Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee

Meeting Information	
Location:	CCHMC S.2.300
Date and Time:	December 9, 2025 7:30 AM
End Time:	8:45 am
Chair:	Stephen Waggoner

Attendance	
Name	**Status**
Bryan Donnelly	Member Scientist
Buddy Goose	Community Member
James Gulick	Member Scientist
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
Rathi Kavanaugh	Member - nonvoting
Patrick Reilly	Member - nonvoting
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
Quorum	7
Voting	9

Minutes from Previous Meeting
11.11.25 Minutes.docx(0.01) The meeting minutes from the November 2025 meeting were reviewed by the committee and approved (9 yes; 0 no; 0 abstain).

Expedited Protocols		
Study ID	**PI**	**Reviewer**
None		

HRS Protocol Renewals

PI:	Chris Mayhew		
Study ID:	IBC2025-0071		
Title:	Human Pluripotent Stem Cell Shared Facility		
Biosafety Items:	DVM		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	James Gulick		
Agents:	Human Derived Blood and Blood Types 293T H1 H9 Human iPSC Lines Human Skin Fibroblast Line Digestive Tissue Adeno-Associated Virus Lentivirus Murine stem cell virus (Retrovirus) Sendai Virus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D Experiments that Require Institutional Biosafety Committee Approval Before Initiation Section III-D-3-a Experiments involving the use of infectious or defective Risk Group 2 viruses in the presence of a helper system may be conducted at BL2 Section III-D-3-b Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3 Section III-D-3-e Experiments involving the use of infectious or defective viruses in the presence of a helper system which are not covered in Sections III-D-3-a through III-D-3-d may be conducted at BL1		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Alex Bondoc
Study ID:	IBC2025-0062
Title:	Mechanisms and therapy of pediatric liver tumors
Biosafety Items:	DAVM
Primary Reviewer:	Ian Lewkowich

Secondary Reviewer:	Karnail Singh		
Agents:	Human Derived Blood and Blood Types HELA HEP-G2 HuH-6 Huh-7 Human iPSC Lines SK-HEP-1 Human Primary Liver Epithelial Cells Human Primary Liver Fibroblasts Human Liver Tissue Lentivirus		
BSL:	2		
Applicable NIH Guidelines:	Section III-D Experiments that Require Institutional Biosafety Committee Approval Before Initiation Section III-D-3-a Experiments involving the use of infectious or defective Risk Group 2 viruses in the presence of a helper system may be conducted at BL2 Section III-E Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation Section III-E-1 Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Christine Phillips
Study ID:	IBC2025-0063
Title:	A Second Infusion (Early Reinfusion) of Tisagenlecleucel in Children and Young Adults with B-Cell Acute Lymphoblastic Lymphoma (B-ALL)
Biosafety Items:	HGT
Primary Reviewer:	Stephen Waggoner
Secondary Reviewer:	Sherry Thornton
Agents:	Human Derived Blood and Blood Types Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation

	Section III-C-1 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 D Large scale recombinant DNA projects exceeding 10 Liters of culture at one time.		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

Protocol Amendments

PI:	Peng Wu
Study ID:	SAMEND202500000229
Title:	Mechanisms of tumorigenesis in pediatric liver cancer
Biosafety Items:	DAVM
Modification	Adding AAV
Primary Reviewer:	Sherry Thorton
Agents:	293T HEP-G2 Human Primary Liver Epithelial Cells Digestive Tissue AAV Type 8 Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-D-3-b Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3 Section III-D-4-a 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 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 Section III-E-3 Experiments Involving Transgenic Rodents Section III-E-3-a Experiments involving the breeding of certain BL1 transgenic rodents are exempt under Section III-F, Exempt Experiments A Use of recombinant or synthetic nucleic acids in tissue culture. B Use of recombinant or synthetic nucleic acids in animals, including use of genetically modified model organisms.		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	James Wells
Study ID:	SAMEND202500000247
Title:	Development and Diseases of the Digestive Tract
Biosafety Items:	DAVM
Modification	Adding AAV
Primary Reviewer:	James Gulick
Agents:	H1 H9 HEK293FT Human iPSC Lines AAV Type 2 Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-D-3-b Experiments involving the use of infectious or defective Risk Group 3 viruses in the presence of a helper system may be conducted at BL3 Section III-D-4-a 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 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 Section III-E-1 Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus Section III-E-3 Experiments Involving Transgenic Rodents A Use of recombinant or synthetic nucleic acids in tissue culture.		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

Discussion items
NIH Listening sessions – Tamara Rausch Tamara Rausch informed the committee of the upcoming listening sessions provided by the NIH.