

Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee

Meeting Information

Location: Virtual
Date and Time: May 12, 2026, 7:36 AM
End Time: 9:14 AM
Chair: Stephen Waggoner

Attendance

Name	Status
Brenna Carey	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
Scott Rankin	Member Scientist
Tamara Rausch	Member Scientist - BSO
Debbie Slovut	Community Member
Benjamin Tourdot	Member Scientist
Stephen Waggoner	Member Scientist - Chair
Rathi Kavanaugh	Non-voting Member
Patrick Reily	Non-voting Member
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	11/10

Minutes from Previous Meeting

April Minutes.docx(0.01)
The meeting minutes from the April 2026 meeting were reviewed by the committee and approved (8 yes; 0 no; 3 abstain). Brenna Carey, Scott Rankin, and Benjain Tourdot abstained from the vote because they were not present for the April 2026 meeting.

Expedited Protocols

Study ID	PI	Reviewer
None		

HRS Amendments

PI:	Joshua Waxman
Study ID:	Amendment for IBC2023-1029
Title:	Mechanisms of cardiovascular development
Biosafety Items:	DAVPM
Modification:	Addition of lentivirus
Primary Reviewer:	Tamara Rausch
Agents:	Human iPSC Lines A-549 Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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> Section III-D-4: <i>Experiments Involving Whole Animals</i> 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> 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> Section III-E: <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i>

	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>		
Motion:	Modifications Required		
Vote:	Yes: 11	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

New HRS Protocols

PI:	Robert Hopkin		
Study ID:	IBC2025-0074		
Title:	A Phase 3 Safety and Efficacy Trial of FLT201 Gene Therapy in Patients with Gaucher Disease Type 1		
Biosafety Items:	HGT		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Brenna Carey		
Agents:	Human Derived Blood and Blood Types Human urine Semen Adeno-Associated Virus		
BSL:	2		
Applicable NIH Guidelines:	Section III-C-1: <i>Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants</i>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

Protocol Renewals

PI:	Yutaka Maeda		
Study ID:	IBC2026-0005		
Title:	Patho-genetic analysis of lung diseases		
Biosafety Items:	DAV		
Primary Reviewer:	James Gulick		
Secondary Reviewer:	Marcia Espinola		
Agents:	293T A-431 A-549 BEAS-2B		

	Calu-3 COS-7 DV-90 H1650 H2009 HCC-827 HELA NCI-H1048 NCI-H1437 NCI-H1975 NCI-H2122 NCI-H2228 NCI-H292 NCI-H3122 NCI-H358 NCI-H441 NCI-H82 SW-480 THP-1 WI-38 Human Primary Bronchial Epithelial Cells Human Primary Nasal Epithelial Cells Respiratory Tissue Adeno-Associated Virus Adenovirus type 5 Lentivirus Murine leukemia virus (Retrovirus)
BSL:	2
Applicable NIH Guidelines:	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> Section III-D-4: <i>Experiments Involving Whole Animals</i> 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</i>

	<i>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> 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> 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> 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> Section III-E-3: <i>Experiments Involving Transgenic Rodents</i> Section III-E-3-a: <i>Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments</i>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

PI:	Timothy LeCras
Study ID:	IBC2026-0027
Title:	Pathogenesis of Pediatric Vascular Diseases
Biosafety Items:	DAV
Primary Reviewer:	Stephen Waggoner
Secondary Reviewer:	Brenna Carey
Agents:	Human Skin Fibroblast Line Human Endothelial Progenitor Cells Human Primary Dermal Lymphatic Endothelial Cells (HPDLEC) Lentivirus
BSL:	2

Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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> Section III-E: <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i> Section III-E-3: <i>Experiments Involving Transgenic Rodents</i> Section III-E-3-a: <i>Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments</i>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0		Absent: 1

PI:	Rana Herro
Study ID:	IBC2026-0019
Title:	Studies of Tissue remodeling, fibrosis and Inflammation
Biosafety Items:	DAPTM
Primary Reviewer:	Marcia Espinola
Secondary Reviewer:	Tamara Rausch
Agents:	A-549 BEAS-2B HEP-G2 LX-2 NHLF Aspergillus fumigatus Human Primary Bronchial Epithelial Cells Human Primary Liver Epithelial Cells Human Primary Liver Fibroblasts Human Primary Lung Fibroblasts Human Primary Pancreatic Fibroblasts Human Primary Trophoblast Cells Human placenta Diphtheria toxin (Not Select Agent) Staphylococcal enterotoxins Respiratory syncytial virus (Paramyxoviruses)

	Rhinoviruses (Picornaviruses)		
BSL:	2		
Applicable NIH Guidelines:	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> Section III-E: <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

PI:	Paul Spearman		
Study ID:	IBC2026-0015		
Title:	Blue Lake BLB-201-002 Intranasal RSV Vaccine Study for Infants/Children		
Biosafety Items:	PH		
Primary Reviewer:	Ian Lewkowich		
Secondary Reviewer:	Brenna Carey		
Agents:	Human Derived Blood and Blood Types Human Respiratory Specimens Parainfluenza Virus Type 5		
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 Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants</i> Section III-E: <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i> 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>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0

	Recuse:0	Absent: 1
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PI:	David Hildeman		
Study ID:	IBC2026-0030		
Title:	Immune Response in Autoimmune Diseases		
Biosafety Items:	DT		
Primary Reviewer:	Brenna Carey		
Secondary Reviewer:	Buddy Goose		
Agents:	Diphtheria Toxin Pertussis Toxin		
BSL:	2		
Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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> 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> Section III-E: Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation Section III-E-3: <i>Experiments Involving Transgenic Rodents</i>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse:0	Absent: 1	

PI:	Daniel Starczynowski
Study ID:	IBC2026-0016
Title:	Molecular and Cellular Pathology of Myelodysplastic Syndromes/Acute Myeloid Leukemia
Biosafety Items:	DAVM
Primary Reviewer:	Tamara Rausch
Secondary Reviewer:	Scott Keely
Agents:	Human Derived Blood and Blood Types 293 293T AML-193 F-36P GDM-1 HEL HL-60 K-562 KASUMI-1 KASUMI-3 KASUMI-6 KBM-3 KG-1 Lenti-x MDS92 MDSL MM.1R MOLM-13 MOLM-14 MOLM-16 MOLT-16 MOLT-4 MUTZ-1 MUTZ-3 MV4-11 NB-4 NOMO-1 OCI-AML2 OCI-AML3 Plat-E RC-DLBCL SET-2 SKM-1 TF-1 THP-1 U-2 OS

	U-937 Human Bone Marrow Mononuclear Cells Human CD34+ Cells Human Peripheral Blood Mononuclear Cells Adeno-Associated Virus Gammaretrovirus Lentivirus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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> Section III-D-4: <i>Experiments Involving Whole Animals</i> Section III-E: <i>Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</i> 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>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

PI:	Benjamin Tourdot
Study ID:	IBC2026-0013
Title:	Regulators of Hemostasis and Thrombosis
Biosafety Items:	DAM
Primary Reviewer:	James Gulick
Secondary Reviewer:	Deborah Slovut
Agents:	Human Derived Blood and Blood Types 293T Human iPSC Lines THP-1
BSL:	2
Applicable NIH Guidelines:	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>

	Section III-F-8-C-VII: <i>The purchase or transfer of transgenic rodents, BSL1 only</i>		
	Section III-F-8-C-VIII: <i>Generation of BL1 Transgenic Rodents via Breeding</i>		
Motion:	Modifications Required		
Vote:	Yes: 11	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

Discussion items
Upcoming HRS Changes – Tabitha Dowdy NIH Reportable Event -Tamara Rausch