Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
10/14/2025
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
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
Matthew Surdel (Medicine)	R/SNA Technology Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting
James Case (Non-MCW)	Non-Affiliated Member
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

9/9/2025 (Zoom)

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

4 New Business

1. IBC CE: NIH Biosafety Modernization Initiative

   The Biological Safety Officer (BSO) notified the Institutional Biosafety Committee (IBC) that the National Institute of Health (NIH) has launched an initiative to modernize and strengthen biosafety policy in order to keep pace with science and technology advances. As part of this effort, the framework of the NIH Guidelines may be revamped to become risk-based rather than technique-based; in some cases, the scope of the Guidelines may be expanded while at the same time reducing oversight for recombinant experiments which are now considered low-risk. The BSO explained that this effort is expected to unfold over the next year and that the research community, biosafety professionals and the public are encouraged to participate in regional listening sessions and submit comments through an online portal. The Committee was encouraged to contact the Biosafety Office with questions.

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.

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IBC20180018_AME09 Tissues, cell lines and virus for CMV/HSV research

Principal Investigator:	Ravit Boger
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-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

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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) proposes to study the expression of a recombinant enzyme complex essential for human cytomegalovirus (HCMV) DNA replication in Spodoptera frugiperda (Sf9) cells. This complex requires proper folding and necessary post-translational modifications for optimal enzymatic activity and function. The amendment adds a baculovirus expression vector system (BEVS) and Sf9 cells. The PI's current protocol involves investigating the antiviral activities and mechanisms of action of several antiviral agents using multiple cell lines (including human, mouse, and pig fibroblasts, Vero cells (monkey kidney epithelial cells), glioma cells (U373), and retinal epithelial cells (ARPE-19)) and viruses (including clinical isolates of CMV and herpesvirus (HSV) 1 and 2, lab strains of HSV1 and CMV, mouse CMV (MCMV), guinea pig CMV (GPCMV), and porcine CMV (PCMV)). Cells will be infected with these viruses, which will then be followed by treatment and lysis. Finally, virus replication will be quantified. The clustered regularly interspaced short palindromic repeats (CRISPR)-based knockout system will be used to study the roles of targeted host genes in virus replication and dissemination. 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 comprehensive. The Reviewers had one minor change request that the PI include the additional information on the CRISPR/Cas9 system. The Biological Safety Officer requested that the PI upload a vector map for the added baculovirus. The Animal Containment Expert had no additional comments. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20210050_AME06 Cancer Immunotherapy

Principal Investigator:	Xue-Zhong Yu
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-E, Section III-F-2, Section III-F-8 (C-I), Section III-F-8 (C-II), Section III-F-8 (C-III)
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 wishes to include the use of viral vectors and human plasma samples used in projects studying cancer immunology in mouse models. Biological materials include viral vectors (retrovirus/lentivirus) to modify human and mouse lymphocytes and tumor lines (e.g., CD19 CAR, Pim-2, luciferase), recombinant DNA (rDNA) (plasmids, short hairpin RNA (shRNA)/ small interfering RNA (siRNA), clustered regularly interspaced short palindromic repeats (CRISPR) guide RNAs (gRNAs) with Cas9) for gain/loss of function, microorganisms (probiotic bacteria and engineered Saccharomyces boulardii), human cells (primary T and B cells), and murine tumor lines. Mice will receive intravenous (IV) injections of gene-modified human lymphocytes and luciferase-labeled tumor cells, and probiotic microbiome agents are delivered orally. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are adequate. The Reviewers requested a few changes, including that the PI clarify how human plasma samples and viral vectors containing potential oncogenes will be used, ensure that study staff have completed appropriate training, and confirm whether microorganisms will be used for plasmid propagation. The Biological Safety Officer (BSO) had no additional comments. After brief discussion, upon a motion duly made by

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

IBC20180070_REN02 Molecular mechanisms of synapse elimination

Principal Investigator:	Sang Lee
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

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 studies the mechanisms of synapse elimination, which are linked to mood disorders, Alzheimer's disease, and schizophrenia. The PI's lab tests the role of specific genes (such as PRR7 or TAFA2) using adeno-associated virus (AAV)-mediated (clustered regularly interspaced short palindromic repeats) CRISPR gene deletion in vitro with cultured rat or mouse hippocampal neurons or in vivo by injection into specified mouse brain regions. AAV-transduced mice will undergo behavioral tests and/or be euthanized for studies on brain tissue. 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 confirm whether murine primary cells will be used, include the plasmids created in the lab that will be used to create the AAV, and clarify how the guide RNA and Cas9 will be administered for the CRISPR system. 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.

IBC20220069_REN01 Nakagawa IBC application

Principal Investigator:	Pablo Nakagawa
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-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, allowing the Primary Reviewer to elaborate on the study. The Principal Investigator (PI) studies molecular and physiological mechanisms that regulate arterial blood pressure and neural function. The PI uses non-viral recombinant DNA (rDNA) (including plasmids) and clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 to edit human and rodent cell lines (e.g., HEK293, N41) in order to modulate targets such as angiotensin receptors, ß-arrestin, and signaling molecules (ERK, calcium, cytokines; renin/angiotensinogen). Small interfering RNA (siRNA) is also

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used in rodent and human cells. Adeno-associated virus (AAV) vectors expressing Cre, reporters, or blood-pressure genes will be used in mice and in cell culture. Lentiviral vectors will also be used in mice to enable gene ablation (agtr1a, ren1, atp6ap2) or introduce (designer receptor exclusively activated by designer drugs) DREADDs/opsins. Human tissues from the Medical College of Wisconsin (MCW) Tissue Bank will be used for transcriptome analyses. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are sufficient. The Reviewers requested several changes, including that the PI clarify whether microorganisms will be used for plasmid construction or transformation, provide the location that viral vectors will be administered to mice, and describe the hazards of transporting the relevant biological materials. The Animal Containment Expert (ACE) requested that the PI indicate that biological safety cabinets (BSCs) will be used for animal handling. The Biological Safety Officer (BSO) stated a study team member needs to renew her bloodborne pathogens training. A Committee member noted that the vector map for both AAV entries was the same and requested that the PI confirm whether there should be a different vector map uploaded for one of the entries. After discussion, upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to approve the renewal pending the requested changes.

IBC20190058_REN02 Role of cell bioenergetics and redox function in normal and cancer cell proliferation and therapeutic strategies

Principal Investigator:	Jacek Zielonka
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-3, 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 Primary Reviewer described the study. The Principal Investigator's (PI's) goal is to develop probes for tracking cellular oxidants, develop small molecules that modulate redox and bioenergetics, and test the impact of those small molecules on cell proliferation in normal and cancer cells. Recombinant DNA (rDNA) transfection and lentiviral-mediated gene overexpression in cell lines are used test the impact of relevant candidate genes on bioenergetics, redox function, and cellular stress. Lentiviral delivery of clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 are also used to knockout genes of interest. Primary patient-derived human pancreatic cancer cells are used to validate the most promising drug candidates. Example target genes are not considered oncogenes or tumor suppressors. The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers had one minor request that the PI include a description of the use of animal cell lines. The Animal Containment Expert (ACE) had no additional concerns. The Biological Safety Officer stated a study staff member needs to renew her bloodborne pathogens training. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve the renewal pending the requested changes.

IBC20220094_REN01 Heart regeneration and angiogenesis

Principal Investigator:	Ziqing Liu
Motion:	Decision Pending Changes
Yes Votes:	12

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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-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 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 develop novel strategies for heart regeneration by enhancing cardiac reprogramming and angiogenesis. Genes of interest will be targeted in vitro using small interfering RNA (siRNA), lentiviral overexpression, or clustered regularly interspaced short palindromic repeats (CRISPR)-knockout (KO) approaches. Models include human and mouse endothelial cell lines, primary human endothelial cells or in vivo genetically-engineered mouse models (for angiogenesis studies) and primary human fibroblasts (for cardiac reprogramming studies). Mice may also be studied following lentiviral-, retroviral-, or nanoparticle-mediated gene modulation. Viral and CRISPR vectors may be cloned or expanded in the lab. 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 protocol is well-written, and the risk assessment and mitigation strategies are appropriate. The Reviewers requested a couple of minor changes, including that the PI include a room with a biosafety cabinet (BSC) which will be used when working with nanoparticles containing Cas9/guide RNA (gRNA) and clarify what biological materials she has training and experience in handling. 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.

IBC20240014_AME02 Bacterial-host interactions

Principal Investigator:	Matthew Surdel
Motion:	Decision Pending Changes
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
NIH Guidelines:	Section III-D-1, Section III-D-2, Section III-D-4, Section III-E, Section III-F-1, Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2

Deliberations: (A Committee member left the meeting at 2:23 pm due to a conflict of interest. Quorum was maintained with 11 voting members.) 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) wishes to include additional cloning strategies using clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 to target genes in Leptospira. 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 for the CRISPR/Cas9 work are well written and clearly describe the limited safety concerns for the laboratory workers. The Primary and Secondary Reviewers requested a few clarifications, including how sharps will be decontaminated for disposal, where cells infected with Leptospira will be manipulated, and whether surgical masks will be used when handling Leptospira. The Biological Safety Officer (BSO) requested that the PI clarify how glass slides that come into

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contact with Leptospira are discarded. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 2:29 pm. The next regularly scheduled meeting will be held on Tuesday, November 11, 2025 at 1:00 pm in Zoom.