Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
7/8/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:03 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 III (Finance and Administration)	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
Nikki Lytle (Surgery)	R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert
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

Tyce Kearl (Medicine)	R/SNA Technology Expert HGT Expert

3 Meeting Minutes Reviewed at this Meeting

6/10/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11

4 New Business

1. NOT-OD-25-127 - Dangerous Gain-of-Function Research

   The Chair provided the Institutional Biosafety Committee (IBC) with an update regarding the Executive Order NOT-OD-25-127, which was released on June 18, 2025. Per this order, the National Institute of Health (NIH) required that institutions review all research to identify projects involving dangerous gain-of-function research and notify the NIH of any such project by June 30, 2025. The Chair, Biosafety Officer, and Research Safety Committees (RSC) Manager reviewed all work with biological materials performed at Versiti Blood Research Institute (BRI), Children's Wisconsin (CW), Froedtert (FH), and the Medical College of Wisconsin (MCW). Principal Investigators (PIs) with work involving risk group (RG)2 microorganisms were contacted to attest whether they were performing any gain-of-function research. As of the July 8, 2025 IBC Meeting, there is no research in any of the institutions that IBC oversees that falls under this category. The Chair thanked the BSO and RSC Manager for their hard work and notified the IBC that he would bring any further developments before the Committee.

2. 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.

3. Exempt Rodent Report

   The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20240016_AME01 Protocols for intracellular pathogen infection of C. elegans

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

5 Application Reviews

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 (PI) is adding C. elegans-specific expression plasmids and derivatives to the study, which will be purchased from outside vendors and/or propagated by the PI's lab, and delivered to C. elegans. The goal is to define the role of Heparan Sulfate (HS) modifications on single-chain variable fragment antibodies in microsporidia (modeled by N. parisii) infection in C. elegans. The lab is currently approved to deliver single guide RNA (sgRNA), RNA interference (RNAi), and other biological materials into C. elegans. The plasmids included with this amendment will not impact the biological safety levels (BSL) currently observed 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 the risk assessment and mitigation strategies are appropriate. The Reviewers requested that the PI provide a brief description of the expression plasmids and derivatives being added to the study. The Biological Safety Officer 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 change.

IBC20130704_REN04 Analysis of ocular development and disease

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

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 (PI) utilizes genetically engineered zebrafish to investigate Notch, Hippo, Wnt, and BMP signaling in cellular processes in ocular development and disease, and beyond. Germline editing in zebrafish is accomplished by injecting recombinant DNA expressing clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 components and morpholinos directly into developing zebrafish. The Primary and Secondary Reviewers stated the risk assessment and mitigation strategies are appropriate. The reviewers requested that the PI clarify if Escherichia (E.) coli will be used in the lab for cloning and whether multiple strains are used in the lab. The reviewers also noted a study team member had expired training that needs to be renewed. 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 renewal application pending the requested changes.

IBC20130036_REN04 Human Pathogen Research and Diagnostic Development

Principal Investigator:	Kelly Henrickson
Motion:	Decision Pending Changes
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11

5 Application Reviews

NIH Guidelines: Section III-D-2, Section III-D-7, Section III-F-1, Section III-F-8 (C-I)

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) oversees the Midwest Respiratory Virus Program which develops novel diagnostics for common respiratory pathogens. The lab isolates viruses/viral genomes from clinical specimens, propagates viruses to high titers, and quantifies titers using tissue culture or chicken eggs. The lab also performs clinical testing on human samples (including respiratory specimens and blood) for Children's Wisconsin (CW). Residual clinical samples may be used to develop new diagnostic tests. The lab's scope includes viral, bacterial, and eurkoratyotic pathogens. The Reviewers requested that the PI clarify whether Escherichia (E.) coli would be used for cloning, propagation, or protein production and whether Varicella was used in the study. They also requested that the PI confirm the biological safety level used for work with Influenza A. The Biological Safety Officer (BSO) stated the PI needs to renew her recombinant DNA (rDNA) training. 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.

IBC20160019_REN04 Over-expresson or knockout/knockdown of PCPE1 and PCPE2

Principal Investigator: Mary Sorci Thomas

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-2, 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 describe the study. The Principal Investigator (PI) investigates the interactions of PCPE2 and SR-BI and their role in reverse cholesterol transport. The PI's lab uses in vitro animal cell assays that overexpress or knockdown the PCPE2 protein with either lentivirus or transient transfection (via plasmids with lipofectamine). Additionally, lentiviral vectors are administered to mice to overexpress PCPE2. 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 minor clarifications, including confirming if microorganisms will be used for propagation of plasmids in lab, adding entries for cells and tissues collected from animals after lentivirus administration, and clarifying if centrifuge safety cups will be used. The Animal Containment Expert (ACE) and 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.

IBC20190020_REN02 NTHI phasevarion

Principal Investigator: Kenneth Brockman

Motion: Decision Pending Changes

Yes Votes: 11

No Votes: 0

5 Application Reviews

Abstained: 0
Recused: 0
Total Votes: 11
NIH Guidelines: Section III-D-1, Section III-E
Biosafety Level(s): BSL1, BSL2

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 (PI) studies otitis media (OM) (middle ear infection) due to non-typeable Haemophius influenza (NTHI). The PI is investigating a novel mechanism that is used by the bacteria to adapt to microenvironments. To this end, they use a number of in vitro techniques including bacterial culture and tissue culture. The bacteria used are less pathogenic than typical strains, as they are not capsulated. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Reviewers requested a few minor changes, including that the PI add a statement that human source materials may contain unknown pathogens and will be handled with universal precautions, confirm the shipping procedures that will be used, and clarify sterilization time for work surfaces. 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.

IBC20190027_REN02 hPSC models of early human embryogenesis

Principal Investigator: Kenichiro Taniguchi
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-E, Section III-F-1, 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 renewal of an Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to elaborate on the study. The Principal Investigator's (PI's) goal is to identify molecular and cellular mechanisms associated with peri-implantation human embryonic development using mouse models and pluripotent stem cells (PSC) (including embryonic stem cells and induced PSCs (iPSCs) from humans, monkeys, and mice). Recombinant DNA (rDNA) (including lentivirus, plasmid vectors, and synthetic oligonucleotides) is used to express or inhibit candidate genes in cultured human and mouse cell lines. Small molecules are used to assess protein functions through in vitro PSC systems. Genetically modified mice are used to investigate the effects of genes on early development. 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 thorough. The Reviewers requested that the PI confirm whether lentivirus will be transported onsite, update the Occupational Health phone number provided, and remove an attached protocol for a material that is not included in the application. The Biological Safety Officer (BSO) requested that the PI update the NIH Guideline provided for non-human primate induced pluripotent stem cells. 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.

5 Application Reviews

IBC20100713_REN04 Neuroprotection, cardioprotection, and disease modeling

Principal Investigator:	Xiaowen Bai
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: 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 (PI) will continue to study the genetic, environmental, and drug-related factors impacting neurodegeneration, cardiotoxicity, and stem cell-mediated myocardial regeneration. This study utilizes microorganisms (Escherichia (E.) coli K12), viral vectors (including 3rd generation Lentivirus, retrovirus, adeno-associated virus (AAV), adenovirus, and Sendai virus), recombinant DNA (including non-viral vectors and oligonucleotides), human source materials (human cells including stem cells and comatic cells), and animal products (including mouse tissues, mouse stem cells, and somatic 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 stated that the planned experiments are very well described, and the risk assessment and mitigation strategies are appropriate. The Reviewers requested a few changes, including that the PI clarify how adenovirus will be used in the study, confirm whether lentivirus will be administered to animals, and describe when biological safety level (BSL)2+ precautions will be employed and the practices involved. 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.

IBC20100727_REN05 Type 1 Diabetes Research

Principal Investigator:	Yi-Guang Chen
Motion:	Approved
Yes Votes:	11
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	11
NIH Guidelines:	Section III-D-4, Section III-F-1
Biosafety Level(s):	BSL1

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application. The Primary Reviewer went on to describe the study, in which the Principal Investigator (PI) will continue current research toward defining the genetic basis of autoimmunity driving type 1 diabetes. The PI's lab utilizes recombinant DNA (rDNA) for polymerase chain reactions (PCR) and reverse transcription (RT-PCR), and animal 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 agreed that the risk assessment and mitigation strategies are appropriate. The Reviewers had no concerns, nor did the Animal Containment Expert

5 Application Reviews

(ACE) and the Biological Safety Officer (BSO). Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this renewal.

IBC20190040_REN02 Functional Validation of Gene Variants

Principal Investigator:	Angela Mathison
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: (A Committee member left the meeting at 2:32 pm due to a conflict of interest. Quorum was maintained with 10 voting members.) The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer elaborated on the study. The Principal Investigator (PI) aims to determine whether gene sequence variants alter gene function and how mutations in epigenetic readers, writers, or regulators contribute to rare diseases or the development and progression of pancreatic cancer. Recombinant DNA (including lentiviral, adenoviral, non-viral plasmid vectors, and small interfering RNA (siRNA)) will be used in primary cells from patients, human cancer cell lines, and animal cell lines to overexpress or inhibit candidate genes and their variants. Target genes include several epigenetic regulators relevant to pancreatic cancer and rare diseases. 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 where work with cell lines will occur and update the recommended personnel protective equipment from “N95 respirator” to “respirator” to allow for individuals who may not be able to use an N95 respirator. 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.

6 Adjournment

There being no further business, the meeting was adjourned at 2:36 pm. The next regularly scheduled meeting will be held on Tuesday, August 12, 2025 at 1:00 pm in Zoom.