

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

Meeting Information	
Location:	Virtual
Date and Time:	July 8, 2025 7:30 AM
End Time:	9:00 AM
Chair:	Stephen Waggoner

Attendance	
Name	Status
Brenna Carey	Member Scientist
Bryan Donnelly	Member Scientist
Marcia Espinola	Member Scientist – Non Affiliate
James Gulick	Member Scientist
Scott Keely	Community Member
Tamara Rausch	Member Scientist - BSO
Karnail Singh	Member Scientist
Debbie Slovut	Community Member
Sherry Thornton	Member Scientist
Stephen Waggoner	Member Scientist – Chair
Patrick Reily	Non-voting Member
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	10

Minutes from Previous Meeting
06.10.25. Minutes.docx(0.01) The meeting minutes from the June 2025 meeting were reviewed by the committee and approved (10 yes; 0 no; 0 absent; 0 abstain).

Expedited Protocols		
Study ID	PI	Reviewer
None		



HRS Amendments

PI:	Nandan Gokhale		
Study ID:	Amendment for IBC2024-0091		
Title:	RNA and RNA-binding proteins in innate immunity		
Biosafety Items:	DVM		
Modification:	Additional agents		
Primary Reviewer:	Stephen Waggoner		
Agents:	Yellow Fever and West Nile Virus		
BSL:	2		
Applicable NIH Guidelines	Section III-D Section III-D-3-b Section III-E Section III-E-1		
Motion	Modifications Required		
Vote	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

HRS Protocols

PI:	Cuixia Tian		
Study ID:	IBC2024-0078		
Title:	A Phase 1/2/3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD)		
Biosafety Items:	HGT		
Action:	New		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Bryan Donnelly		
Ad-hoc Reviewer:	Bruce Trapnell		
Agents:	AAV Type 8		
BSL:	1		
Applicable NIH Guidelines:	Section III-A Section III-C		
Motion:	Modifications required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 1	

PI:	Bruce Trapnell		
Study ID:	IBC2025-0015		
Title:	A First-In-Human Clinical Trial of Lentiviral-mediated CSF2RA Gene Transfer/Pulmonary Macrophage Transplantation Therapy of Hereditary Pulmonary Alveolar Proteinosis		
Biosafety Items:	HGT		
Action:	Renewal		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	James Gulick		
Agents:	Human materials Human cell lines Lentivirus		
BSL:	2		
Applicable NIH Guidelines:	Section III-C Section III-C-1		
Motion:	Modifications Required		
Vote:	Yes: 9	No: 0	Abstain:1 (Brenna Carey abstained)
	Recuse:0	Absent:1	

PI:	Scott Witting		
Study ID:	IBC2025-0014		
Title:	Cell Processing Facility and Cell Manipulation Lab		
Biosafety Items:	DVM		
Action:	Renewal		
Primary Reviewer:	Bryan Donnelly		
Secondary Reviewer:	Buddy Goose		
Agents:	Lentivirus Sendai Virus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D Section III-D-1 Section III-D-1-a Section III-E Section III-E-1		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain:0
	Recuse:0	Absent:1	

PI:	Scott Witting		
Study ID:	IBC2025-0027		
Title:	Induced Pluripotent Stem Cells		

Biosafety Items:	DVM		
Action:	Renewal		
Primary Reviewer:	James Gulick		
Secondary Reviewer:	Scott Keely		
Agents:	Human materials Human cell lines Lentivirus Sendai virus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D Section III-D-1-a Section III-E Section III-E-1		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain:0
	Recuse:0	Absent:1	

PI:	Debora Sinner		
Study ID:	IBC2025-0028		
Title:	Molecular mechanisms of large airway patterning and pulmonary differentiation		
Biosafety Items:	DAVM		
Action:	Renewal		
Primary Reviewer:	Marcia Espinola		
Secondary Reviewer:	Brenna Carey		
Agents:	Human materials Human cell lines Adeno-Associated Virus Baculovirus Lentivirus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D Section III-D-3 Section III-E Section III-E-1		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain:0
	Recuse:0	Absent:1	

Discussion items

- 1) Needlestick Incident – James Gulick informed the committee of a recent needlestick incident that took place.

