

**Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee**

Meeting Information

Location: Virtual
Date and Time: June 10, 2025 7:30 AM
End Time: 8:47 AM
Chair: Ian Lewkowich (Vice Chair)

Attendance

Name	Status
Brenna Carey	Member Scientist
Bryan Donnelly	Member Scientist
Marcia Espinola	Member Scientist – Non Affiliate
Buddy Goose	Community Member
James Gulick	Member Scientist
Scott Keely	Community Member
Ian Lewkowich	Member Scientist – Vice Chair
Tamara Rausch	Member Scientist - BSO
Debbie Slovut	Community Member
Sherry Thornton	Member Scientist
Rathi Kavanaugh	Non-voting Member
Patrick Reily	Non-voting Member
Michael Jordan	Non-voting Member
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	10

Minutes from Previous Meeting

[5.13.25 Minutes.docx\(0.02\)](#)

The meeting minutes from the May 2025 meeting were reviewed by the committee and approved (8 yes; 0 no; 1 absent; 1 abstain). Debbie Slovut had not arrived; Sherry Thornton abstained because she was not present at the meeting.

Expedited Protocols

Study ID	PI	Reviewer
IBC2025-0021	Benjamin Cocanougher: D	Jim Gulick

Expedited protocols approved since the last meeting were presented to the committee.

New HRS Protocols

PI:	Robert Hopkin		
Study ID:	IBC2024-0073		
Title:	A Phase 1/2, Single Dose, Dose Escalation Study of Intravenous AAV5-GLA (AMT-191) in Adult Males with Classic Fabry Disease		
Biosafety Items:	HGT		
Action:	New		
Primary Reviewer:	Ian Lewkowich		
Secondary Reviewer:	Tamara Rausch		
Ad-hoc Reviewer:	Michael Jordan		
Agents:	Human Derived Blood and Blood Types Human Fecal Specimens Human urine Saliva Semen AAV Type 5		
Applicable NIH Guidelines:	Section III-C Section III-C-1		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain:0
	Recuse:0	Absent:1	

PI:	Jesse Skoch		
Study ID:	IBC2025-0022		
Title:	Translational Research in Craniosynostosis		
Biosafety Items:	AZM		
Action:	New		
Primary Reviewer:	James Gulick		
Secondary Reviewer:	Sherry Thornton		
Agents:	Sheep Blood, Tissue, or Body Fluids		
Applicable NIH Guidelines:	N/A		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

HRS Protocol Renewals

PI:	Michael Jordan		
Study ID:	IBC2025-0007		
Title:	Immune Regulatory Mechanisms		
Biosafety Items:	DAVPTM		
Action:	Renewal		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	Marcia Espinola		
Agents:	Escherichia coli BL21(DE3) Listeria monocytogenes Staphylococcus aureus Streptococcus pneumoniae Human Derived Blood and Blood Types 293 293T Human Peripheral Blood Mononuclear Cells Diphtheria toxin (Not Select Agent) Adenovirus type 1 Baculoviruses Epstein Barr virus (Herpesvirus) Influenza virus type A (Orthomyxoviruses) Lentivirus Lymphocytic choriomeningitis virus (LCM) (neurotropic strains) (Arenaviruses) Lymphocytic choriomeningitis virus (non-neurotropic strains) (Arenaviruses) Murine cytomegalovirus (Herpesvirus) Murine gammaherpesvirus 68 Murine leukemia virus (Retrovirus) Vaccinia virus		
Applicable NIH Guidelines:	Section III-D-4-c-(2) Section III-E-3		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0		Absent: 0

PI:	Ronald Waclaw		
Study ID:	IBC2025-0012		
Title:	Genetic Mechanisms of Vertebrate Brain Development		
Biosafety Items:	DA		
Action:	Renewal		
Primary Reviewer:	Brenna Carey		
Secondary Reviewer:	Buddy Goose		

Agents:	Recombinant or Synthetic Nucleic Acids Animals		
Applicable NIH Guidelines:	Section III-F Section III-F-8-C-VII Section III-F-8-C-VIII		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Christine Phillips		
Study ID:	IBC2025-0010		
Title:	A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation (EOC) therapy		
Biosafety Items:	HGT		
Action:	Renewal		
Primary Reviewer:	Bryan Donnelly		
Secondary Reviewer:	Scott Keely		
Agents:	Tissues, Blood, or Body Fluids (only human, non-human primates, and sheep) Viruses or Prions (to include Viral Vectors) Recombinant or Synthetic Nucleic Acids Human Gene Transfer/Human Clinical Trial (please also select 'Recombinant or Synthetic Nucleic Acids')		
Applicable NIH Guidelines:	Section III-D-1-a		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

Discussion items

- 1) Needlestick Incident – Tamara Rausch informed the committee of the needlestick incident that took place.
- 2) MaBION Cincinnati – Tamara Rausch informed the committee of the upcoming MaBION symposium in August.