

Minutes

BRI 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 9 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)

Lezi E (Cell Biology, Neurobiology and Anatomy)

Benjamin Gantner (Medicine)

Kunal Gupta (Neurosurgery)

Anna Huppler (Pediatrics)

Eric Jensen (Research Office)

Nikki Lytle (Surgery)

Angela Mathison (Surgery)

Qizhen Shi (Pediatrics)

Laura Stephens (Non-MCW)

Matthew Surdel (Medicine)

Committee Members Absent

Kenneth Allen (Research Office)

James Case (Non-MCW)

Biological Safety Officer

R/SNA Technology Expert

Chair

R/SNA Technology Expert

R/SNA Technology Expert

Animal Containment 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

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: 9
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 9

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

IBC20170013_AME01 Studies in VCMB

Principal Investigator: Peter Newman

Motion: Decision Pending Changes

Yes Votes: 9
No Votes: 0
Abstained: 0
Recused: 0
Total Votes: 9

NIH Guidelines: Section III-C-1, 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), Section III-F-8 (C-VII)

5 Application Reviews

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 explain the study. The Principal Investigator (PI) would like to expand their study on immune responses to platelets and the biology of platelet endothelial cell adhesion molecule (PECAM-1). The amendment adds the use of messenger RNA (mRNA) encoding APLDQ-cß3-E2-Fc, which will be delivered via lipid nanoparticles and administered intravenously to mice. The goal is to selectively target anti-HPA-1a antibodies and evaluate the therapeutic potential of this approach in a mouse model of fetal and neonatal alloimmune thrombocytopenia, by analyzing immune responses in collected tissues. Additionally, the study includes the use of lentiviral vectors in vitro, non-viral recombinant DNA (rDNA) (plasmids, siRNA), Escherichia (E.) coli, human cell lines (including induced pluripotent stem cell (iPSC) lines derived from peripheral blood mononuclear cells (PBMCs)), rodent cell lines, and insect cell lines. Clustered regularly interspaced short palindromic repeats (CRISPR) will be used to edit human leukocyte antigens (HLAs) and platelet antigen-encoding genes in iPSCs, which will then be differentiated into platelets. 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 changes, including that the PI clarify if murine cß3-E2-Fc (murine IgG2a) will be transported onsite, include additional information about the E. coli being used in the study, and update the wash time for skin after exposures. 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 amendment pending the requested changes.

IBC20131068_REN04 Inflammation and thrombosis

Principal Investigator: Yan-Qing Ma

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-F-8

(C-I), Section III-F-8 (C-II)

Biosafety Level(s): BSL1, BSL2, BSL2+

Deliberations:

(Committee members joined the meeting at 1:27 pm and 1:36 pm. Quorum was maintained with 11 Committee members.) 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 the mechanisms underlying the crosstalk between inflammation and thrombosis, exploring potential targets for developing anti-inflammatory and anti-thrombotic therapies. Lentivirus is used to manipulate the expression of key regulators, such as Kindlin-3 and FERMT3, in hematopoietic cells. Human and mouse cells, as well as mouse models, will be used in the 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 the protocol is well written and the and risk assessment and mitigation strategies are thorough. The Reviewers requested a few minor updates, including indicating that solid waste is generated when working with human blood samples, clarifying if any of the materials in this study will be shipped, and including a powered air purifying respirator (PAPR) to the list of personal protective equipment (PPE) that may be used, as not all employees may be able to wear an N95 respirator. The Animal Containment Expert (ACE) requested that the PI clarify where biological materials will be administered to animals and confirm the period of infectivity

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Application Reviews

of cells administered to animals that have been transduced with viral vectors. The Biological Safety Officer (BSO) had no additional comments. A Committee member requested the PI update the attached Lentiviral Vector standard operating procedure (SOP) to make it consistent with information provided in the IBC application SmartForm. Upon a motion duly made by the Primary Reviewer and seconded, the Committee voted to approve this amendment pending the requested changes.

IBC20250019 Usage of recombinant reporter viruses

Principal Investigator: Jieqing Zhu

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-F-8 (C-I)

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's (PI's) goal is to evaluate the inhibitory activity of antiviral proteins using a cell-based assay. Recombinant reporter viruses will be used to assay for virus inhibition using human and animal 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 requested a few changes, including that the PI clarify to which cells Influenza A will be administered, indicate that solid waste will be generated in this study, and include standard operating procedures (SOPs) for the work with virus. The Biological Safety Officer (BSO) had no additional comments. After brief discussion, upon a motion duly made by the Secondary Reviewer and seconded, the Committee voted to approve this application pending the requested changes.

6 Adjournment

There being no further business, the meeting was adjourned at 1:53 pm. The next regularly scheduled meeting will be held on Tuesday, August 12, 2025 at 1:00 pm in Zoom.