

Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee

Meeting Information

Location: Virtual
Date and Time: June 9, 2026 7:36 AM
End Time: 8:45 AM
Chair: Ian Lewkowich

Attendance

Name	Status
Brenna Carey	Member Scientist
Marcia Espinola	Member Scientist – Non Affiliate
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
Patrick Reily	Non-voting Member
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	9

Minutes from Previous Meeting

[05.12.26 Minutes.docx\(0.01\)](#)

The meeting minutes from the May 2026 meeting were reviewed by the committee and approved (9 yes; 0 no; 0 abstain).

Expedited Protocols

Study ID	PI	Reviewer
IBC2026-0010	Gang Wu: DM	James Gulick
IBC2026-0026	Aynara Wulsin: DM	James Gulick
Expedited protocols approved since the last meeting were presented to the committee.		

New HRS Protocols

PI:	Joseph Pressey		
Study ID:	IBC2026-0024		
Title:	Single-Arm, Open-Label, Multicenter, Phase 1b/2 Study Evaluating the Safety and Efficacy of AUTO1 in Pediatric Patients with CD19-positive Relapsed/Refractory (R/R) B Cell Acute Lymphoblastic Leukemia (B ALL) and R/R Aggressive Mature B Cell Non-Hodgkin Lymphoma (B NHL)		
Biosafety Items:	HGT		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Ian Lewkowich		
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-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> Section III-D-1: <i>Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems</i>		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Robert Frenck		
Study ID:	IBC2026-0029		
Title:	A randomized, placebo-controlled, participant- and investigator-blinded study to assess the efficacy and safety and tolerability of EDI048 in a Cryptosporidium Controlled Human Infection Model (CHIM) using ABO809 in healthy participants		
Biosafety Items:	PHM		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	Marcia Espinola		
Agents:	Human derived materials Cryptosporidium parvum		
BSL:	2		
Applicable NIH Guidelines:	N/A		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

Protocol Renewals

PI:	Brian Turpin		
Study ID:	IBC2026-0034		
Title:	A Phase 1/2, Open-Label, Basket Study to Assess the Safety, Tolerability, and Anti-Tumor Activity of Afamitresgene Autoleucel in Pediatric Subjects with MAGE-A4 Positive Tumors		
Biosafety Items:	HGT		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Ian Lewkowich		
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 Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants</i> Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> Section III-D-1-a: <i>Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment</i>		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain: 0
	Recuse: 0	Absent:	

PI:	Douglas Millay
Study ID:	IBC2026-0020
Title:	Development and disease of skeletal muscle
Biosafety Items:	DAVTM
Primary Reviewer:	James Gulick
Secondary Reviewer:	Tamara Rausch

Agents:	293T Cardiotoxin (Not Select Agent) Adeno-Associated Virus Baculoviruses Lentivirus Murine leukemia virus (Retrovirus)
BSL:	2
Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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-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-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: <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>		
	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: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

PI:	Lubov Timchenko		
Study ID:	IBC2026-0025		
Title:	Unstable RNA repeats in neuro-muscular diseases		
Biosafety Items:	DAM		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	Buddy Goose		
Agents:	Human Derived Blood and Blood Types COS-7 HELA HEP-G2 HuH-6 Human EBV Immortalized Lymphoblasts Human Skin Fibroblast Line Skeletal Tissue		
BSL:	2		
Applicable NIH Guidelines:	Section III-F: <i>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: 9	No: 0	Abstain: 0
	Recuse:0	Absent:	

PI:	Elisa Boscolo
Study ID:	IBC2026-0032
Title:	Study of Vascular Anomalies
Biosafety Items:	DAVM
Primary Reviewer:	Stephen Waggoner
Secondary Reviewer:	James Gulick
Agents:	Human iPSC Lines Human Skin Fibroblast Line Human Peripheral Blood Mononuclear Cells Human Primary Dermal Lymphatic Endothelial Cells (HPDLEC) Human Primary Umbilical Vein Endothelial Cells Cardiovascular Tissue Lymphatic Tissue Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-D: <i>Experiments that Require Institutional Biosafety Committee Approval Before Initiation</i> 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-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-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: <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</i>

	<i>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: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Elif Erkan		
Study ID:	IBC2026-0011		
Title:	Akt mediates albumin endocytosis in proximal tubule epithelial cells The role lipid metabolites in FSGS		
Biosafety Items:	DAM		
Primary Reviewer:	Brenna Carey		
Secondary Reviewer:	Scott Keely		
Agents:	Human materials HKC-8 Human podocytes		
BSL:	2		
Applicable NIH Guidelines:	N/A		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Nikolai Timchenko		
Study ID:	IBC2026-0021		
Title:	Elucidating the mechanisms behind liver cancer		
Biosafety Items:	DAM		
Primary Reviewer:	Marcia Espinola		
Secondary Reviewer:	Debbie Slovut		
Agents:	Human Derived Blood and Blood Types HEK293FT HELA HEP-G2		

	HuH-6 Human Primary Liver Fibroblasts Human Liver Tissue		
BSL:	2		
Applicable NIH Guidelines:	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>		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

Discussion items

BSAA Webinar – Tabitha Dowdy provided a recap of a recent biosafety administrators' webinar. Presentation and documents will be sent to the committee when received from the presenter.