

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

Meeting Information

Location: Virtual
Date and Time: September 9, 2025 7:30 AM
End Time: 9:18 AM
Chair: Stephen Waggoner

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
Karnail Singh	Member Scientist
Debbie Slovut	Community Member
Sherry Thornton	Member Scientist
Stephen Waggoner	Member Scientist - Chair
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	12

Minutes from Previous Meeting

07.08.25. Minutes.docx(0.02)
 The meeting minutes from July 2025 meeting were reviewed by the committee and approved (11 yes; 0 no; 1 abstain). Ian Lewkowich abstained because he was not present
 08.12.25 Minutes.docx(0.01)
 The meeting minutes from the August 2025 meeting were reviewed by the committee and approved (12 yes; 0 no; 0 abstain).

Expedited Protocols

Study ID	PI	Reviewer
IBC2025-0035	Kathryn Weaver: AM	James Gulick
Expedited protocols approved since the last meeting were presented to the committee.		

HRS Amendments

PI:	Rathnakumar Kumaragurubaran		
Study ID:	Amendment for IBC2024-0004		
Title:	Single Cell Genomics Facility		
Biosafety Items:	M		
Modification:	Adding Lentivirus		
Primary Reviewer:	Tamara Rausch		
Agents:	Human derived materials Lentivirus		
BSL:	2+		
Applicable NIH Guidelines:	N/A		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse:0	Absent: 0	

New HRS Protocols

PI:	Hermine Brunner
Study ID:	IBC2025-0053
Title:	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted Nex-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)
Biosafety Items:	HGT
Primary Reviewer:	Stephen Waggoner
Secondary Reviewer:	Sherry Thornton
Ad Hoc Reviewer:	Bruce Trapnell
Agents:	Human Derived Materials Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-C <i>Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation</i> Section III-C-1 <i>Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA</i>

	<i>Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants</i>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse:0	Absent: 0	

PI:	Xiaofei Sun		
Study ID:	IBC2025-0045		
Title:	Signaling pathways critical to mouse pregnancy		
Biosafety Items:	DAM		
Primary Reviewer:	Ian Lewkowich		
Secondary Reviewer:	Buddy Goose		
Agents	rDNA TG rodents Human Derived Materials		
BSL:	2		
Applicable NIH Guidelines	<i>Section III-D-4-c-(2) The purchase or transfer of BL1 transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments</i>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Nina Prasanphanich		
Study ID:	IBC2025-0052		
Title:	Role of placental innate immune factors in pregnancy and neonatal infections		
Biosafety Items:	DPM		
Primary Reviewer:	Bryan Donnelly		
Secondary Reviewer:	Scott Keely		
Agents:	Fusobacterium nucleatum Listeria monocytogenes Streptococcus agalactiae Human Derived Materials		
BSL:	2		
Applicable NIH Guidelines:	<i>Section III-E Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse:0	Absent: 0	

HRS Protocol Renewals

PI:	Mohammad Azam		
Study ID:	IBC2025-0061		
Title:	Mechanisms of chemoresistance and immunoresistance in blood cancers.		
Biosafety Items:	DAVM		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	James Gulick		
Agents:	Lentivirus Human Derived Materials Retrovirus		
BSL:	2		
Applicable NIH Guidelines:	<p>Section III-D-3-a <i>Experiments involving the use of infectious or defective Risk Group 2 viruses in the presence of a helper system may be conducted at BL2</i></p> <p>Section III-D-3-b <i>Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3</i></p> <p>Section III-D-4-c-(1) <i>Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments Involving Transgenic Rodents</i></p> <p>Section III-D-4-c-(2) <i>The purchase or transfer of BL1 transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments</i></p> <p>Section III-F-8-C-VII <i>The purchase or transfer of transgenic rodents, BSL1 only</i></p> <p>Section III-F-8-C-VIII <i>Generation of BL1 Transgenic Rodents via Breeding</i></p>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Catherine Makarewich		
Study ID:	IBC2025-0039		
Title:	Dissecting the role of novel calcium regulatory proteins in the cardiovascular system		
Biosafety Items:	DAV		
Primary Reviewer:	James Gulick		
Secondary Reviewer:	Deborah Slovut		

Agents:	Human Derived Materials AAV Adenovirus Lentivirus Retrovirus		
BSL:	2		
Applicable NIH Guidelines:	<p>Section III-D-3-a <i>Experiments involving the use of infectious or defective Risk Group 2 viruses in the presence of a helper system may be conducted at BL2</i></p> <p>Section III-D-3-b <i>Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3</i></p> <p>Section III-D-4 <i>Experiments Involving Whole Animals</i></p> <p>Section III-D-4-a <i>Recombinant or synthetic nucleic acid molecules, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study</i></p> <p>Section III-D-4-c-(1) <i>Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments Involving Transgenic Rodents</i></p> <p>Section III-D-4-c-(2) <i>The purchase or transfer of BL1 transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments</i></p> <p>Section III-E-1 <i>Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus</i></p> <p>Section III-E-3 <i>Experiments Involving Transgenic Rodents</i></p> <p>Section III-E-3-a <i>Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments</i></p>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Michael Helmrath
Study ID:	IBC2025-0046
Title:	Building a Human Intestine
Biosafety Items:	DATM

Primary Reviewer:	Marcia Espinola		
Secondary Reviewer:	Karnail Singh		
Agents:	Human Derived Materials Conotoxins Tetrodotoxin TG Rodents		
BSL:	2		
Applicable NIH Guidelines:	<p>Section III-D-4-a <i>Recombinant or synthetic nucleic acid molecules, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study</i></p> <p>Section III-D-4-b <i>For experiments involving recombinant or synthetic nucleic acid molecules, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Section III-D-1 or Section III-D-4-a, the appropriate containment shall be determined by the Institutional Biosafety Committee. Experiments involving gene drive modified animals generated by recombinant or synthetic nucleic acid molecules shall be conducted at a minimum of BL2 or BL2-N</i></p> <p>Section III-D-4-c(2) <i>The purchase or transfer of BL1 transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments</i></p> <p>Section III-E-3 <i>Experiments Involving Transgenic Rodents</i></p>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Jason Tchieu
Study ID:	IBC2025-0042
Title:	Understanding the role of glia in neurological disorders
Biosafety Items:	DVP
Primary Reviewer:	Brenna Carey
Secondary Reviewer:	Ian Lewkowich
Agents:	Human Derived Materials Lentivirus

	Sendai Virus		
BSL:	2		
Applicable NIH Guidelines:	<p>Section III-D <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i></p> <p>Section III-D-3-b <i>Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3</i></p> <p>Section III-D-4-c-(1) <i>Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments Involving Transgenic Rodents</i></p> <p>Section III-D-4-c-(2) <i>The purchase or transfer of BL1 transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments</i></p> <p>Section III-E <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i></p> <p>Section III-E-1 <i>Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus</i></p> <p>Section III-E-3-a <i>Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments</i></p>		
Motion:	Modifications Required		
Vote:	Yes: 12	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

Discussion items
None

