

Minutes

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

Statements of Confidentiality and Conflicts of Interest 1

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.

Attendees 2

Committee Members Present

Lewis Bowen III (Finance and Administration)

Benjamin Gantner (Medicine) Kunal Gupta (Neurosurgery)

Anna Huppler (Pediatrics)

Eric Jensen (Research Office)

Tyce Kearl (Medicine)

Nikki Lytle (Surgery)

Angela Mathison (Surgery) Qizhen Shi (Pediatrics)

Laura Stephens (Non-MCW) Matthew Surdel (Medicine)

Committee Members Absent

Kenneth Allen (Research Office)

Biological Safety Officer

Chair

R/SNA Technology Expert R/SNA Technology Expert Animal Containment Expert

R/SNA Technology Expert

HGT Expert

R/SNA Technology Expert R/SNA Technology Expert R/SNA Technology Expert Non-Affiliated Member R/SNA Technology Expert

Alternate Animal Containment

Expert, Non-Voting

James Case (Non-MCW)
Lezi E (Cell Biology, Neurobiology and Anatomy)

Non-Affiliated Member 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 to review the Administrative Report and then invited discussion. No concerns were raised.

6. Exempt Rodent Report

The Exempt Rodent Report was provided to the Committee members.

5 Application Reviews

IBC20131009_REN04 MCW/BRI Viral Vector Core

Principal Investigator: L Cashdollar

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-E-

1, 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 elaborated on the study. The Principal Investigator (PI) oversees the Versiti Blood Research Institute (VBRI)/Medical College of Wisconsin (MCW) Viral Vector Core, which produces replication-defective viral vectors and provides them to laboratories located primarily at the VBRI and MCW. The viral vectors produced by the Core include murine retroviruses, lentiviruses, adenoviruses, and adeno-associated viruses. 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 protocol is well written, the risk assessment is thorough, and the mitigation strategies are appropriate. The Reviewers requested that the PI clarify whether animal cells will be used in the study and update references of N95 masks that will be used during biological safety level (BSL)2+ work to respirators to account for individuals who may not be able to use an N95 mask. 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 renewal application pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 2:13 pm. The next regularly scheduled meeting will be held on Tuesday, July 8, 2025 at 1:00 pm in Zoom.