Minutes
Cincinnati Children's Hospital
Institutional Biosafety Committee

Meeting Information	
Location:	Virtual
Date and Time:	October 14, 2025 7:30 AM
End Time:	9:10 AM
Chair:	Stephen Waggoner

Attendance	
Name	**Status**
Brenna Carey	Member Scientist
Bryan Donnelly	Member Scientist
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
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
Quorum	7
Voting	10

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

Expedited Protocols		
Study ID	**PI**	**Reviewer**
IBC2025-0037	Marie-Dominique Filippi: AMC	James Gulick
Expedited protocols approved since the last meeting were presented to the committee.		

Cincinnati Children's
changing the outcome together

New HRS Protocols

PI:	Jeremy Rubinstein		
Study ID:	IBC2025-0008		
Title:	A phase 2 study of wu-cart-007, an anti-cd7 allogeneic car-t cell therapy, in patients with relapsed or refractory t-cell acute lymphoblastic leukemia and lymphoblastic lymphoma (t-rrex)		
Biosafety Items:	HGT		
Primary Reviewer:	Ian Lewkowich		
Secondary Reviewer:	Bryan Donnelly		
Ad Hoc Reviewer:	Bob Frenck		
Agents:	Tissues, Blood, or Body Fluids (only human, non-human primates, and sheep) Recombinant or Synthetic Nucleic Acids Human Gene Transfer/Human Clinical Trial		
BSL:	BSL2		
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*		
Motion:	Modifications Required		
Vote:	**Yes:** 10	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Sanjay Jain
Study ID:	IBC2025-0068
Title:	Animal Models to Develop New Regimens for S. aureus Implant-Associated Infections
Biosafety Items:	DAPM
Primary Reviewer:	Stephen Waggoner
Secondary Reviewer:	Marcia Espinola
Agents	Borrelia burgdorferi Enterobacter cloacae Enterococcus faecalis Klebsiella pneumoniae Mycobacterium abscessus Mycobacterium avium Pseudomonas aeruginosa Staphylococcus aureus Streptococcus agalactiae Yersinia enterocolitica Yersinia pseudotuberculosis

	BT-474 MCF-7 MDA-MB-231 THP-1 Aspergillus flavus Aspergillus fumigatus Aspergillus niger Cryptococcus neoformans Candida albicans		
BSL:	BSL2		
Applicable NIH Guidelines	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-D-4 *Experiments Involving Whole Animals* Section III-F-8-C-II *Experiments that use Escherichia coli K-12 host-vector systems* 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:** 0	

HRS Protocol Renewals

PI:	Basilia Zingarelli
Study ID:	IBC2025-0051
Title:	Molecular mechanisms of sepsis and trauma
Biosafety Items:	DAPM
Primary Reviewer:	Marcia Espinola
Secondary Reviewer:	Ian Lewkowich
Agents:	Pseudomonas aeruginosa Staphylococcus aureus Human Derived Blood and Blood Types A549 BEAS-2B EN HL-60 THP-1 Human Primary Umbilical Vein Endothelial Cells Influenza viruses 1918-1919 H1N1 (1918 H1N1) (Orthomyxoviruses)
BSL:	BSL2
Applicable NIH Guidelines:	Section III-D Experiments that Require Institutional Biosafety Committee Approval Before Initiation

	Section III-D-7-c 1918 H1N1 Section III-E Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation 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:** 0	

PI:	Kyle McCracken
Study ID:	IBC2025-0047
Title:	Interrogating human kidney development and disease using hPSCs
Biosafety Items:	DAVM
Primary Reviewer:	James Gulick
Secondary Reviewer:	Scott Keely
Agents:	293T H1 H9 Human iPSC Lines Lentivirus
BSL:	BSL2
Applicable NIH Guidelines:	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-D-4-c-(1) Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments Involving Transgenic Rodents 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-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. C Experiments involving DNA derived from pathogenic agents or genetic modification of pathogenic agents (Viruses, bacteria, fungi, lower eukaryotes).		
Motion:	Modifications Required		
Vote:	**Yes:** 10	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	David Hildeman		
Study ID:	IBC2025-0049		
Title:	Innate sensing in the induction of adaptive immune responses		
Biosafety Items:	DAVM		
Primary Reviewer:	Karnail Singh		
Secondary Reviewer:	Deborah Slovut		
Agents:	Human Derived Blood and Blood Types PCC-1 Human Peripheral Blood Mononuclear Cells Pertussis toxin (Not a select agent) Lentivirus Murine cytomegalovirus (Herpesvirus)		
BSL:	BSL2		
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-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 Experiments Involving Whole Animals		
Motion:	Modifications Required		
Vote:	**Yes:** 10	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Linde Miles
Study ID:	IBC2025-0040
Title:	Clonal Evolution of Acute Myeloid Leukemia
Biosafety Items:	DAVM
Primary Reviewer:	Sherry Thornton
Secondary Reviewer:	Tamara Rausch
Agents:	HL-60 OCI-AML2 OCI-AML3 THP-1 Human Bone Marrow Mononuclear Cells Human Peripheral Blood Mononuclear Cells

	Lentivirus Murine stem cell virus (Retrovirus)
BSL:	BSL2
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-4 Experiments Involving Whole Animals 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 Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation 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:** 0

PI:	Karnail Singh
Study ID:	IBC2025-0059
Title:	Viral Immunology, Vaccine Development and Evaluation Research.
Biosafety Items:	DVZM
Primary Reviewer:	Brenna Carey
Secondary Reviewer:	Buddy Goose
Agents:	Human Derived Blood and Blood Types Non Human Derived Blood and Blood Types 293T HEK293FT NK-92 THP-1 Cynomolgus Monkey Bone Marrow Cells Cynomolgus Monkey Lymph Node B Cells Cynomolgus Monkey Lymph Node Dendritic Cells Cynomolgus Monkey Lymph Node Macrophage Cells Cynomolgus Monkey Lymph Node Monocyte Cells Cynomolgus Monkey Lymph Node NK Cells Cynomolgus Monkey Lymph Node T Cells

	Cynomolgus Monkey Peripheral Blood Mononuclear Cells Cynomolgus Monkey Spleen B Cells Cynomolgus Monkey Spleen Dendritic Cells Cynomolgus Monkey Spleen Macrophage Cells Cynomolgus Monkey Spleen Monocyte Cells Cynomolgus Monkey Spleen NK Cells Cynomolgus Monkey Spleen T Cells Human Peripheral Blood Mononuclear Cells Immune Tissue Lentivirus		
BSL:	BSL2		
Applicable NIH Guidelines:	A Use of recombinant or synthetic nucleic acids in tissue culture. C Experiments involving DNA derived from pathogenic agents or genetic modification of pathogenic agents (Viruses, bacteria, fungi, lower eukaryotes).		
Motion:	Modifications Required		
Vote:	**Yes:** 9	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

PI:	Timothy Chlon
Study ID:	IBC2025-0055
Title:	Study of mechanisms driving bone marrow failure and hematologic malignancies
Biosafety Items:	DAVM
Primary Reviewer:	Bryan Donnelly
Secondary Reviewer:	Stephen Waggoner
Agents:	Human Derived Blood and Blood Types 293T HL-60 Human iPSC Lines MOLM-13 THP-1 Human Peripheral Blood Mononuclear Cells Lentivirus Murine leukemia virus (Retrovirus)
BSL:	BSL2
Applicable NIH Guidelines:	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-4-c-(1) Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments Involving Transgenic Rodents 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 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 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 A Use of recombinant or synthetic nucleic acids in tissue culture.		
Motion:	Modifications Required		
Vote:	**Yes:** 10	**No:** 0	**Abstain:** 0
	Recuse:0	**Absent:** 0	

Discussion items
December IBC Meeting – Tabitha Dowdy