IBC Meeting Minutes Cleveland Clinic Main Campus

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Date:		Location:	
June 25 th , 2025		Zoom	
IBC Member Attendance:		·	
⋈ Ahern, Philip	☐ DiDonato, Josep	oh	☑ Dragan, Amanda (BSO/Acting Chair)
⊠ Fox, Alan	⊠ Hajjar, Adeline		
☑ Kerr, Travis	□ Lindner, Daniel		☑ McDonald, Christine (IBC Chair)
☑ Mortimer, Joanne	☐ Southern, Brian		Speranza, Emily
⊠ Such, Kimberly			
Guests: Anthony Santilli*, N * Cleveland Clinic Main Ca ** Cleveland Clinic Florida	mpus		•
Call To Order:		Adjourn:	
2:32 PM		3:12 PM	

I. Review of May 28th, 2025 Meeting Minutes

Committee Comments:				
None presented				
Motion Annuarial	T	A ! A	A 14-!	NI 4 D
Motion Approval:	For:	Against:	Abstain:	Not Present:

II. Administrative Business

- **a.** The committee was presented with Expedited Review items, personnel additions, and updates to programmatic SOPs.
- **b. Incident Reports:** No incidents were reported for the month of June 2025.
- **c. Lab Audits:** Members were informed of Annual Lab Audits and Preliminary Audits occurring during the month of June 2025. No major deficiencies were identified.

III. Clinical Research:

a. Applications:

Clinical Application #1	Protocol ID: Application #1	PI: Kennedy	Biosafety Level: BSL2	NIH Cat.: III-C-1, III-E
Project Title: RPL16. Study Comparing Vus	,	· ·	olled, Multicenter	for the second s

Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]									
Associated Grant Numbers:									
N/A Protocol Summary:									
Protocol Summary:									
Function/Nature of Recombinant Genes to be Expressed: □ N/A □ Oncogene ☑ Tumor Suppressor Gene ☑ Structural □ Signaling □ Antimicrobial ☑ Immunomodulatory □ Toxin □ Antibiotic Resistance □ Reporters □ Other									
Species of Recombina □ N/A ⋈ Human □				□ Other					
Committee Commen None	ts:		_						
Facilities, Procedure ⊠ Yes □ No	s, and Safety Pra	ctices I	Reviewed (Y/N):					
PI/Supervisor Traini ⊠ Yes □ No	ing (Y/N):			Handler ☐ ⊠ Yes	Fraining	· · · /			
Motion Approval:		Ī.,				Not			
Approved		For: 10	Against:	Abstain:	Recuse 0	e: Present:			
Clinical Application #2	Protocol ID: Application #2		PI: Caimi	Biosafet Level: BSL2		NIH Cat.: III-C-1, III-E			
of BMS-986393, a GI	Project Title: A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple								
Associated Grant Nu N/A	ımbers:								
Protocol Summary:									
□ N/A □ Oncogene □ Immunomodulatory	☐ Tumor Suppresso	or Gene	☐ Structura	_	_	Antimicrobial			

2000			_						
□ N/A ⊠ Human	☐ Mouse ☐ Rat ☐	Bacteri	al 🗆 Viral	☐ Other					
Committee Comm	onts								
None	ients.								
	res, and Safety Pra	ectices	Reviewed (V/N)•					
✓ Yes ☐ No	ires, and Salety 112	ictices	ixevieweu (1/11).					
PI/Supervisor Tra	ining (V/N):		Har	ıdler Traini	nσ (V	/N)·			
⊠ Yes □ No	mmg (1/1/).				-	11).			
Motion Approval:									
Approved		For:	Against:	Abstain:	Rec		Present:		
		10	0	0	0	,	1		
T N CH 1	ъ.								
IV. Non-Clinical									
a. New App	olications:								
Basic Research	Protocol ID:	Ι	PI:	Biosafe	tv	N	IH Cat.:		
Application #1	Application #1		AlHilli	Level	•		-1-a, III-D-4-		
	11			BSL2	,		b		
				ABSL	-				
Project Title:									
The Impact of Dieta	ary Fat and Obesity	on Ova	rian Cancer	Progression	1				
Associated Grant	Numbers:								
N/A									
Protocol Summary	,								
•	of replication defici		-						
	n of tissue culture co	ells and	l administra	tion <i>in vivo</i>					
 Human tissu 	ie culture cells								
Franctica /Nictions of	Decembinant Cons	- 4- 1- 1	C						
	Recombinant Genes			1		7 A4:			
_	e ⊠ Tumor Suppress			_	_	⊐ Anu	microbiai		
	ry □ Toxin 図 Antibi	one Res	sistance 🖾 R	teporters 🖾	Other				
Species of Recomb	inant Genes to be Ex	xpresse	d:						
	⊠ Mouse □ Rat □			⊠ Other					
Committee Comm	ents:								
 Administrat 	ive edits and update	s to wo	rding						
 Sample prepared 	paration for unfixed	BSL2 i	items need t	o be further	descri	bed			
 Relevan 	t SOPs will be provi	ided to	PI.						
			_						
•	res, and Safety Pra	actices	Reviewed ((Y/N):					
⊠ Yes □ No			_	T++	.		T. (%. T)		
PI/Supervisor Tra	ining (Y/N):			Handler		٠,	Y/ N):		
⊠ Yes □ No			_	⊠ Yes		No			

Motion Approval: Approved w/ Administrative Revisions	For: 10	Against:	Abstain:	Recuse:	Not Present:
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b. Renewals Not Applicable to NIH Guidelines:

Basic Research	Protocol ID:		PI:	Biosafety	, NI	H Cat.:						
Renewal #1	IBC 2127	Vac	nharajani	Level:		NA						
				BSL2								
Project Title:												
Immune response in sepsis												
Associated Grant Numbers:												
R01GM99807												
Protocol Summar	•											
-	quisition from healthy	-	-									
_	n and propagation of N	MRSA a	ınd <i>Staphylo</i>	coccus spp.	for tissue co	ulture						
infection												
 Human and 	d mammalian tissue cu	ulture c	ells lines									
			_									
	f Recombinant Genes		_									
	ne 🗆 Tumor Suppress			_	_	imicrobial						
☐ Immunomodulate	ory 🗆 Toxin 🗆 Antibi	otic Res	istance \square Re	porters \square O	ther							
Species of Peromi	binant Genes to be Ex	nraccad										
_	\square Mouse \square Rat \square		_	7 Other								
△ N/A □ Human	. Li Mouse Li Kat Li	Dacteria	ı 🗆 viiai L	1 Other								
Committee Comm	 nents:											
Administra												
	e of MRSA <i>Staphyloc</i>	2000118 5	nn ac a neu	, hazard								
	on-IBC <i>in vivo</i> proced		pp. as a new	nazaru								
• Remove ne	m-mc in vivo proced	urcs.										
Facilities, Proced	ures, and Safety Pra	ctices F	Reviewed (Y	/N):								
⊠ Yes □ No	_			,.								
PI/Supervisor Tra	aining (Y/N):		Handler T	raining (Y/N	<u>v):</u>							
⊠ Yes □ No	•		⊠ Yes	□ No	,							
Motion Approval	:	E		41.4.		Not						
Approved w/ Adn		For:	Against:	Abstain:	Recuse:	Present:						
Revisions		10	0	0	0	1						

c. Amendments:

Basic Research	Protocol ID:	PI:	Biosafety	NIH Cat.:
Amendment #1	IBC 2047	Wu	Level:	III-D-1-a, III-D-
			BSL2	2-a, III-D-3-a

Project Title:									
Elucidating the mechanisms of intrinsic stem cell resistance to virus infection									
Associated Grant Numbers:									
NA									
Summary of Approved Items:									
Generation of replication defective lentiviral									
Generation of attenuated Yellow Fever Viru	s (YFV) and i	nfection of	tissue cultu	ire cells;					
Human-derived materials	10 80 								
Requested Additions/Changes:									
 Updated procedures for propagation 	of YFV								
 Mammalian tissue culture cells 									
 Updates to research activity location 	S								
Room additions									
Function/Nature of Recombinant Genes to b	e Expressed:								
N/A □ Oncogene □ Tumor Suppressor (Gene □ Struc	tural 🗆 Sig	naling \square	Antimicrobial					
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic		_	_						
		1							
Species of Recombinant Genes to be Expres	sed:								
⊠ N/A □ Human □ Mouse □ Rat □ Bac		☐ Other							
Committee Comments:									
None									
Facilities, Procedures, and Safety Practice	es Reviewed (Y/N):							
⊠ Yes □ No									
PI/Supervisor Training (Y/N):	Handler	Training (Y/N):						
⊠ Yes □ No	⊠ Yes	□ No							
Motion Approval: For	: Against:	Abstain:	Recuse:	Not Present:					
Approved 10	0	0	0	1					

Basic Research	Protocol ID:	PI:	Biosafety	NIH Cat.:
Amendment #2	IBC 2022	Jung	Level:	III-D-1-a, III-D-
			BSL2,	4-b, III-E
			ABSL2	
Duciest Titles.				

Project Titles:

Molecular basis of cancer-associated viruses

Associated Grant Numbers:

R01DE028521, R01CA251275, R01AI151013, R01AI181758-01A1, R01CA295170-01

Summary of Approved Items:

Propagation of Hepatitis B Virus (HBV) particles and recombinant modified and WT Orf Virus (ORFV) and Kaposi's sarcoma-associated herpes virus (KSHV) particles, and infection of tissue culture cells; acquisition of WT and recombinant modified cell lines that are positive for KSHV, Epstein Barr Virus (EBV); Administration of cells *in vivo*. Processing of human

blood positive for EBV and Cytomegalovirus (CMV), Non K-12 <i>E.Coli</i> ; Human-derived material.									
Requested Additions/Changes:									
 Generation of replication deficient lentiviral particles for tissue transduction. Mammalian expression plasmids Gene expression library Human tissue culture cells Updates to safety information and disinfectant list. 									
□ N/A ☑ Oncoger □ Immunomodulato	Recombinant General Recombinant General Recombinant Suppressity Toxin Antibinant Genes to be Expression Recombinant Genes to be Expression Recombinated Rec	ssor Ger iotic Res	ne □ Struct sistance ⊠ F				Antimicrobial		
□ N/A ⊠ Human	☐ Murine ☐ Rat ☐	l Bacteri	al 🗆 Viral	⊠ Other					
Committee Comm None									
	res, and Safety Pra	actices]	Reviewed (Y/N):					
⊠ Yes □ No	• • • • • • • • • • • • • • • • • • • •		TT 11	T !! 0	X Z / N T N				
PI/Supervisor Tra	ining (Y/N):		1	Training (Y/N):				
☑ Yes ☐ No ☑ Yes ☐ No									
		For:					Not Present:		
Motion Approval: Approved		For: 10	Against: 0	Abstain: 0	Recu 0		Not Present:		
	Protocol ID: IBC 1407	10		Biosafe Level BSL2	ety 1: 2,	III-	Not Present: 1 NIH Cat.: -D-1-a, III-Da III-D-4-b		
Approved Basic Research	Protocol ID:	10	0 PI:	Biosafe Level	ety 1: 2,	III-	1 NIH Cat.: -D-1-a, III-D-		
Basic Research Amendment #3 Project Titles: Phosphorylation an	Protocol ID: IBC 1407 d activation of B3 in	10 F	0 PI: Byzova	Biosafo Level BSL2 ABSL	ety 1: 2,	III-	1 NIH Cat.: -D-1-a, III-D-		
Approved Basic Research Amendment #3 Project Titles:	Protocol ID: IBC 1407 d activation of B3 in	10 F	0 PI: Byzova	Biosafo Level BSL2 ABSL	ety 1: 2,	III-	1 NIH Cat.: -D-1-a, III-D-		
Basic Research Amendment #3 Project Titles: Phosphorylation an Associated Grant R01 HL071625 Summary of Appr Generation of replice	Protocol ID: IBC 1407 d activation of B3 in Numbers:	10 Fintegrins	PI: Byzova in angioger	Biosafo Level BSL2 ABSI nesis	ety 1: 2,2	III- 3	1 NIH Cat.: -D-1-a, III-D- -a III-D-4-b		
Basic Research Amendment #3 Project Titles: Phosphorylation an Associated Grant R01 HL071625 Summary of Appr Generation of replicadministration of tr Requested Addition Replication	Protocol ID: IBC 1407 d activation of B3 in Numbers: coved Items: cation defective lent ansduced cells in vis	ivirus p	PI: Byzova in angioger earticles; transan-derived	Biosafe Level BSL2 ABSI nesis	ety 1: 2,2	III- 3	1 NIH Cat.: -D-1-a, III-D- -a III-D-4-b		
Basic Research Amendment #3 Project Titles: Phosphorylation an Associated Grant R01 HL071625 Summary of Appr Generation of replicadministration of tr Requested Addition • Replication • Updated pro Function/Nature of N/A □ Oncogen	Protocol ID: IBC 1407 d activation of B3 in Numbers: coved Items: cation defective lent ansduced cells in vis ons/Changes: deficient lentiviral vis	ivirus p vo; hum vectors. al transo	PI: Byzova in angioger earticles; transan-derived duction of ti Expressed: Structure	Biosafe Level BSL2 ABSI anesis ansduction of material assue culture al Signal	ety : 2,2	III- 3. e cult	NIH Cat.: -D-1-a, III-Da III-D-4-b		

□ N/A □ Human	☑ Murine ☐ Rat I	☐ Bacter	rial 🗆 Viral	□ Other							
	w.										
CONTRACTOR	Committee Comments: • Clarify disinfection of liquid waste disposal										
1	frame of tissue tra		-								
Facilities, Procedu	was and Safaty Di	ractions	Poviowed (V/N).							
✓ Yes □ No	res, and Salety Fi	ractices	Keviewea ((1/14):							
PI/Supervisor Train	ining (Y/N):			Handler			Y/N):				
Motion Approval: ✓ Yes □ No				⊠ Yes		No	Not				
Approved w/ Adm	inistrative	For: 10	Against:	Abstain:	Recu 0		Present:				
Revisions		10		U	U		1				
Basic Research	Protocol ID:		PI:	Biosaf	-		NIH Cat.:				
Amendment #4	IBC 2124		Chen	Leve BSL2			-D-1-a, III-D- -a, III-D-4-b				
				ABSI	-	3.	-a, III-D-4-0				
Project Titles:		•	. 1								
Targeting ZDHHC1 Associated Grant		oylatıor	i for melano	ma treatmer	<u>it</u>						
R00CA234097	Numbers.										
Summary of Appr											
Generation of replication of transfer administration of transfer administra					f tissue	e cult	ture cells,				
Requested Additio		100, 11u	<u>man-derived</u>	i iliateriai.							
Gene targets	S										
Mammalian	tissue culture cell	lines									
Function/Nature of	Recombinant Gen	es to be	Expressed:								
□ N/A □ Oncogen	e ⊠ Tumor Suppre	essor Ge	ene 🗆 Struc	tural 🗆 Sig	naling	$\square A$	Antimicrobial				
☐ Immunomodulator	y □ Toxin □ Anti	biotic Re	esistance 🗆 1	Reporters	Other						
Species of Recomb	inant Genes to be I	Expresse	ed:								
□ N/A ⊠ Human				\square Other							
Committee Comm	ents:										
None	ents.										

E B .								
Facilities, Procedu	ires, and Safety Pr	actices	Reviewed ((Y/N):				
357 605 Windows 15 15 STATES	⊠ Yes □ No							
PI/Supervisor Training (Y/N):			Handler Training (Y/N):					
✓ Yes □ No		⊠ Yes □ No						
Motion Approval:		For: 10	Against:	Abstain:	Recus	e: Not Present:		
Approved	Approved			0	U	1		
Basic Research	Protocol ID:	PI: Biosafety NI		NIH Cat.:				
Amendment #5	IBC 2409		Chen	Level:		III-D-1-a, III-D-		
				BSL2,		3-a, III-D-4-b, III-		
				ABSI	.2	E		
Project Titles:								
	Mechanism and therapeutic potential of PTEN-regulated MDSCs in glioblastoma							
Associated Grant								
R01 NS127824, R0								
Summary of Approved Items: Generation of replication defective lentivirus particles, transduction of tissue culture cells, and								
1					f tissue	culture cells, and		
	administration of transduced cells <i>in vivo</i> . Human-derived materials.							
Requested Addition		4:-1	_					
_	defective lentiviral	particle	2					
Gene target	S							
Eurotion/Nature of	Francisco Niction of Proceedings of Connected by F							
	Function/Nature of Recombinant Genes to be Expressed:							
	□ N/A □ Oncogene □ Tumor Suppressor Gene □ Structural □ Signaling □ Antimicrobial □ Immunomodulatory □ Toxin □ Antibiotic Resistance □ Reporters □ Other							
	ry 🗆 Ioxiii 🖾 Aliut	DIOLIC RE	esistance 🖾 i	keporters L	Other			
Species of Recomb	inant Genes to be F	xpresse	eq.					
Species of Recombinant Genes to be Expressed: □ N/A □ Human □ Murine □ Rat □ Bacterial □ Viral ☒ Other								
17/1 - 11 min - 17 min - 1 Kat - 1 bacterial - 1 vital - 20 mei								
Committee Comm	ents:							
None								
Facilities, Procedu	res, and Safety Pr	actices	Reviewed (Y/N):				
⊠ Yes □ No								
PI/Supervisor Training (Y/N): Handler Training (Y/N):								
⊠ Yes □ No	⊠ Yes □ No ⊠ Yes □ No							
Motion Approval:	otion Approval:		Against:	Abstain:	Recus	Not		
Approved	Approved		Against:	Abstain:	0	Present:		
	10 0 0 1				1			
Basic Research	Basic Research Protocol ID: PI: Biosafety NIH Cat.				NIH Cat.:			
Amendment #6	IBC 1203		Lathia		l:	III-D-1-a, III-D-		
1 menument π0	150 1203		Launa			3-a, III-D-4-b, III-		
				BSL2 ABSI	-	E		
				11001		<u>. </u>		

Project Titles:

Interrogating the interface between car	ncer ste	m cells and	the immune	cyctem			
Associated Grant Numbers:	icci stc.	in cens and	inc minimunc	system			
R01 CA184090, R01 NS089641, R01 NS096376, P30 CA043703, R01 NS109742, R01 NS117104							
Summary of Approved Items:							
Generation of replication defective len	tivinas	transduction	of tigging o	ultura aalla	and		
administration of transduced cells to in							
bacterial strains and administration to <i>in vivo</i> ; Administration of plasmid to mice; Acquisition							
· · · · ·	of Adeno-Associated Virus (AAV) particles and administration in vivo; Administration of						
Diphtheria Toxin (DT) in vivo; Human	ı-derive	d material.					
Requested Additions/Changes:							
Human cytomegalovirus (HCM)	IV) info	ected human	tissue cultu	ire cells for	in vivo		
administration							
Gene targets							
 Updated stepwise procedures 							
Function/Nature of Recombinant Gene	es to be	Expressed:					
□ N/A ☑ Oncogene □ Tumor Suppres	sor Gen	e 🗆 Structui	al ⊠ Signal	ling 🗆 An	timicrobial		
☐ Immunomodulatory ☐ Toxin ☐ Antil	biotic Re	esistance 🗆 1	Reporters	Other			
	,						
Species of Recombinant Genes to be Expressed:							
□ N/A ⊠ Human ⊠ Murine □ Rat □ Bacterial □ Viral □ Other							
Committee Comments:							
Administrative edits							
Add HCMV infected cells to "New Hazards" section							
Contingent Items: Updates needed for ABSL2 cell administration: Clarifornia to be a fine and							
Clarify what locations sample processing is occurring in. If being performed in ARSI 2 facility contact facility representatives for appear to the process of a principle.							
ABSL2 facility, contact facility representatives for proper transport of equipment and other items into and out of the location.							
 Identify steps that generate liquid waste and how it is being collected. 							
E							
Facilities, Procedures, and Safety Practices Reviewed (Y/N): ⊠ Yes □ No							
PI/Supervisor Training (Y/N): Handler Training (Y/N):							
✓ Yes □ No		⊠ Yes		±/11/J•			
Motion Approval:		Γ΄		I _	Not		
Approved w/ Contingency.	For:	Against:	Abstain:	Recuse:	Present:		
Rereview needed prior to approval	10	0	0	1	0		
zazzaten needed prior to approvar		I		I .	•		

V. New SOPs:

SOP a: ABSL2 Autoclave SOP	Comments: Administrative edits			
Motion Approval:	For:	Against:	Abstain:	Recuse:
Approved w/ Administrative Revisions	10	0	0	1

VI. Updated SOPs:

SOP b: ABSL1/2 Waste Disposal	Comments: None				
Motion Approval:	For:	Against:	Abstain:	Recuse:	
Approved	10	0	0	1	