Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
1/13/2026
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:00 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 (Campus Operations)	Biological Safety Officer
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
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

3 Meeting Minutes Reviewed at this Meeting

12/9/2025 (Zoom)

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

4 New Business

1. Public Attendance at IBC Meetings

   The Chair notified the Institutional Biosafety Committee (IBC) that a staff member had requested to attend IBC meetings, as she creates and uses IBC applications in her position and she would like to learn more about how the IBC works. The Chair noted that while IBC Meeting Minutes are posted publicly, the IBC has not had members of the public request to attend meetings previously. While the NIH suggests that meetings be made public, they do not require them to be public. The Chair posed the question to the Committee of whether the IBC should allow individuals not associated with the IBC to attend meetings. Committee members discussed the request, and while some IBC members had no concerns, some members noted that having visitors present may impact discussions during the meeting. The Chair stated that the IBC would not allow visitors listen to discussions about applications with which they are associated. The Safety Committee Manager also clarified that visitors would not have access to the Meeting's Agenda or the full Meeting Minutes. A Committee member asked if visitors would be bound by the confidentiality statement given at the beginning of the meeting, and the Chair stated that the legal department would be consulted about this question. This topic will be revisited at a future meeting.

2. IBC Position Statement: *Non-toxic subunits of biological toxins*

   The Chair introduced the Institutional Biosafety Committee (IBC) Position Statement: *Non-toxic subunits of biological toxins*, which outlines when IBC approval would be required for work with biological toxins and asked the IBC if they had any questions or concerns. A Committee member pointed out that Cholera toxin subunit A was not described in this statement, but the B subunit and nucleic acid are described. She asked if the A subunit should be included as well. The Biological Safety Officer (BSO) clarified that this Position Statement addresses toxins that do not need IBC approval. After discussion, the wording was updated in the Position Statement to clarify that "work involving the functional toxin" would require IBC approval. The Chair called for a vote and upon a motion made by a Committee member and seconded, the Committee voted to adopt this Position Statement with the requested change.

3. IBC Standard: *IBC Application Requirements*

   The Chair presented the Institutional Biosafety Committee (IBC) Standard: *IBC Application Requirements* to the Committee, noting that this Standard would allow a labs and Principal Investigators (PIs) to have consortium-like IBC applications that could cover multiple PROs, including PROs under the supervision of collaborators. The Chair opened the floor for questions and concerns. The Biological Safety Officer noted that the standard specifies that human source material requires IBC approval if it undergoes processing with the potential to produce aerosols or if it is used to generate cell lines and asked if this statement should be updated to indicate work with human source material in any manner would require IBC approval. After discussion, the Committee determined

that this change would not be necessary at this time. A Committee member asked if a separate IBC application would be needed for a tissue bank if all processing of materials occurs under a research IBC application and then those materials are transferred to a tissue bank. The Committee agreed that if all processing would occur under another IBC application, an additional IBC application would not be required for the bank. Another Committee member asked whether a Principal Investigator (PI) could add a collaborator to the PI's IBC application if the collaborator wished to work in the PI's laboratory space in order to use a biological material the PI is already approved to use. The Chair stated that PIs are free to choose which collaborators they wish to add as study staff; PIs are responsible for all work occurring under their IBC applications, so if a collaborator creates any infractions all work under that particular IBC application would be halted. After discussion, upon a motion duly made by a Committee member and seconded, the Committee voted to adopt this Standard.

4. 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.

5. Exempt Rodent Report

   The Exempt Rodent Report was provided to the Committee members.

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IBC20250043 Discarded Materials

Principal Investigator:	Ashraf El-Meanawy
Motion:	Tabled
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-2, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Principal Investigator (PI) proposes to use discarded human kidneys and blood products for various physiologic and molecular studies. The PI also wishes to test the impact of free light chains (FLCs) in tubular cell function and to deliver lipid-encapsulated RNA, including small interfering RNA (siRNA), or DNA to cell lines or live animals to overexpress or silence genes of interest. The application uses recombinant DNA (morpholino oligos and lipid encapsulated RNA) and human source materials. 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 that the PI confirm whether animals or animal products will be used in this study, specify the materials will be administered to animals, and clarify the risks of exposure to human source material and lipid-encapsulated RNA. The Animal Containment Expert (ACE) requested that the PI remove the Translational and Biomedical Research Center (TBRC) location for animal inoculation. The Biological Safety Officer (BSO) requested that the PI clarify the experiments that will be performed in this study, include urine as a biological material, and specify where animal work will be done. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to table this application.

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IBC20190014_AME06 Grobe Lab IBC Application

Principal Investigator:	Justin Grobe
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), Section III-F-8 (C-VII), Section III-F-8 (C-VIII)
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) would like to add tetanus toxin light chain (TeLC) as a transgene used in research. An adeno-associated virus (AAV) vector will be leveraged to express Cre-dependent TeLC in mouse brain cells. Following AAV-transduction, cell specific Cre-mediated recombination of the vector leads to TeLC expression and subsequent inhibition of those (Cre-expressing) 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 specify that the TelC-expressing AAV be handled with biological safety level (BSL)2 precautions, clarify the routes of onsite transport for this material, and confirm whether microorganisms will be used for plasmid expansion in the lab. The Animal Containment Expert (ACE) had no additional comments. The Biological Safety Officer (BSO) requested the PI include a description of the risks of the new AAV into the IBC application. 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.

IBC20220092_REN01 Structural Biology of Estrogen Signaling

Principal Investigator:	Lan Zhu
Motion:	Decision Pending Changes
Yes Votes:	12
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	12
NIH Guidelines:	Section III-D-3, 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 renewal of an Institutional Biosafety Committee (IBC) application and the Secondary Reviewer went on to explain the study. The Principal Investigator (PI) studies the G-protein–coupled estrogen receptor (GPER). The work generates recombinant DNA constructs and overexpresses proteins in insect and/or mammalian cells using a baculovirus system, followed by purification for structural analysis of human GPER. 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 provide a description of the potential risks of the materials used in the study, clarify whether GPER promotes tumors, and confirm whether plasmids are propagated in the lab. The Animal

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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 renewal pending the requested changes.

IBC20140009_REN04 Host-Spirochete Interactions

Principal Investigator:	Jenifer Coburn
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-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 how pathogenic spirochetes are able to cause persistent infection in immunocompetent hosts, with the goal of devising vaccines or non-antibiotic supplemental therapeutics that will prevent or diminish disease severity. Mutant strains of common pathogenic species (including Leptospira (L.) interrogans and Borrelia (B.) burgdorferi) are generated then tested via infection of mice, ticks, or hamsters. Additionally, genes from pathogenic strains are expressed in non-pathogenic strains to determine if those genes functionally cause pathogenic-like traits. Mice may be immunized with recombinant adhesins to test for disease reduction, or used for phage display screening for bacterial fragments with altered adhesive activity. 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, risk assessment, and mitigation strategies are well-written and appropriate. The Reviewers requested that the PI clarify how toxins will be used in the study and to include any non-pathogenic strains that will be used. The Animal Containment Expert (ACE) had no additional concerns. The Biological Safety Officer confirmed that the PI had appropriate shipping training. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal pending the requested changes.

IBC20250050 AAV injection in Pigs

Principal Investigator:	Quinn Hogan
Motion:	Decision Pending Changes
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
NIH Guidelines:	Section III-D-4
Biosafety Level(s):	BSL1

Deliberations: (A Committee member left the meeting at 2:27 pm. Quorum was maintained with 11 voting members.) The Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to explain the study. The Principal Investigator (PI) wishes to test a new method for the introduction of adeno-associated virus (AAV) vectors directly to the dorsal root ganglion of pigs. Tissue will be harvested

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after euthanasia to determine transduction efficiency. The ultimate goal is for this method to be used clinically to block persistent pain without other side effects. 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 couple minor changes, including that the PI clarify the vectors that will be used in the study and specify the transport route onsite. The Animal Containment Expert (ACE) had no additional concerns. The Biological Safety Officer (BSO) requested that the PI update the NIH Guideline for work with animal tissue. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20250034_AME01 Hu Yang Lab IBC protocol

Principal Investigator:	Hu Yang
Motion:	Approved
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
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. The Secondary Reviewer described the study, noting it was being brought back before the Committee after being tabled at the December 9, 2025 IBC Meeting. The Principal Investigator (PI) wishes to add a human carcinoma cell line to support ongoing cancer biology studies. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Secondary Reviewer confirmed that the PI responded to the IBC's change requests and clarified the materials that were added with this amendment, included a description of how animal models will be used, and included risk assessments for all biological materials in the application. The Reviewers stated that the risk assessment and mitigation strategies were appropriate. The Animal Containment Expert (ACE) and the 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.

IBC20220103_REN01 Efficacy and safety of Cav3.2iPA and NaviPAs in human sensory neurons

Principal Investigator:	Hongwei Yu
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-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. This Primary

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Reviewer stated this application was reviewed at the November 11, 2025 IBC Meeting and being brought back before the Committee because the Principal Investigator (PI) added biological agents and experiments that weren't associated with the IBC's Change Requests. The PI studies the efficacy of the inhibitory peptide aptamer (iPA) on CaV3.2, a voltage-dependent (T-type) calcium channel protein subunit, or the sodium channel inhibitory peptide aptamer NaviPAs, using induced pluripotent stem cell (iPSC)-derived neurons or human dorsal root ganglion (DRG) neurons. Lentivirus is used to introduce small peptides derived from natural Cav3.2 into cultured cells, including hIPSC-SN and HeLa cells. A select neuron toxin (Tetrodotoxin) will also be used in this protocol, as well as DRG sensory neurons from rats. 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. The Reviewers requested a few changes, including that the PI confirm the physical form of the tetrodotoxin used in the lab, clarify whether lentivirus will be administered to animal cells, and clarify whether human cells used in the study are recombinant. The Biological Safety Officer (BSO) requested that the PI confirm that the microorganisms used in study are recombinant. After brief discussion, upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20160061_REN03 Exploration of the role of angiogenesis in lung development and regeneration

Principal Investigator:	Akiko Mammoto
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-8 (C-I), Section III-F-8 (C-II)
Biosafety Level(s):	BSL1, BSL2, BSL2+

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Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. The Reviewer noted that this application was being brought back before the Committee after being tabled at the November 11, 2025 IBC Meeting. The Principal Investigator (PI) will continue studies on the role of angiogenesis in lung development and regeneration. Studies are performed in vitro, using cell lines and primary cells, as well as in vivo, using mouse, rat, and pig models. Genes of interest (including angiopoietin like 7, adiponectin, Twist1, YAP1, and Wnts), are manipulated with various methods including mammalian expression vectors (pcDNA), viral vectors, or small interfering RNA (siRNA). The application uses microorganisms (including human influenza A and non-pathogenic E coli), viral vectors (including adeno-associated virus (AAV), amphotropic murine retrovirus, and 2nd generation lentivirus), recombinant DNA (including siRNA and pcDNA expression plasmid), human source materials (including human lung tissue, modified and non-modified human primary cell lines, and HEK293 cells), and animal products (rat and mouse tissues with human or animal cells, mouse/pig/rat primary 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 stated that the risk assessment and mitigation strategies are appropriate. The Reviewers had a few change requests, including that the PI specify that animals should be handled at animal biological safety level (ABSL)2 after being administered oncogenic plasmids, update the contact time for Cavicide, and clarify who would be at risk of a potential spill during transport. The Animal Containment Expert (ACE) requested that the PI indicate that the route of shedding for expression plasmids is unknown. 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.

IBC20120845_REN04 Functional and Molecular Analysis of Distinct Populations of Nociceptors

Principal Investigator:	Cheryl Stucky
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

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 perception of pain through nociceptors and uses of a variety of in vivo and in vitro system to test the importance certain genes as well as cellular interactions. The application uses biological toxins (Botulinum toxin B, diphtheria toxin, tetrodotoxin, Shiga toxin), microorganisms (E coli K-12), viral vectors (adeno-associated virus (AAV), 3rd generation lentivirus), recombinant DNA (expression plasmids, plasmids expressing small interfering RNA (siRNA), and siRNA), human source materials (human keratinocyte and skin cancer cell lines), and animal products (mouse tissue and cells). The Primary and Secondary Reviewers stated that the risk assessment and mitigation strategies are appropriate. The Reviewers requested several changes, including that the PI describe experiments that will use AAV knockdown and expression of oncogenes, ensure that all study team members have the appropriate safety training, and clarify how Cas9 will be administered. The Animal Containment Expert (ACE) and the Biological Safety Officer (BSO) 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 application pending the requested changes.

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6 Adjournment

There being no further business, the meeting was adjourned at 2:53 pm. The next regularly scheduled meeting will be held on Tuesday, February 10, 2026 at 1:00 pm in Zoom.