Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
8/12/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:00 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 9 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
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
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
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
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert

Benjamin Gantner (Medicine)	Chair
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

7/8/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	9
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	9

4 New Business

1. Administrative Report

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

2. Exempt Rodent Report

   The Exempt Rodent Report was provided to the Committee members.

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IBC20160061_AME07 Exploration of the role of angiogenesis in lung development and regeneration

Principal Investigator:	Akiko Mammoto
Motion:	Decision Pending Changes
Yes Votes:	9
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	9
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), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2, BSL2+

Deliberations: The Vice 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) would like to add the delivery of adeno-associated viral vectors (AAV) (such as angiopoietin like 7, adiponectin) to mouse lung via intra-tracheal administration. The PI's lab studies how angiogenesis regulates development and regeneration in lung and skin. The PI also examines how deregulation causes disease. In vitro studies include the use of human, rat, and mouse cells and gene manipulations. For in vivo studies, modified cells are implanted into lung or adipose tissue. The lab also uses human lung samples and performs in vivo studies in mouse, rat, and swine. 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 that the PI clarify whether microorganisms are used for cloning, how biological materials are transported from the lab to animal holding areas, and the risks associated with AAV. They also requested that the PI make minor updates to the attached standard operating procedure (SOP) to make it consistent with the information provided in the IBC Application. The Animal Containment Expert (ACE) requested that the PI confirm whether investigative staff would provide animal husbandry care for

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animals administered AAV and to update the caging used from static micro-isolation cages to ventilated micro-isolation cages. 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 amendment pending the requested changes.

IBC20220094_AME04 Heart regeneration and angiogenesis

Principal Investigator:	Ziqing Liu
Motion:	Decision Pending Changes
Yes Votes:	9
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	9
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 Vice 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 develop cardiac regeneration strategies through direct cardiac reprogramming and angiogenesis. To study angiogenesis, the PI will use small interfering RNA (siRNA), lentivirus, and clustered regularly interspaced short palindromic repeats (CRISPR) in human primary umbilical vein endothelial cell lines in vitro. The PI will also perform in vivo experiments using CRISPR or overexpression through lentivirus or nanoparticles in transgenic mouse models. The PI studies cardiac reprogramming by utilizing (murine leukemia virus) MMLV to provide reprogramming factors to transdifferentiate various human fibroblast cell lines back into cardiac muscle. This amendment adds the use of nanoparticles containing non-target or target plasmids to knockout genes of interest using CRISPR. The nanoparticles will be obtained from a vendor, and the plasmid will be cloned by the lab. These will be administered to mice intravenously (IV). The lipid nanoparticles themselves will be handled at BSL2 due to risk of insertional mutagenesis. 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 the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI clarify whether nanoparticles containing plasmids will be administered to cell lines, whether microorganisms will be used for cloning or plasmid expansion, and whether nanoparticles containing plasmids will be transported onsite. After discussion, the Animal Containment Expert (ACE) requested that the PI indicate that animals administered nanoparticles containing plasmids be held at animal biological safety level (ABSL)2 for 48 hours following administration of the material, after which time the animals could be housed at ABSL1. 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 amendment pending the requested changes.

IBC20210026_AME02 Collection of head and neck cancer specimens at the time of surgical resection for future in vitro and in vivo studies

Principal Investigator:	Joseph Zenga
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0

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Total Votes: 8

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

Biosafety Level(s): BSL1, BSL2

Deliberations: (A Committee member left the meeting at 2:27 pm. Quorum was maintained with 8 voting members.) The Vice Chair introduced this amendment of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. The Principal Investigator (PI) aims to incorporate lentiviral vectors for knocking in or out genes in murine and human cell lines, potentially aiding in the elucidation of treatment resistance mechanisms and the development of improved cancer therapies. A variety of head and neck tumors (including amended Vestibular Schwannoma tissue) and blood specimens are collected at the time of surgical resection for future pre-clinical studies. Transduced tumor cells are transplanted into immunodeficient NOD scid gamma (NSG) mice. Clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 will be used to disrupt specific genes. 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 several changes, including asking the PI to clarify what genes that would be manipulated with lentiviral vectors, describe the procedures lab staff follow in the event of an exposure to lentivirus, and update the attached lentiviral standard operating procedure (SOP) to include a description of the genes used, how long cells will be transduced, and how long cells will be cultured after transduction before being administered to animals. The Committee requested that the PI also include in the attached SOP a description of the PPE, engineering controls, and procedures to be used for work with lentiviral vectors that require biological safety level (BSL)2+ containment. The Biological Safety Officer (BSO) requested the PI remove the animal housing location “Biocontainment” from areas that lentivirus will be used, as lentivirus will not be directly administered to animals. The Animal Containment Expert (ACE) had no additional comments. After discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20130712_REN04 Functional studies of vertebrate ocular development

Principal Investigator: Elena Semina

Motion: Decision Pending Changes

Yes Votes: 8

No Votes: 0

Abstained: 0

Recused: 0

Total Votes: 8

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 Vice Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to describe the study. The Principal Investigator (PI) studies vertebrate ocular development, identifying genetic variants from human samples and then testing the functions of wild-type and mutant proteins in human cell lines (including 2D and 3D culture systems) or zebrafish. The choice of targets for study is guided by the patient samples, with the majority of genes representing transcription factors, enzymes, membrane proteins, or having undefined function. The application uses biological microorganisms (Escherichia (E.) coli K-12 strains), recombinant DNA (rDNA) (including multiple plasmids including clustered regularly interspaced short palindromic repeats (CRISPR)-Cas9 associated and expression plasmids, nucleic acids, messenger RNA (mRNA)), human source material (including cell lines, patient fluids and tissues, human induced pluripotent stem (iPS) cell line), and animal products (zebrafish tissues). The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with

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the materials described. The Primary and Secondary reviewers agreed the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI clarify whether the E. coli K12 strains are currently in use in the lab or are only being stored. The Animal Containment Expert (ACE) and the Biological Safety Officer (BSO) had no additional concerns. Upon a motion by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20220036_REN01 Cellular therapies and T cell biology for cancer and infection

Principal Investigator:	Matthew Kudek
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8
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 Vice 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) investigates how differential pathophysiology and features of hypo- or hyperactive immune responses can be leveraged for novel anti-cancer immunotherapies. The study examines mechanisms regulating the generation and maintenance of effector and memory CD8 T cells that protect against viral and bacterial infections, as well as their roles in tumorigenesis. Murine stem cell virus-derived retroviral vectors (MSCV) or lentiviral vectors pseudotyped with vesicular stomatitis Indiana virus (VSIV) will be used to express genes involved in transcriptional regulation of immune cell development and function. Some immune cells will be depleted using diphtheria toxin. Mammalian cell lines will be used for viral production and titration. In addition, Listeria monocytogenes will be engineered to introduce T cell–specific antigenic peptides into host cells for both in vitro and in vivo studies. 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 clarification of how cell lines are used in the study, confirmation of whether lentiviral vectors will have any human DNA sources, and a description of how engineering controls are used during the propagation of viral stocks. 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 application pending the requested changes.

IBC20220066_REN01 Role of epigenetics marks in cancer

Principal Investigator:	Victor Jin
Motion:	Decision Pending Changes
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8

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

Biosafety Level(s): BSL1, BSL2

Deliberations: The Vice Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and went on to describe the study. The Principal Investigator (PI) investigates epigenetic modifications in cancer. The PI's lab utilizes in vitro experiments to look at cancer samples, and then uses clustered regularly interspaced short palindromic repeats (CRISPR) to target genes in cancer cell lines for infection and study in vivo. The Primary and Secondary Reviewers requested that the PI clarify the risks posed to personnel of CRISPR that is targeting human genes, and to confirm whether human samples will be transported onsite. The Biological Safety Officer (BSO) stated the PI needs to renew his recombinant DNA (rDNA) training. The Animal Containment Expert had no additional concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal application.

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, September 9, 2025 at 1:00 pm in Zoom.