being shipped offsite, so someone on the study team will need to complete the appropriate shipping training. After discussion, upon a motion duly made by the Primary Reviewer, the Committee voted to approve this amendment pending the requested changes.

IBC20230066_AME01 Cardiovascular disease mechanism

Principal Investigator:	Chun Liu
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-1, Section III-D-2, Section III-D-3, Section III-D-4, Section III-E, Section III-F-2, Section III-F-8 (C-I), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2, BSL2+

Deliberations: The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to describe the study. The Principal Investigator (PI) would like to add human induced pluripotent stem cells (iPSC)-derived cardiac organoids, vascular organoids, and other human iPSC-derived organoids to the scope of the existing IBC protocol for in vitro studies and transplantation into rodents under the corresponding approved animal protocol. These organoids will be generated from the human iPSC lines already covered by this protocol. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewer requested several changes, including that the PI confirm whether microorganisms will be used to expand plasmids, clarify if adeno-associated viral vectors (AAV) will be administered to human cell lines or transported onsite, and clarify the timing of transduction of cells before they administered to animals. The Animal Containment Expert (ACE) and Biological Safety Officer (BSO) had no additional concerns. After brief discussion, upon a motion duly

5 Application Reviews

made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20160053_AME05 Rodent heart regeneration and repair

Principal Investigator:	Caitlin O'Meara
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-1, Section III-D-2, Section III-D-3, 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, BSL2+

Deliberations: The Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer went on to explain the study. The Principal Investigator (PI) studies cardiac repair using non-viral rDNA (small interfering RNA (siRNA), plasmids), viral vectors (adeno-associated virus (AAV), adenovirus, and lentivirus), and a biological toxin (diphtheria toxin) in human cell lines and primary peripheral blood mononuclear cells (PBMC)-derived macrophages, rodent primary cells and cell lines, and transgenic mouse/rat models. The PI would like produce lentiviral vectors in her lab and update the maximum containment from biological safety level (BSL)2 to BSL2+ because some experiments involve lentiviral transduction in human cells and clustered regularly interspaced short palindromic repeats (CRISPR)/lentiviral constructs targeting putative tumor suppressors or genes of unknown function. 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 clarify which viral vectors will be used in vivo versus in vitro and confirm the personal protective equipment (PPE) that will be used for work with lentiviral vectors. 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 amendment pending the requested changes.

IBC20250002_AME01 Investigate immune response in primary human organoids

Principal Investigator:	Guangbo Chen
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-1, Section III-F-8 (C-I)
Biosafety Level(s):	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) aims to add lentiviral vectors for engineering human T cells from their existing spleen organoid system to express a B cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR), and test in downstream co-culture killing assays. The

5 Application Reviews

PI's goal is to understand mechanisms of immune protection induced by inactivated influenza vaccines by monitoring immune response in primary human spleen organoids. They plan to incorporate genetically modified chimeric antigen receptor (CAR), donor-matched T cells. 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 changes, including that the PI include the CAR T cells in the application, confirm who will provide hands-on training for working with lentiviral vectors, and clarify the risks associated with CAR T cells. The Biological Safety Officer (BSO) had no additional concerns. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20230049_REN01 gRNA/Cas9 in pulmonary/lung functions

Principal Investigator:	Girija Ganesh Konduri
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-D-4, Section III-E, 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 Primary Reviewer elaborated on the study. The Principal Investigator (PI) studies the molecular signaling involved in pulmonary hypertension in fetuses. They will deliver a plasmid with guide RNA (gRNA) and Cas9 conjugated to nanoparticles to live animals by intravenous (IV) or retrobulbar injection. 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 were adequate. The Reviewers requested that the PI indicate that, as the plasmid will contain both the gRNA and Cas9, the whole application reflect that work with this plasmid observe biological safety level (BSL)2 precautions as is described in the risk assessment. The Animal Containment Expert (ACE) requested that the PI indicate that animals will be housed in biocontainment facilities after administration gRNA/Cas9 plasmid. The Biological Safety Officer had no additional comments. 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.

6 Adjournment

There being no further business, the meeting was adjourned at 2:47 pm. The next regularly scheduled meeting will be held on Tuesday, June 9, 2026 at 1:00 pm in Zoom.