Minutes

MCW Institutional Biosafety Committee
Institutional Biosafety Committee
6/10/2025
1:00 pm
Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:02 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 8 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
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
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

5/13/2025 (Zoom)

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

4 New Business

1. IBC Membership – Non-Affiliated Member replacement

   The Chair notified the Institutional Biosafety Committee (IBC) that one of the non-affiliated IBC members will be stepping down from the Committee by the end of summer. The Chair requested that the Committee send any recommendations they may have for potential non-affiliated IBC members to the Research Safety Committees Manager.

2. Scope of reviews for Amendments vs. Renewals/New Applications

   (2 Committee member joined the meeting at 1:13 pm. Quorum was maintained with 10 voting members.) The Chair reminded the Committee that when they review amendments, the focus of the review should be on the changed sections. Committee members are not expected to review the entire IBC Application. Renewals, on the other hand, should be reviewed in their entirety, similar to New Applications. After discussion, the Chair encouraged reviewers to bring amendments to the attention of the Committee if there are changes in the amendment that may impact the safety of the application as a whole, but reiterated that is not an expectation of amendment review.

3. IBC Position Statement: *Biosafety Level Classification for Urine*

   The Chair reminded the Committee that IBC Standards and Position Statements are reviewed on a periodic basis so that they can be revised as needed in response to programmatic evolution. The current IBC Standard on the biological safety level (BSL) for Urine was revised in the form of a Position Statement to align with the IBC's new approach to Position Statements vs. Standards. The Committee reviewed the IBC Position Statement: *Biosafety Level Classification for Human Bodily Fluids* which was created to replace that Standard. After brief discussion, upon a motion duly made by the Biological Safety Officer (BSO) and seconded, the Committee voted to accept the new IBC Position Statement.

4. Agents to be included on IBC Applications/Training Requirements

   (A Committee member joined the meeting at 1:37 pm. Quorum was maintained with 11 voting members.) The Chair posed the question to the Committee on whether non-pathogenic Escherichia (E.) coli should be listed on IBC applications as this material poses a minimal safety risk. After discussion, the Committee determined that these strains of E. coli should continue to be listed on IBC applications when they are used in a study to give IBC reviewers sufficient information to ensure that strains the Principal Investigator (PI) states are exempt are truly non-pathogenic. The Chair reminded the Committee that only agents requiring IBC Approval should be included in IBC Applications and should form the basis for training requirements. If a biological material that is not under the IBC's purview (such as recombinant animal tissue) is listed in the application, that material should not be considered when determining the safety training that Study Team members listed on the application are required to have. During the Pre Review, the Biosafety Office should request any such material be removed from the application; if they are unsure, they should post a comment in the IBC SmartForm for Committee consideration.

5. 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.

6. Exempt Rodent Report

   The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20250005 Leone- Viruses In Vivo

Principal Investigator:	Gustavo Leone
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):	BSL2

Deliberations: The Chair introduced this new Institutional Biosafety Committee (IBC) application, allowing the Primary Reviewer to describe the study. The Principal Investigator (PI) investigates the role of transcription factors, oncogenes, and tumor suppressors in cancer through modification of genes (through suppression, deletion and/or activation of the mouse gene using adenoviral vectors) in existing mouse models. This study will use adenoviral vectors to introduce Cre recombinase (Cre) which will conditionally knockout genes including Rb, p53, and E2F in animals with full body floxed (fl/fl) alleles of the genes of interest. 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 were appropriate. The Reviewers requested several changes, including clarifying if this study will use lentiviral vectors, confirm whether adenovirus will be used with genes other than Cre, and clarify the methods of adenovirus administration to animals. The Biological Safety Officer (BSO) stated that the PI needs to include the potential hazards of shipping adenovirus. The Animal Containment Expert (ACE) had no additional concerns. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

IBC20220011_REN01 OLA1 phosphorylation regulates mitochondrial homeostasis in vascular cells.Novel mechanism of endothelial cell dysfunction

Principal Investigator:	Adeleye Afolayan
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-4, Section III-E, Section III-E-1, Section III-F-2, Section III-F-8 (C-I)
Biosafety Level(s):	BSL1, BSL2, BSL2+

5 Application Reviews

Deliberations: The Chair introduced this renewal of an Institutional Biosafety Committee (IBC) application and the Primary Reviewer went on to explain this renewal was being brought back before the Committee after being tabled at the April 8, 2025 IBC Meeting. The Principal Investigator (PI) examines the mechanism by which genes in mitochondrial redox and metabolic homeostasis contribute to changes in the vascular in pediatric patients with pulmonary hypertension. Testing the effects of the OLA1 and PP1A genes will use methods such as inhibitor treatment, lentiviral expression of short hairpin RNA (shRNA), lentiviral and adeno-associated virus (AAV) overexpression of genes and variants, and AAV introduction of clustered regularly interspaced short palindromic repeats (CRISPR) into animals. The effects of these processes will be tested with in vivo (rats and mice) and in vitro cell culture systems. 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 the biological safety level (BSL)2+ precautions and personal protective equipment (PPE) that will be used, indicate that the guide RNA used in mice will be handled with BSL2 precautions, and clarify the models intraamniotic administration will be used with. The Animal Containment Expert (ACE) and 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 application pending the requested changes.

IBC20240005_AME02 Mechanosensation in Muscle Disease

Principal Investigator:	Brian Lin
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), 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, allowing the Primary Reviewer to elaborate on the study. The Principal Investigator (PI) proposes to add a large animal model into their protocol to study the role of mechanosensitive signaling pathways that influence the progression and severity of striated muscle diseases, such as Duchenne muscular dystrophy (DMD). Adenovirus and adeno-associated virus (AAV) will be used to modify DMD genes for in vivo mouse, rat, and pig model studies. Adenovirus and lentivirus will be used for in vitro human cell line 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 stated that the protocol is well written, the risk assessment is thorough, and the mitigation strategies are appropriate. The Reviewers requested that the PI clarify if clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 will be administered via a lipid delivery using plasmids. Of so, they asked that these plasmids be included with the recombinant DNA (rDNA) in the IBC Application SmartForm. The Animal Containment Expert (ACE) and the 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 this change.

6 Adjournment

There being no further business, the meeting was adjourned at 3:53 pm. The next regularly scheduled meeting will be held on Tuesday, July 8, 2025 at 1:00 pm in Zoom.