

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

Meeting Information

Location: CCHMC S.2.300
Date and Time: January 13, 2026 7:30 AM
End Time: 9:00 AM
Chair: Stephen Waggoner

Attendance

Name	Status
Bryan Donnelly	Member Scientist
Marcia Espinola	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
Debbie Slovut	Community Member
Sherry Thornton	Member Scientist
Stephen Waggoner	Member Scientist - Chair
Patrick Reilly	Non-voting member – vet services
Rathi Kavanaugh	Non-voting member - OSEH
Tabitha Dowdy	Biosafety Office
Courtney Roher	Biosafety Office
<i>Quorum</i>	7
<i>Voting</i>	10

Minutes from Previous Meeting

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

Expedited Protocols

Study ID	PI	Reviewer
None		

New HRS Protocols

PI:	Katherine Somers		
Study ID:	IBC2025-0005		
Title:	Nant 2021-01: Phase Ii Study Of Ex-Vivo Expanded Allogeneic Universal Donor Tgfβi Nk Cell Infusions In Combination With Temozolomide, Irinotecan, Dinutuximab, And Sargramostim In Patients With Relapsed Or Refractory Neuroblastoma The STING (Sequential Temozolomide, Irinotecan, NK cells and GD2 mAb) Trial		
Biosafety Items:	HGT		
Primary Reviewer:	Stephen Waggoner		
Secondary Reviewer:	Ian Lewkowich		
Ad hoc Reviewer:	Bob Frenck		
Agents:	N/A		
BSL:	N/A		
Applicable NIH Guidelines:	<p><i>Section III-C</i> Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation</p> <p><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 M</p> <p><i>Section III-D</i> Experiments that Require Institutional Biosafety Committee Approval Before Initiation</p>		
Motion:	No vote – application may not require IBC review		
Vote:	Yes: 0	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

HRS Protocol Renewals

PI:	Susanne Wells		
Study ID:	IBC2025-0079		
Title:	Molecular basis of epithelial tumors		
Biosafety Items:	DAVTM		
Primary Reviewer:	Tamara Rausch		
Secondary Reviewer:	Debbie Slovut		
Agents:	Human Derived Blood and Blood Types Human urine 293 293T		

	<p>CAL-27 CaSki Human iPSC Lines NIKS OHSU-974 SiHa UDSCC2 UMSCC1 UMSCC22b UM-SCC-47 UM-SCC-6 Primary Human Mucosal Stratified Squamous Epithelium Cells Primary Human Oral Squamous Cell Carcinoma Cells Digestive Tissue Integumentary Reproductive Tissue Cholera toxin (Not a select agent) Adenovirus type 5 Feline endogenous virus (Retrovirus) Herpes simplex types 1 (Herpesvirus) Human papilloma virus (Papovavirus) Lentivirus Murine leukemia virus (Retrovirus)</p>
BSL:	2
Applicable NIH Guidelines:	<p><i>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-(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 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).</p>

Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Mei Xin
Study ID:	IBC2025-0090
Title:	Regulation of cardiovascular development and diseases
Biosafety Items:	DAVPTM
Primary Reviewer:	Sherry Thornton
Secondary Reviewer:	James Gulick
Agents:	293 293T HEK293FT HELA Human Primary Aortic Endothelial Cells (HPAOEC) Human Primary Cardiac Microvascular Endothelial Cells (HPCMEC) Human Primary Umbilical Vein Endothelial Cells Adeno-Associated Virus Adenovirus type 5 Lentivirus Murine leukemia virus (Retrovirus)
BSL:	2
Applicable NIH Guidelines:	<p><i>Section III-D</i> Experiments that Require Institutional Biosafety Committee Approval Before Initiation</p> <p><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</p> <p><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</p> <p><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</p> <p><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</p>

	<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		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0	Absent: 0	

PI:	Ty Troutman
Study ID:	IBC2024-0060
Title:	Inflammation and Disease
Biosafety Items:	DAVPTM
Primary Reviewer:	Marcia Espinola
Secondary Reviewer:	Stephen Waggoner
Agents:	293T HEP-G2 Human iPSC Lines THP-1 U937 Human Peripheral Blood Mononuclear Cells Diphtheria toxin (Not Select Agent) Lentivirus Murine leukemia virus (Retrovirus)
BSL:	2
Applicable NIH Guidelines:	<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-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-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-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>A</i> Use of recombinant or synthetic nucleic acids in tissue culture. <i>B</i> 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:	Braxton Forde		
Study ID:	IBC2025-0073		
Title:	Protocol for Handling Biohazards, and Sample Manipulations (Mice, Rats, Sheep & Human)		
Biosafety Items:	AZM		
Primary Reviewer:	Ian Lewkowich		
Secondary Reviewer:	Bryan Donnelly		
Agents:	Sheep Blood, Tissue, or Body Fluids Amniotic Fluid Human Primary Amniotic Endothelial Cells Reproductive Tissue		
BSL:	2+		
Applicable NIH Guidelines:	<p><i>Section III-D</i> Experiments that Require Institutional Biosafety Committee Approval Before Initiation</p> <p><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</p> <p><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</p> <p><i>Section III-E</i> Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation</p> <p><i>Section III-E-3</i> Experiments Involving Transgenic Rodents</p> <p><i>Section III-F</i> Exempt Experiments</p> <p><i>Section III-F-1</i> 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</p>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse:0	Absent: 0	

Protocol Amendments

PI:	Xufeng Xue		
Study ID:	Amendment for IBC2024-0068 (AAV) (Jan meeting)		
Title:	Understanding human development and diseases using bioengineered organoids		
Biosafety Items:	MV		
Modification	Adding AAV		
Primary Reviewer:	James Gulick		
Agents:	Human iPSC Lines AAV Type 1 AAV Type 9		
BSL:	2		
Applicable NIH Guidelines:	<p><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</p> <p>A Use of recombinant or synthetic nucleic acids in tissue culture.</p>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0
	Recuse: 0		Absent: 0

PI:	Jeffrey Steimle		
Study ID:	Amendment for IBC2025-0043 (Jan meeting)		
Title:	Transcription factor biology of cardiopulmonary development and disease		
Biosafety Items:	DAVPM		
Modification	Adding LV		
Primary Reviewer:	James Gulick		
Agents:	293T HELA AAV Type 9 Lentivirus		
BSL:	2		
Applicable NIH Guidelines:	<p><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</p> <p><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</p>		

	<p><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</p> <p><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</p> <p><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</p> <p><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</p> <p><i>Section III-E-3</i> Experiments Involving Transgenic Rodents</p> <p><i>Section III-F-2</i> Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (eg, encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes</p> <p><i>Section III-F-8-C-II</i> Experiments that use Escherichia coli K-12 host-vector systems</p> <p><i>Section III-F-8-C-VII</i> The purchase or transfer of transgenic rodents, BSL1 only</p> <p><i>Section III-F-8-C-VIII</i> Generation of BL1 Transgenic Rodents via Breeding</p> <p>A Use of recombinant or synthetic nucleic acids in tissue culture.</p> <p>B Use of recombinant or synthetic nucleic acids in animals, including use of genetically modified model organisms.</p>		
Motion:	Modifications Required		
Vote:	Yes: 10	No: 0	Abstain: 0



	Recuse: 0	Absent: 0
--	------------------	------------------

PI:	Paul Spearman/Sanjay Jain
Study ID:	Amendment for IBC2025-0068 (Jan Meeting)
Title:	Evaluation of Virulence and Therapeutic Strategies for Infectious Agents in Animal Models
Biosafety Items:	DAPM
Modification	<p><i>New agents:</i></p> <p>ESBL Escherichia coli BL21(DE3) Escherichia coli Seattle 1946 Escherichia coli Xen14 Mycobacterium smegmatis Salmonella typhi BT-474 MCF-7 MDA-MB-231 THP-1 Aspergillus versicolor Mucorales spp. Candida albicans Cryptococcus neoformans Aspergillus niger Aspergillus fumigatus Aspergillus flavus Yersinia pseudotuberculosis Yersinia enterocolitica Streptococcus agalactiae Pseudomonas aeruginosa Mycobacterium avium Mycobacterium abscessus Klebsiella pneumoniae Enterococcus faecalis Borrelia burgdorferi Enterobacter cloacae</p>
Primary Reviewer:	Tamara Rausch
Agents:	<p>Borrelia burgdorferi Enterobacter cloacae Enterococcus faecalis Escherichia coli BL21(DE3) Escherichia coli Seattle 1946 Escherichia coli Xen14 Klebsiella pneumoniae Mycobacterium abscessus Mycobacterium avium Mycobacterium smegmatis</p>

	<p>Pseudomonas aeruginosa Salmonella typhi Staphylococcus aureus Streptococcus agalactiae Yersinia enterocolitica Yersinia pseudotuberculosis MCF-7 MDA-MB-231 THP-1 Aspergillus flavus Aspergillus fumigatus Aspergillus niger Aspergillus versicolor Cryptococcus neoformans Mucorales spp. Candida albicans</p>
BSL:	2
Applicable NIH Guidelines:	<p><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>Section III-D-4</i> Experiments Involving Whole Animals <i>Section III-F-8-C-II</i> Experiments that use Escherichia coli K-12 host-vector systems <i>B</i> Use of recombinant or synthetic nucleic acids in animals, including use of genetically modified model organisms.</p>
Motion:	Modifications Required
Vote:	Yes: 10 No: 0 Abstain: 0
	Recuse:0 Absent: 0

Discussion items

NIH Listening Session – Tamara Rausch

Tamara Rausch provided the committee with the upcoming NIH Listening Session details.