Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee

Meeting Information	
Location:	Virtual
Date and Time:	March 10, 2026 7:30 AM
End Time:	9:04 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
Tamara Rausch	Member Scientist - BSO
Karnail Singh	Member Scientist
Debbie Slovut	Community Member
Sherry Thornton	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
Quorum	7
Voting	11

Minutes from Previous Meeting

2.10.26 Minutes.pdf(0.01)
The meeting minutes from the February 2026 meeting were reviewed by the committee and approved (10 yes; 0 no; 1 abstain). Scott Keely abstained because he was not present in February.

Expedited Protocols

Study ID	PI	Reviewer
There were no expedited protocols approved since the last meeting.		

HRS Amendments

PI:	Scott Witting		
Study ID:	Amendment for IBC2024-0054 (March Meeting)		
Title:	General Biosafety Protocol for the Analytical and Quality Control Laboratory (AQCL)		
Biosafety Items:	DVMC		
Modification:	New agents: Aspergillus niger Bacillus subtilis Candida albicans		
Primary Reviewer:	Tamara Rausch		
Agents:	Bacillus subtilis Human Derived Blood and Blood Types 293 293T C8166 HT-1080 Human EBV Immortalized Lymphoblasts JURKAT K-562 Aspergillus niger Human Peripheral Blood Mononuclear Cells Lentivirus Murine leukemia virus (Retrovirus) Candida albicans		
BSL:	2		
Applicable NIH Guidelines:	Section III-D *Experiments that Require Institutional Biosafety Committee Approval Before Initiation* Section III-D-1 *Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems* Section III-D-1-a *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* 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:** 11	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Senad Divanovic		
Study ID:	Amendment for IBC2024-0007 (March Meeting)		
Title:	Immune Responsiveness in Inflammatory and Metabolic Diseases		
Biosafety Items:	DAVPZM		
Modification:	Adding Diphtheria Toxin		
Primary Reviewer:	Marcia Espinola		
Agents:	Listeria monocytogenes Mycobacterium bovis BCG vaccine strain Human Derived Blood and Blood Types Non Human Derived Blood and Blood Types 293T HEP-G2 THP-1 Histoplasma capsulatum Human Peripheral Blood Mononuclear Cells Human Primary Adipocyte Cells Human Primary Liver Epithelial Cells Human Adipose Tissue Diphtheria toxin (Not Select Agent) Influenza virus type A (Orthomyxoviruses)		
BSL:	2		
Applicable NIH Guidelines:	Section III-E-3 *Experiments Involving Transgenic Rodents* Section III-F *Exempt Experiments*		
Motion:	Modifications Required		
Vote:	**Yes:** 11	**No: 0**	**Abstain: 0**
	Recuse:0	**Absent: 0**	

New HRS Protocols

PI:	Ruby Khoury
Study ID:	IBC2026-0004
Title:	Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+

	B-cell Acute Lymphoblastic Leukemia (B-ALL)		
Biosafety Items:	HGT		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Ian Lewkowich		
Ad-Hoc Reviewer:	Bruce Trapnell		
Agents:	HGT		
BSL:	2		
Applicable NIH Guidelines:	Section III-D *Experiments that Require Institutional Biosafety Committee Approval Before Initiation* Section III-D-1 *Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems*		
Motion:	Modifications Required		
Vote:	**Yes:** 11	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Le Xu		
Study ID:	IBC2026-0012		
Title:	Lung development, repair and regeneration		
Biosafety Items:	DAVP		
Primary Reviewer:	Sherry Thornton		
Secondary Reviewer:	Stephen Waggoner		
Agents:	AAV Type 8 AAV Type 9 Influenza virus type A (Orthomyxoviruses)		
BSL:	2		
Applicable NIH Guidelines:	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* Section III-E-3 *Experiments Involving Transgenic Rodents* Section III-F *Exempt Experiments*		
Motion:	Modifications Required		
Vote:	**Yes:** 11	**No: 0**	**Abstain: 0**
	Recuse:0	**Absent: 0**	

PI:	James Cronk
Study ID:	IBC2025-0086
Title:	Development of genetically engineered myeloid cell immunotherapy and combinatorial therapeutic strategies for the treatment of cancer
Biosafety Items:	DAV
Primary Reviewer:	Ian Lewkowich
Secondary Reviewer:	Sherry Thornton
Agents:	293T CSTX002 Lentivirus
BSL:	2
Applicable NIH Guidelines:	Section III-D *Experiments that Require Institutional Biosafety Committee Approval Before Initiation* Section III-D-3 *Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of a Helper System in Tissue Culture Systems* 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-E *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation* 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* Section III-F *Exempt Experiments* Section III-F-8-C-VII *The purchase or transfer of transgenic rodents, BSL1 only* Section III-F-8-C-VIII *Generation of BL1 Transgenic Rodents via Breeding* 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. C - Experiments involving DNA derived from pathogenic agents or genetic modification of pathogenic agents (Viruses, bacteria, fungi, lower eukaryotes).		
Motion:	Modifications Required		
Vote:	**Yes:** 11	**No: 0**	**Abstain: 0**
	Recuse:0	**Absent: 0**	

PI:	David Haslam
Study ID:	IBC2025-0050
Title:	Role of the microbiome in immunity and infection
Biosafety Items:	DAPM
Primary Reviewer:	Marcia Espinola
Secondary Reviewer:	Tamara Rausch
Agents:	Bacteroides spp. Clostridioides difficile Enterobacter cloacae Enterococcus faecalis Escherichia coli (strains bearing K1 antigen) Escherichia coli BL21(DE3) Klebsiella oxytoca Klebsiella pneumoniae Parabacteroides spp. Pseudomonas aeruginosa Staphylococcus aureus Human Fecal Specimens Human Respiratory Specimens HELA HEP-G2 VERO-B4 Clostridium difficile, Toxin B (TcdB) (Not a select agent)
BSL:	2
Applicable NIH Guidelines:	Section III-F-1 *Synthetic nucleic acids that cannot replicate/generate nucleic acids that can replicate in any living cell, are not designed to introduce a stable genetic modification, and do not produce a lethal toxin for vertebrates at an LD50 of less than 100 nanograms per KBW*

	C - Experiments involving DNA derived from pathogenic agents or genetic modification of pathogenic agents (Viruses, bacteria, fungi, lower eukaryotes).		
Motion:	Modifications Required		
Vote:	**Yes:** 11	**No: 0**	**Abstain: 0**
	Recuse:0	**Absent: 0**	

Protocol Renewals

PI:	Shijie Liu
Study ID:	IBC2025-0092
Title:	Hippo and Wnt signaling pathway in cardiac regeneration and repair
Biosafety Items:	DAVTM
Primary Reviewer:	Karnail Singh
Secondary Reviewer:	Scott Keely
Agents:	293T Human iPSC Lines Diphtheria toxin (Not Select Agent) Adeno-Associated Virus Adenovirus type 5
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* Section III-E-3 *Experiments Involving Transgenic Rodents* 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:** 10	**No: 0**	**Abstain: 0**
	Recuse:0	**Absent:** 1	

PI:	Maria Fields		
Study ID:	IBC2026-0003		
Title:	Immune Landscape in Metabolic Disease		
Biosafety Items:	DAVTM		
Primary Reviewer:	James Gulick		
Secondary Reviewer:	Buddy Goose		
Agents:	Human Derived Blood and Blood Types HEP-G2 THP-1 Human Peripheral Blood Mononuclear Cells Human Primary Adipocyte Cells Human Primary Liver Epithelial Cells Human Adipose Tissue Human Liver Tissue Diphtheria toxin (Not Select Agent)		
BSL:	2		
Applicable NIH Guidelines:	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* Section III-F-1 *Synthetic nucleic acids that cannot replicate/generate nucleic acids that can replicate in any living cell, are not designed to introduce a stable genetic modification, and do not produce a lethal toxin for vertebrates at an LD50 of less than 100 nanograms per KBW*		
Motion:	Modifications Required		
Vote:	**Yes:** 10	**No: 0**	**Abstain: 0**

	Recuse:0	**Absent:** 1

Discussion items
None