Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
12/9/2025
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 11 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 (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
Sandy Montes-Gruber (Non-MCW)	Non-Affiliated Member
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
Qizhen Shi (Pediatrics)	R/SNA Technology Expert

3 Meeting Minutes Reviewed at this Meeting

11/11/2025 (Zoom)

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

4 New Business

The first and second business items were discussed before the past Meeting Minutes and Administrative Report were reviewed.

1. IBC Standard: *Review of IBC Applications*

   The Chair presented the updated Institutional Biosafety Committee (IBC) Standard: *Review of IBC Applications* to the Committee. The updated Standard includes clarification that while all new IBC Applications and renewals are to be reviewed in their entirety, the focus of amendment review should be on the changes that have been made in the IBC Application, as discussed at the November 11, 2025 IBC Meeting. A Committee member asked if amendment reviews should also include sections of the IBC Application that may not have been updated by the Principal Investigator in the submitted amendment but are affected by recently approved or updated IBC Position Statements or have issues that may have been missed in the original approval. The Chair explained that such issues will be identified when applications are reviewed at the time of renewal, so unless the changes made in the current amendment affect the safety of previously approved materials, Committee members should focus on the changes that were made in the amendment. . A Committee member noted she recently reviewed an amendment which added more to the application than was stated in the Amendment Summary, and asked how the reviewers should handle these situations. The Chair stated that reviewers should utilize functionality in eBridge that highlights where changes have been made in the SmartForm. If Committee members need assistance with this, they may contact the IBC Office. The reviewers should also request that the PI update the Amendment Summary to include all changes made. There being no further discussion, upon a motion duly made by a Committee member and seconded, the Committee voted to approve the updates to the IBC Standard.

2. 2026 IBC Meeting Dates

   The Chair provided the Institutional Biosafety Committee the meeting dates for 2026.

   (A Committee member joined the meeting at 1:30 pm. Quorum was maintained with 12 Committee members.)

3. Administrative Report

   The Chair asked the Committee Members if they had any comments or discussion about the Designated Reviews which were completed since the last Institutional Biosafety Committee (IBC) meeting. There being none, the work was approved to continue with no change to the approval dates recorded at the time of the Designated Review.

4. Exempt Rodent Report

The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20190005_AME04 Tissue engineering in bone, dental, cardiovascular, and digestive system

Principal Investigator:	Bo Wang
Motion:	Decision Pending Changes
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12
NIH Guidelines:	Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, 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) is adding Staphylococcus (S.) aureus, which will be used in a mouse wound model to see how amniotic membrane affects wound healing. 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 adequate for the materials and procedures added with the amendment. The Reviewers requested a few changes, including that the PI confirm whether rats, mice, or both, would be administered S. aureus; clarify the potential hazards of shipping S. aureus; and remove a statement regarding fixation of samples. The Biological Safety Officer (BSO) requested that the PI clarify whether tissues will be transported as fresh samples or in a fixative. The Animal Containment Expert (ACE) 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.

IBC20131212_AME01 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-I)
Biosafety Level(s):	BSL1, 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 non-infectious filarial nematode species Dirofilaria (D.) immitis (cause of dog heartworm) and Brugia (B.) malayi (one of the causative agents of lymphatic filariasis). Adults (B. malayi) and microfilariae (B. malayi and D. immitis) will be used in mechanistic studies of energy production. Both of these species are pathogenic in humans but are only infectious in the larvae stage which requires an insect intermediate host, and should be handled at BSL2 during this stage. The PI states that the lab will not be using either organism during the infectious larval stage. 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 description of why the microorganisms are non-infectious and don’t pose a risk to lab personnel is adequate and standard BSL2 precautions are described in the risk mitigation strategies. The Reviewers requested a few changes,

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including that the PI provide a description of how the organisms will be used, confirm throughout the application the stages of B. malayi that will be used, and include a brief description of the risks of working with adult B. malayi. The Animal Containment Expert (ACE) and 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.

IBC20250034_AME01 Hu Yang Lab IBC protocol

Principal Investigator:	Hu Yang
Motion:	Tabled
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12
NIH Guidelines:	Section III-D-4, Section III-F-8 (C-I), Section III-F-8 (C-II), Section III-F-8 (C-VII)
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) wishes to add a human carcinoma cell line to support ongoing cancer biology studies. The Primary and Secondary Reviewers requested that the PI clarify the materials that were added with this amendment, include a description of how animal models will be used, and include risk assessments for all biological materials in the application, as appropriate. The Biological Safety Officer (BSO) stated that the PI needs to complete recombinant DNA (rDNA) training. The Animal Containment Expert (ACE) had no additional comments. After discussion, upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to table this amendment.

IBC20200001_REN02 Molecular Characterization of Copy Number Variations in Cancer

Principal Investigator:	Pradeep Chaluvally-Raghavan
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-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, allowing the Primary Reviewer to describe the study. The Principal Investigator (PI) examines the contribution of RNA binding proteins and downstream effectors to oncogenesis in cancer cells. The PI uses both in vitro and in vivo models and utilizes small interfering RNA (siRNA), plasmids, lentivirus, and retrovirus in the study. Cells will be transfected with plasmids and then inoculated into mice. 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 adequate. The Reviewers requested a few minor changes,

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including that the PI clarify what cells will be used in animals, provide the PI's training and experience with the materials described in the application, and confirm whether microorganisms will be used for plasmid propagation and cloning. 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.

IBC20220102_REN01 Pre-clinical cancer research

Principal Investigator:	Nikki Lytle
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-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: (A Committee member left the meeting at 2:37 pm due to a conflict of interest. Quorum was maintained with 11 voting members.) The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Secondary Reviewer went on to explain the study. The Principal Investigator (PI) investigates signals that may contribute to tumor initiation, progression to metastasis, or therapy resistance in cancer. Lentivirus, adeno-associated virus (AAV), and recombinant DNA (rDNA) will be used to knock down or knockout tumor suppressors or overexpress oncogenes to create clinically relevant mouse models or human cells and tissues from pancreatic, breast, and colorectal cancers. Human cell lines, organoids, and patient-derived xenografts will be utilized in the studies. Diphtheria toxin may be used to deplete specific cell populations in genetically engineered mice expressing the diphtheria toxin receptor. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Secondary Reviewers stated that the overall protocol is well written, and the risk assessment and mitigation strategies are thorough. The Reviewers requested a few changes, including that the PI include a description for reconstituting diphtheria toxin, add clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9, and clarify if viral vectors will be administered to animals. The Biological Safety Officer (BSO) requested that the PI confirm whether microorganisms will be used in the study. The Animal Containment Expert (ACE) had no additional concerns. Upon a motion duly made by the Secondary 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, January 13, 2026 at 1:00 pm in Zoom.