IBC Meeting Minutes Cleveland Clinic Main Campus

Date:		Location:	
July 30 th , 2025		Zoom	
IBC Member Attendance:			
☐ Ahern, Philip	⊠ DiDonato, Jo	oseph	☑ Dragan, Amanda (BSO)
⊠ Fox, Alan		ine	☐ Heemers, Hannelore
⊠ Kerr, Travis	□ Lindner, Dar	niel	☑ McDonald, Christine (IBC Chair)
	☐ Southern, Br	rian	
⊠ Such, Kimberly			
Guests: Anthony Santilli*, Anna Abby Biffano*, Sara Tavakoli**, * Cleveland Clinic Main Campu ** Cleveland Clinic Florida Res	, Dylan Champe us	<i>y</i> **	
Call To Order:		Adjourn:	
2:31 pm		4:38 pm	
· · · · · · · · · · · · · · · · · · ·	·	·	·

I. Review of June 25th, 2025 Meeting Minutes

Committee Comments:			
N/A			
Motion Approval:	For:	Against:	Abstain:
Approved	10	0	1

II. Administrative Business

- **a.** Committee presented with Expedited Review items, personnel additions, and updates to programmatic SOPs
- **b.** Committee was presented with updated disinfection requirements for infectious agents.
- **c. Incident Report:** IBC Members were informed of incidents involving a failure to follow approved containment conditions and spill. The resulting risk assessments and corrective actions taken to prevent further occurrence were also presented.
- **d. Lab Audits:** Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of June, 2025. No major deficiencies identified.

III. Clinical Research:

a. Applications:

Clinical Application #1	Protocol ID: Application #1	V	PI: Vinter	Biosafet Level: BSL2	У	NIH Cat.: III-C-1, III-E				
Project Title: The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients										
Associated Grant N Non-NIH Funding	umbers:									
Protocol Summary:										
•	on of replication d	lefectiv	e lentiviral	transduced c	ells to hu	mans				
Function/Nature of R	ecombinant Gene	es to be	Expressed:							
□ N/A □ Oncogene	☐ Tumor Suppre	ssor Ge	ne 🗆 Struc	tural 🗆 Sig	naling [☐ Antimicrobial				
					_					
Species of December	ant Canas to ba	Evanos =	ad.							
Species of Recombin □ N/A ⋈ Human		_		Other						
I IVII Z IIuman	□ Wurme □ Dae	terrar L		Julei						
Committee Comme	Committee Comments: N/A									
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):						
⊠ Yes □ No										
PI/Supervisor Train	ing (Y/N):			Handler T	raining (Y/N):				
⊠ Yes □ No				⊠ Yes	□ No					
Motion Approval:		For:	Against:	Abstain:	Recuse	: Not Present:				
Approved		10	0	0	0	1				
Clinical	Protocol ID:		PI:	Biosafet	y	NIH Cat.:				
Application #2	Application #2	(Caimi	Level: BSL2		III-C-1, III-E				
Project Title:		41	- C-C (1 E.C.	e i vii o	1.4. A				
A Phase 1/2 Multi-Ce	•	_	•	•						
CD19/CD20 Dual-Ta Aggressive B-Cell N				1-Cell Ther	apy in P	articipants with				
Associated Grant N		риона								
Non-NIH Funding	umpers.									
Protocol Summary:										
_	on of replication d	lefectiv	e lentiviral	transduced c	ells to hu	mans				
Function/Nature of R	ecombinant Gene	es to be	Expressed:							
□ N/A □ Oncogene	☐ Tumor Suppre		_		naling [☐ Antimicrobial				
				_	_					
Species of Recombin	ant Genes to be F	vnress	ed.							
	☐ Murine ☐ Bac	_		Othon						

Committee Comme	nts:							
N/A								
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):				
⊠ Yes □ No								
PI/Supervisor Train	ing (Y/N):			Handler T		/N):		
⊠ Yes □ No				⊠ Yes	□ No			
Motion Approval: For: Against: Abstain: Recuse: Not Present:								
Approved		10	0	0	0	1		
Clinical	Protocol ID:		PI:	Biosafet	v	NIH Cat.:		
Application #3	Application #3	Ke	ennedy	Level:	•	III-C-1		
ripplication #0	пррисанов по	120	Jinicay	BSL2		III C I		
Project Title:	l	<u> </u>		D 522				
RPL2625: A Single Par	tient compassionate	e use of	RP-1 for Me	etastatic Mela	noma.			
Associated Grant N					· · · · · · · · · · · · · · · · · · ·			
Non-NIH Funding	- - - - - - - - -							
Protocol Summary:								
•	on of recombinant	Hernes	s Simplex V	irus to a sing	ole natient			
1 1011111111111111111111111111111111111	01 100 011101110111	P	, and the second	11 000 00 00 0111	Pre Laurence			
Function/Nature of R	ecombinant Gene	es to be	Expressed:					
□ N/A □ Oncogene			_	-	naling \square	Antimicrobial		
				_	_			
= immunomodulatory		101010110	resistance	_ reperen				
Species of Recombin	ant Genes to be E	Express	ed:					
□ N/A ⊠ Human		_	 '	Other				
Committee Comme	nts:							
N/A								
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):				
⊠ Yes □ No	,							
PI/Supervisor Train	ing (Y/N):			Handler T	raining (Y	(/N):		
⊠ Yes □ No	<i>8</i> ()			⊠ Yes	□ No	,		
Motion Approval:		For:	Against:	Abstain:	Recuse:	Not Present:		
Approved		11	0	0	0	0		
FF - · · · ·			<u> </u>	<u> </u>	· · · · ·	<u>. </u>		
IV. Non-Clinical R	lesearch:							
a. New Appli	cations not appl	icable 1	to NIH Gui	delines:				
Dagia Dagaga	Ducks LID		DI.	D:	4	NIII C-4.		
Basic Research	Protocol ID:		PI:	Biosafe	•	NIH Cat.:		
Application # 1	Application #1	D	hawan	Level		N/A		
D . ATTICLE CO. 15	1361 1	<u> </u>	CT.	BSL2	<u> </u>	1 701		
Project Title: Genetic	c and Molecular	Analysi	is of Tumor	s of the Nerv	ous Syster	m and Their		
Coverings								

Associated Grant N	umbers:					
N/A						
Protocol Summary:	. 1		C 11	1		
• Acquisition, p	processing, and st	orage o	f potentially	infectious l	numan sp	ecimens
Function/Nature of R						
⊠ N/A □ Oncogene						
☐ Immunomodulatory	□ Toxin □ A1	ntibiotic	Resistance	☐ Reporters	☐ Other	•
Species of Recombin	ant Genes to be I	Express	ed:			
⊠ N/A □ Human		-		Other		
Committee Commen						
Minor admini	strative edits					
Facilities, Procedure	es, and Safety Pi	ractices	Reviewed	(Y/N):		
⊠ Yes □ No	•					
PI/Supervisor Train	ing (Y/N) :			Handler To	raining (Y/N):
⊠ Yes □ No				⊠ Yes	□ No	
Motion Approval:	•	For:	Against:	Abstain:	Recuse:	Not Present:
Approved w/ Admin	iistrative	10	0	0	0	1
Revisions						
b. Renewals:						
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:
Renewal # 1	IBC 2122	N	Vemet	Level:	•	II-D-1-a, III-D-
				BSL2, AB	SL2	4-b
Project Titles:						
Gut microbes and car		ease				
Associated Grant No. 1801HL160747	umbers:					
Protocol Summary:						
•	of WT and recom	binant b	acteria and	administrati	on <i>in vivo</i>)
Function/Nature of R					_	
□ N/A □ Oncogene				_	_	
☐ Immunomodulatory	Tox1n □ A1	ıtıbıotıc	Resistance	☐ Reporters	⊠ Othe	r
Species of Recombin	ant Genes to be I	Express	ed:			
\square N/A \square Human		-		Other		
			_ `			
Committee Commen	nts:					
Undate generation	al procedures to r	eferenc	e appropriat	te space		

Suggestion from committee to add additional room for <i>in vivo</i> work.									
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):					
⊠ Yes □ No									
PI/Supervisor Train	ing (Y/N):			Handler T	raining (Y/N):			
⊠ Yes □ No				⊠ Yes	□ No				
Motion Approval:		For:	Against:	Abstain:	Recuse:	Not Present:			
Approved w/ Administrative 10 0 1 1 0									
Revisions		10	U	U	1	U			
Basic Research	Protocol ID:		PI:	Biosafe	ty	NIH Cat.:			
Renewal #2	IBC 2121	S	Silver	Level	i	II-D-1-a, III-D-			
				BSL1, BS	SL2,	4-a, III-D-4-b			
				ABSL1, Al	BSL2				
Project Titles: Remodeling host imm	nunity in oral can	cer witl	h personaliz	zed RNA naı	noparticle	vaccines			
Associated Grant N	umbers:		•						
Non-NIH Funding									
Protocol Summary:		1		. C 11	1 14	11			
1 -	of WT and recomb		· ·			ells			
	on of bacteria and								
• Mammalian e	expression plasmi	as for g	eneration o	i mkna vac	cines and	administration			
	n in cell culture								
Human-deriv	ed materials								
Function/Nature of R	Pecombinant Gene	es to be	Evpressed:						
	☐ Tumor Suppre		_	tural 🗆 Sice	nalina 🗆	Antimicrobial			
✓ Immunomodulatory	* *			Reporters	•				
	/ □ IOXIII □ AI	шыыс	Resistance	△ Keporters					
Species of Recombin	ant Genes to be F	Expresse	ed:						
_	\boxtimes Murine \boxtimes Back	-		Other					
			· • 						
Committee Comme	nts:								
Administrativ									
	y the specific SO	Ps refer	enced in PI	PE description	on				
	iption of bacteria/			-					
1	o fecal collection			_					
				1					
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):					
⊠ Yes □ No									
PI/Supervisor Train	ning (Y/N):			Handler T		Y/N):			
⊠ Yes □ No		1		⊠ Yes	□ No				
Motion Approval:		For:	Against:	Abstain:	Recuse:	Not Present:			

Approved w/ Administrative	9	0	0	2	0
Revisions					

c. Renewals Not Applicable to NIH Guidelines:

		1				
Basic Research	Protocol ID:		PI:	Biosafe		NIH Cat.:
Renewal #3	IBC 2119	N	Markle	Level		N/A
				BSL2		
Project Titles:						
CRU procedures for l		agent:	Clostridioid	es difficile (C. diff)	
Associated Grant N	umbers:					
Non-NIH Funding						
Protocol Summary:						
 Acquisition of 	f samples from C	lostridi	oides diffici	le (C. diff) i	nfected pat	ients,
handling, prod	cess and aliquoted	d, shipn	nent or shor	t term storag	ge	
 Human-derive 	ed materials.					
Function/Nature of R	ecombinant Gene	es to be	Expressed:			
⊠ N/A □ Oncogene	☐ Tumor Suppre	ssor Gei	ne ☐ Struct	tural 🗆 Sig	naling \square	Antimicrobial
☐ Immunomodulatory	□ Toxin □ At	ntibiotic	Resistance	☐ Reporters	□ Other	
·				1		
Species of Recombin	ant Genes to be F	Express	ed:			
⊠ N/A □ Human	☐ Murine ☐ Bac	terial [□ Viral □ C	Other		
Committee Commer	nts:					
 Update disinfe 	ectant concentrat	ion and	contact time	e.		
1						
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):		
⊠ Yes □ No	,			,		
PI/Supervisor Train	ing (Y/N):		Handler	Training (Y/N):	
⊠ Yes □ No	g (* *)*		⊠ Yes	□ No	,.	
Motion Approval:			<u> </u>			
Approved w/ Admin	istrative	For:	Against:	Abstain:	Recuse:	Not Present:
Revisions		10	0	0	0	1
110 (1510115				ı		
Basic Research	Protocol ID:		PI:	Biosafe	ty	NIH Cat.:
Renewal #4	IBC 2120	N	Markle (Level	:	N/A
				BSL2		
Project Titles:						
CRU procedures for l	Handling Sample	s from	Patients with	h Known In	fection	
Associated Grant N	umbers:					
Non-NIH Funding						

Protocol Summary:						
	f samples from p	atients w	vith known	infections (1	RG2 and	HIV), handling,
<u> </u>	iquoted, shipmer			`),8,
Human-derive				8		
Function/Nature of R			-			
⊠ N/A □ Oncogene						
☐ Immunomodulatory	\square Toxin \square A ₁	ntibiotic 1	Resistance	☐ Reporters	☐ Oth	er
	~					
Species of Recombin		-		_		
⊠ N/A □ Human	⊔ Murine ⊔ Bac	terial L	J Viral ⊔ O	ther		
Committee Commen	14a•					
	ectant concentrat	ion and	contact time	2		
• Opuate distint	cetani concentrat	ion and	comact time	··		
Facilities, Procedure	es, and Safety Pi	actices	Reviewed ((Y/N):		
⊠ Yes □ No			1			
PI/Supervisor Train	ing (Y/N):			Training (Y/N):	
⊠ Yes □ No			⊠ Yes	□ No		
Motion Approval:	•	For:	Against:	Abstain:	Recuse	e: Not Present:
Approved w/ Admin	istrative	10	0	0	0	1
Revisions				-		
d. Amend	ments:					
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:
Amendment #1	IBC 1909		Vang	Level:	•	III-D-1-a, III-D-
				BSL2, AB		3-a, III-D-4-b
Project Titles: Nove	l immuno-preven	tion stra	tegies for c			· · · · · · · · · · · · · · · · · · ·
cancer	-					•
Associated Grant No	umbers:					
Non-NIH Funding						
Summary of Approved Items:						
Summary of Approv	ed Items:					
Generation of replica	tion-defective les					
Generation of replica cells, plasmid transfe	tion-defective ler	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transfe animals; Propagation	tion-defective ler ction of tissue cu of rDNA modifi	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transferanimals; Propagation Human-derived mate	tion-defective ler ction of tissue cu of rDNA modifi rial.	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mater Requested Additions	tion-defective ler ction of tissue cu of rDNA modifi rial. s/Changes:	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mate Requested Additions Mammalian to	tion-defective ler ction of tissue cu of rDNA modifi rial.	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mater Requested Additions	tion-defective ler ction of tissue cu of rDNA modifi rial. s/Changes:	lture cel	ls, and adm	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transferant animals; Propagation Human-derived mater Requested Additions • Mammalian to Genes targets	tion-defective lenction of tissue cu of rDNA modificial. s/Changes: ssue culture cells	lture cel ed Liste	ls, and adm ria monocyt	inistration c	of transd	uced cells to
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mate Requested Addition Mammalian ti Genes targets Function/Nature of R	tion-defective ler ction of tissue cu of rDNA modifi rial. s/Changes: ssue culture cells	lture cel ed Liste	ls, and adm ria monocyt Expressed:	inistration o	f transd adminis	uced cells to stration <i>in vivo</i> ;
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mate: Requested Additions Mammalian ti Genes targets Function/Nature of R N/A Oncogene	tion-defective lenction of tissue cu of rDNA modificial. s/Changes: ssue culture cells ecombinant General	lture cel ed Liste	ls, and adm ria monocyt Expressed: ene □ Str	inistration of togenes and	of transd adminis	uced cells to stration in vivo;
Generation of replica cells, plasmid transfe animals; Propagation Human-derived mate Requested Addition Mammalian ti Genes targets Function/Nature of R	tion-defective lenction of tissue cu of rDNA modificial. s/Changes: ssue culture cells ecombinant General	lture cel ed Liste	ls, and adm ria monocyt Expressed: ene □ Str	inistration of togenes and	of transd adminis	uced cells to stration in vivo;

□ N/A □ Human ⋈ Murine □ Bacterial □ Viral □ Other										
Committee Comments: N/A										
Facilities, Procedure	es, and Safety Pr	actices	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 Presen										
Approved 9 0 0 1 1										
Basic Research	Protocol ID:		PI:	Biosafety 1	Level:	NIH Cat.:				
Amendment #2	IBC1907	Cha	kraborty	BSL1, BS		III-D-1-a, III-D-				
				ABSL1, A	BSL2	3-a, III-D-4-b				
Project Titles:										
Epigenetic Dysregula		argetab	le Vulnerat	oilities in Ca	ncer					
Associated Grant Non-NIH Funding	umbers:									
Summary of Approv	ved Items:									
Generation of replica		tivirus	and retrovir	us, transduc	tion of t	issue culture cells				
and administration of										
Requested Addition	s/Changes:									
Replication delication delic	efective lentiviral	particle	es							
 Gene targets 										
	1:	. 1	г 1							
Function/Nature of R					· · · · · 1 · · · ·	□ A4:				
□ N/A □ Oncogene										
☐ Immunomodulatory	□ Ioxin □ Ai	indione	Resistance	□ Reporters	i 🗆 Otno	er				
Species of Recombin	ant Genes to be E	Expresse	ed:							
\square N/A \square Human		-		Other						
Committee Commen	nts:									
N/A										
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):						
	• (\$7.7\$.1)			II 11 T		(X7/NT)				
PI/Supervisor Train	ing (Y/N):			Handler T		` ,				
Motion Approval: No		For:	Against:		□ No Recuse					
Approved		10	Agamst:	Abstain:	()	e: Not Fresent:				
		10	<u> </u>		<u> </u>	1				
	n :	<u> </u>	DI I		, 1					
Basic Research	Protocol ID:	т	PI:	Biosafe	•	NIH Cat.:				
Amendment #3	IBC 1801	1	vanov	Level:		III-D-1-a				
				BSL1, BS	DL2					

Project Titles:								
Regulation of the intestinal epithelial barrier during mucosal inflammation								
Associated Grant N	umbers:							
Non-NIH Funding								
Summary of Approv								
Generation of replica		ntiviral	and retrovir	al particles,	transduction	on of tissue		
culture cells; Human-								
Requested Addition	_							
 Replication de 	efective lentiviral	l particl	es					
Mammalian expression plasmids								
Gene targets a	and genes for edit	ting						
Function/Nature of R			-					
\square N/A \square Oncogene	☐ Tumor Suppr	essor G	ene 🗵 Str	uctural 🗆 S	Signaling	☐ Antimicrobial		
☐ Immunomodulatory	□ Toxin □ Ar	ntibiotic	Resistance	☐ Reporters	□ Other			
Species of Recombin		-						
\square N/A \boxtimes Human	☐ Murine ☐ Bac	terial [□ Viral □ (Other				
Committee Commen		_						
Update room	locations and BS	L						
E iiii D I	10 C + D	4.0	D ' 1	(X / / X /)				
Facilities, Procedure	es, and Safety Pi	ractices	s Reviewed	(Y/N):				
	• (\$7/\$1)			TT 11 75	• • •	7.7% ()		
PI/Supervisor Train	ing (Y/N):			Handler T		(/ N):		
⊠ Yes □ No		Π	1	⊠ Yes	□ No			
Motion Approval:		For:	Against:	Abstain:	Recuse:	Not Present:		
Approved w/ Admin	istrative	10	0	0	0	1		
Revisions								
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:		
Amendment #4	IBC 2222		Stacy	Level	•	I-D-1-a, III-D-		
			~	BSL2, AB		4-b		
Project Titles:	L			,		-		
Oral microbiota-host	interactions in pe	eriodon	titis					
Associated Grant N								
Non-NIH Funding								
Summary of Approv	ed Items:							
		ant and	non-recomb	oinant modif	ied bacter	ia; various		
Generation and culturing of recombinant and non-recombinant modified bacteria; various human and rodent-derived material; administration <i>in vivo</i> ; Human-derived material.								

Requested Additions	s/Changes•						
-	_						
 Wild-type <i>Pseudomonas spp</i>. Recombinant <i>Neisseria spp</i>. 							
Recombinant	iveisseria spp.						
Function/Nature of Recombinant Genes to be Expressed: □ N/A □ Oncogene □ Tumor Suppressor Gene □ Structural □ Signaling □ Antimicrobial □ Immunomodulatory □ Toxin □ Antibiotic Resistance □ Reporters ☒ Other							
Consider CD and the		7	. 1.				
Species of Recombin ☐ N/A ☐ Human		-		Other			
Committee Commer	nts:						
information necombinant b	f <i>in vitro</i> bacteria eeds to be outline pacteria. y information for	ed in the	e stepwise p	rotocols for		•	
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):			
⊠ Yes □ No	• (\$1,0\$1)		T	TT 11 75	• • •	7 (N.T.)	
PI/Supervisor Train	ing (Y/N):			Handler T	0 \	(/ N):	
✓ Yes □ No	_			⊠ Yes	□ No		
Motion Approval:	aammanta	For:	Against:	Abstain:	Recuse:	Not Present:	
Tabled, PI to address	comments	0	8	0	2	1	
and resubmit.							
Basic Research	Protocol ID:		PI:	Biosafe	ty	NIH Cat.:	
Amendment #5	IBC 2117	Ana	ınd-Apte	Level	: II	I-D-1-a, III-D-	
				BSL2, AB		3-a, III-D-4-b	
Project Titles: FGF a	•			-	l-mesench	ymal transition	
and metabolism of R	•	y Fundu	ıs Dystroph	у			
Associated Grant No R01 EY027083	umbers:						
Summary of Approv							
Generation of replica					`	/ 1	
transduction of tissue		ministra	ition of lent	iviral and A.	AV partic	es in vivo;	
Human-derived mater							
Requested Additions	s/Changes:						
Generation of	point mutation o	n appro	oved gene ta	rget			
Function/Nature of R	ecombinant Gene	es to be	Expressed:				
□ N/A □ Oncogene			-		Signaling	☐ Antimicrobial	
☐ Immunomodulatory	• •						
Species of December	ant Canas to be I	Transa ==	ad.				
Species of Recombin □ N/A ⊠ Human		-	<u>ea:</u> ∃Viral □(Other			

Committee Commer	nts•										
N/A											
Facilities, Procedures, and Safety Practices Reviewed (Y/N):											
PI/Supervisor Training (Y/N): Handler Training (Y/N):											
Motion Approval:		For: Against: Abstain: Recuse: Not Pres									
Approved 10 0 0 1											
Basic Research	Protocol ID:		PI:	Biosafet	ty	NIH Cat.:					
Amendment #6	IBC 2406		Ma	Level:	•	-D-1-a, III-D-2-					
				BSL1, BS	SL2 a,	III-D-3-a, III-E					
Project Titles:											
Engineering human in		physio	logy and pa	thology for	precision 1	nedicine					
Associated Grant N	umbers:										
Non-NIH Funding	rad Itamas										
Summary of Approx Generation of lentiving		duction	of tissue c	ulture cells	Human-de	erived materials					
Requested Additions		<u>sauctioi</u>	1 of tissue e	artare ceris.	Truman uv	iived materials					
_	and WT human t	issue ci	ılture cells								
Function/Nature of R □ N/A □ Oncogene □ Immunomodulatory Species of Recombin □ N/A □ Human	☐ Tumor Support Toxin ☐ And And Genes to be Head Indicate ☐ Bace ☐ Murine ☐ Bace	ressor C ntibiotic Express	Gene □ Str Resistance	ructural \square S							
Committee Commer	nts:										
N/A Facilities, Procedure	os and Cafater D	ooticaa	Daviored	(V/N).							
X Yes	es, and Safety Fi	actices	Kevieweu	(1/14):							
PI/Supervisor Train	ing (V/N)·			Handler T	raining (\)	// N)•					
✓ Yes □ No	g (1/1/)•			⊠ Yes	□ No	.71 ()•					
Motion Approval:		For:	Against:	Abstain:	Recuse:	Not Present:					
Approved		10	0	0	0	1					
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:					
Amendment #7	IBC 1104	L	indner	Level		III-D-4-b					
				BSL2, AB	SL1,						
				ABSL	-						
Project Titles:											
Molecular determinar	nts of tumor grov	vth									

Associated Grant No P30CA043703-32, R		R01 C	A257544-02	2									
Summary of Approved Items:													
Administration of non-recombinant and recombinant modified cells in vivo; Human-derived													
materials (CI													
Requested Addition	_	1,	11										
Recombinant mammalian tissue culture cells													
Function/Nature of Recombinant Genes to be Expressed:													
□ N/A □ Oncogene				uctural 🗆 S	ignalin	ng							
				•									
Species of Recombin		_											
□ N/A □ Human	⊠ Murine □ Bac	terial	\square Viral \boxtimes	Other									
Committee Commer	-4~-												
N/A	its:												
Facilities, Procedure	es, and Safety Pr	actices	Reviewed	(Y/N):									
⊠ Yes □ No	,			()									
PI/Supervisor Train	ing (Y/N):			Handler T	rainin	g (Y/N):							
⊠ Yes □ No				⊠ Yes	□N	• ,							
Motion Approval:		For:	Against:	Abstain:	Recu	ise: Not Present:							
Approved		8	0	0	2	1							
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:							
Amendment #8	IBC 2226	Po	nlaweki		•								
		Poplawski Level: III-D-1-a, III-D-											
			piawski	BSL2, AB		2-a, III-D-3-a, III-D-							
			piawski			-							
			piawski			2-a, III-D-3-a, III-							
Project Titles:				BSL2, AB	SL2	2-a, III-D-3-a, III- D-4-a, III-D-4-b, III-E-1							
Investigation of mole		mecha		BSL2, AB	SL2	2-a, III-D-3-a, III- D-4-a, III-D-4-b, III-E-1							
Investigation of mole Associated Grant N		r mecha		BSL2, AB	SL2	2-a, III-D-3-a, III- D-4-a, III-D-4-b, III-E-1							
Investigation of mole Associated Grant Non-NIH Funding	umbers:	mecha		BSL2, AB	SL2	2-a, III-D-3-a, III- D-4-a, III-D-4-b, III-E-1							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx	umbers:		nisms of ne	BSL2, AB	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acqui	wed Items: sition of Adeno-A	Associa	nisms of ne	BSL2, AB	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acquir propagation of replication	wed Items: sition of Adeno-ation deficient len	Associa ntiviral	ted Viral pa	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acqui propagation of replicated administration of transport	wed Items: sition of Adeno-ation deficient lends	Associa ntiviral	ted Viral pa	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acquir propagation of replication and acquire administration of trans Requested Additions	wed Items: sition of Adeno-ation deficient lends	Associa ntiviral ivo. Hu	ted Viral pa	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acqui propagation of replicated administration of trans Requested Additions Mammalian e	wed Items: sition of Adeno-Ade	Associa ntiviral <i>ivo</i> . Hu	ted Viral pa	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acquir propagation of replicated administration of trans • Mammalian e • Gene targets a	ved Items: sition of Adeno-Aation deficient lendsduced cells in vers/Changes: xpression plasmi	Associa ntiviral <i>ivo</i> . Hu ds iing	ted Viral pa particles, tra man-derived	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							
Investigation of mole Associated Grant Non-NIH Funding Summary of Approx Generation and acquir propagation of replicated administration of trans • Mammalian e • Gene targets a	ved Items: sition of Adeno-Ade	Associa ntiviral <i>ivo</i> . Hu ds iing	ted Viral pa particles, tra man-derived	BSL2, AB surodegeneral articles and a ansduction of	SL2	2-a, III-D-3-a, III-D-4-a, III-E-1 egeneration stration in vivo;							

Function/Nature of Recombinant Genes to be Expressed:

□ N/A ⊠ Oncogene	☐ Tumor Suppre	essor Ge	ne 🗆	Struc	tural 🛚 Sig	gnaling	☐ Antimicrobial			
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Other										
Species of Recombinant Genes to be Expressed:										
□ N/A ⊠ Human	⊠ Murine □ Bac	eterial [□ Vira	1 🗆 (Other					
Committee Commer	its:									
N/A										
Facilities, Procedure	es, and Safety Pi	ractices	Revi	ewed	(Y/N):					
⊠ Yes □ No										
PI/Supervisor Train	ing (Y/N):				Handler T	raining	(Y/N):			
⊠ Yes □ No					⊠ Yes	□ No				
Motion Approval:		For:	Aga	inst:	Abstain:	Recuse	e: Not Present:			
Approved		9	(0	0	1	1			
Basic Research	Protocol ID:	PI	-		osafety Lev		NIH Cat.:			
Amendment #9	Jung	IBC 2	:023	E	BSL2, ABSI	L2	III-D-1-a, III-D-			
							2-a, III-D-3-a,			
							III-D-4-b, III-E			

Project Titles: Identifying viral determinants involved in viral-host interactions using infectious clones

Associated Grant Numbers:

R01 AI140705, R01 AI52190, R01AI151013

Summary of Approved Items:

Propagation of non-recombinant Murine Coronavirus, Human Coronavirus, La Crosse Virus, Utinga Virus, Simbu Virus, Manzanilla Virus, Buttonwillow Virus, Ingwavuma Virus, rodent herpesvirus Peru E and L virus, Oropouche Virus and Uukuniemi Virus. Propagation of recombinant Zika virus, Kaposi's Sarcoma associated herpesvirus, Murine Gammaherpesvirus 68 (MuHV-68), Measles virus, Mumps virus, Oropouche Virus (OROV), and Herpesvirus; Generation of replication competent Retroviral particles; Handling of Measles, Mumps, HRTV, SFTSV Viral Vector vaccines; Generation of mRNA vaccines; Administration of all agents to mice. Acquisition and processing of Epstein – Barr virus positive samples, Non K-12 E. coli; Human-derived material

Requested Additions/Changes:

- WT and Recombinant Herpes Simplex Virus-1 and Lab Adapted Indiana Vesiculovirus
- Generation of Potosi Virus
- Generation of replication defective lentivirus particles and transduction of tissue culture cells
- Gene targets and genes for editing
- mRNA vaccine constructs
- Human tissue culture cells

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 Recombinant Genes to be Expressed: □ N/A ⊠ Human □ Murine ⊠ Bacterial □ Viral □ Other									
Committee Comments:									
Facilities, Procedure ⊠ Yes □ No	es, and Sa	afety Pra	ctices Revie	wed	(Y/N):				
PI/Supervisor Train	ing (Y/N):		Han	dler Trai	ning (Y/I	N):		
⊠ Yes □ No						□ No			
Motion Approval: Approved		For: 9	Against:	A	bstain: 0	Recus	e:	Not Present:	
проточе			ı v	l		1			
Basic Research	Protoc	ol ID:	PI:		Bios	afety		NIH Cat.:	
Amendment #10	IBC 2	2315	Jung			vel:	III	-D-1-a, III-D-	
						BSL2,		, III-D-3-a, III-	
Project Titles:					BSL3,	ABSL3	D-	3-b, III-D-4-b	
Identifying effective	drug targe	ets agains	st RNA virus	es					
Associated Grant N		- 1.5 1.B.							
R01 AI52190, R01 A			71201						
Summary of Approv								- 4	
Propagation of non-re						1	•	•	
Coronavirus (MERS-modified Heartland v									
SARS-CoV-2, SARS									
Infection with non-re								•	
Virus, Manzanilla Vi									
virus; Acquisition of						nistration	of re	ecombinant	
and non-recombinant			uman-derive	d ma	iterials.				
Requested Addition Hantaan Virus	_	:S:							
Addition of R	=	nstrumen	at and proced	lures	in BSL3	location			
Function/Nature of R	ecombina	ant Genes	to be Expre	ssed:	<u>.</u>				
⊠ N/A □ Oncogene			-		_	Signaling		Antimicrobial	
☐ Immunomodulatory	□ Toxii	n \square Anti	ibiotic Resista	ince	□ Repor	ters 🗆 O	ther		
Species of Recombin	ant Gene	s to be Ex	pressed:						

⊠ N/A □ Human □	☐ Murine ☐ Bac	terial [□ Viral □ C	Other					
Committee Comments:									
Facilities, Procedure ⊠ Yes □ No	es, and Safety Pr	actices	Reviewed	(Y/N):					
PI/Supervisor Train	ing (Y/N):			Handler T	rainin	g (Y/	/N):		
⊠ Yes □ No			T	⊠ Yes	□ N	o			
Motion Approval: Approved w/ Contin Rereview needed pri approval	oved w/ Contingency. For: Against riew needed prior to 11 0			Abstain:	Recu 0	se:	Not Present:		
при			L		I	I			
Basic Research Amendment #11	Protocol ID: IBC 2022	PI: Jung				III	NIH Cat.: -D-1-a, III-D- , III-D-4-b, III- E		
Project Titles: Molecular basis of ca		riruses	l						
Associated Grant No		TA 2512	75						
R01 DE02852, R35 CA200422, R01 CA251275 Summary of Approved Items: Generation of replication deficient lentiviral particles, transduction of tissue culture cells; 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 <i>in vivo</i> . Processing of human blood positive for EBV and Cytomegalovirus (CMV), Non K-12 E.coli; Human-derived material									
Requested Additions	_								
•	eficient lentiviral xpression plasmi	-	es						
Function/Nature of R ⊠ N/A □ Oncogene □ Immunomodulatory	☐ Tumor Suppre	essor Ge	ene 🗆 Struc	-			Antimicrobial		

Species of Recombinant Genes to be Expressed:										
⊠ N/A □ Human □ Murine □ Bacterial □ Viral □ Other										
Committee Comments:										
Facilities, Procedures, and Safety Practices 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 Presen										
Approved		11	0	0	0		0			
Basic Research	Protocol ID:		PI:	Biosafe	ty		NIH Cat.:			
Amendment #12	IBC 1916	I	Hajjar	Level	:	III	-D-1-a, III-D-			
				BSL1, BS	-	4-a,	, III-D-4-b, III-			
D . (T):(1				ABSL1, Al	BSL2		Е			
Project Titles: Microbial Engineerin	o and Transplant	ation C	ore (Core C	3						
Associated Grant N		ution C	016 (0016 0	<i>')</i>						
P01 HL147823										
Summary of Approx	ved Items:									
Various human and n					-	-				
isolates; generation a						and g	growth of non-			
recombinant bacteria		n vivo;	Human-der	ived materia	ls.					
Requested Addition	_									
 Proteus spp. a WT and recor 	ma <i>E. con</i> nbinant bacterial	aammi	mitios							
	f replication defic			ted viral nar	ticles a	nd a	dministration			
in vivo	r replication deric	ciciii au	CIIO-associa	iicu virai pai	ticies a	iiu a	diffifistration			
Surgical proce	edures									
New Rooms	Jun 105									
Function/Nature of R □ N/A ⊠ Oncogene			-		gnaling		Antimicrobial			
☐ Immunomodulatory	* *			•	•					
Species of Recombin	ant Genes to be I	Expresse	ed:							
□ N/A □ Human	⊠ Murine □ Bac	_		Other						
Committee Commen		GI 2	1	0.			1 1			
	ems - For the ABS									
	1 Update ABSL									
	moved there by orking in the sugg						_			
	is needed.	,coica s	pace, and up	paare apprica		11101	ade mose			

Option 2 Remove all BSL2/ABSL2 work involving the assay and associated equipment. Only work in the approved ABSL1 space would be allowed, and an amendment would be needed at a later date once an alternative space for ABSL2 procedures is identified. Administrative edits Update disinfectant list Facilities, Procedures, and Safety Practices Reviewed (Y/N): ⊠ Yes □ No PI/Supervisor Training (Y/N): Handler Training (Y/N): ⊠ Yes □ No ⊠ Yes \square No **Motion Approval:** Approved w/ Contingency. **Not Present:** For: **Against:** Abstain: **Recuse:** Rereview needed prior to 9 0 2 0 approval Rasic Research Protocol ID: Ы· Riosafety NIH Cat ·

Dusic Heseuren	TIOCOCOTIE.		Diosarcey	1 1111
Amendment #13	IBC 2308	Yildirim	Level:	III-D-1-a, III-D-
			BSL1, ABSL1,	4-b
			ABSL2	
Project Titles:				
Cortical circuits and i	information flow	during task-free lo	comotion and men	nory-guided
perceptual decision-n	naking in health a	nd disease		
Associated Grant N	umbers:			
5R00EB027706-04, 1	Non-NIH Funding			
Summary of Approx	ved Items:			
Acquisition of comm	ercially available	replication defecti	ve adeno-associate	ed virus (AAV)
particles and adminis	tration of adeno-a	ssociated virus par	rticles in vivo.	
Requested Additions	s/Changes:			
 Probiotic (RG 	(1) bacteria mixtu	re for administration	on <i>in vivo</i>	
Function/Nature of R	ecombinant Gene	s to be Expressed:		
⊠ N/A □ Oncogene	☐ Tumor Suppr	essor Gene 🗆 St	ructural	ng 🗆
Antimicrobial	nmunomodulatory	□ Toxin □ Antib	oiotic Resistance	Reporters \square
Other	•			•
Species of Recombin	ant Genes to be E	xpressed:		
\boxtimes N/A \square Human	☐ Murine ☐ Bact	erial 🗆 Viral 🗆 0	Other	
Committee Commen	nts:			
 Administrative 	ve edits			
Facilities, Procedure	es, and Safety Pr	actices Reviewed	(Y/N):	
⊠ Yes □ No				
PI/Supervisor Train	inσ (V/N):		Handler Trainin	g (Y/N):

⊠ Yes □ No			<u> </u>	⊠ Yes □ No							
Motion Approval:	. , ,.	For:	Against:	Abstain:	Recuse:	Not Present:					
Approved w/ Admin	istrative	11	0	0	0	0					
Revisions											
Basic Research	Protocol ID:		PI:	Biosafe	tv	NIH Cat.:					
Amendment #14	IBC 2101		Wu	Level		I-D-1-a, III-D-					
		BSL2, ABSL2 3-a, III-D-4a									
Project Titles:											
Modeling liver diseases using a human pluripotent stem cell derived-multicellular platform											
Associated Grant No	umbers:										
Non-NIH Funding											
Summary of Approv											
Generation of replica											
Hepatitis B Virus, He											
cells, co-infection of				wegian Rat I	Hepatitis V	irus and					
administration in vivo		d mater	ials								
Requested Additions	0										
	replication defic	ient ade	eno-associat	ed viral part	ticles and a	dministration					
in vivo											
Gene targets											
New rooms											
Example of D	acombinant Can	aa ta b a	Examples								
Function/Nature of R					Ni	□ Atii					
□ N/A □ Oncogene					-						
☐ Immunomodulatory	□ Ioxin □ Ai	111010116	Resistance	△ Reporters	s 🖂 Otner						
Species of Recombin	ant Genes to be F	Express	ed·								
-	☐ Murine ☐ Bac	-		Other							
	_ Munific _ Due	terrar i	⊐ vnar △ v	Julei							
Committee Commer	 nts:										
Administrativ											
Update room	list										
1	ted disinfection s	steps an	d locations								
_	vation method										
 Specify equip 											
specify equip	ment focation										
Facilities, Procedure	es, and Safety Pr	ractices	Reviewed	(Y/N):							
⊠ Yes □ No	·			,							
PI/Supervisor Train	ing (Y/N):			Handler T	raining (Y	//N):					
⊠ Yes □ No	3 ()			⊠ Yes	□ No	,					
Motion Approval:		T.		A1 4 *	D	NI 4 D					
Approved w/ Admin	istrative	For:	Against:	Abstain:	Recuse:	Not Present:					
Revisions		11	0	0	0	0					

	T	1								
Basic Research	Protocol ID:		PI:	Biosafe	-	NIH Cat.:				
Amendment #15	IBC 1622	1	Gong	Level		III-D-1-a, III-D-				
				BSL2, AB	SL2	3-a, III-D-4-b				
Project Titles:										
DNA repair pathway as targets for therapy-resistant ovarian cancer										
Associated Grant Numbers:										
R01 CA222195										
Summary of Approved Items: Generation of replication defective lentivirus particles, transduction of tissue culture cells, and										
administration of transduced cells <i>in vivo</i> ; human derived material.										
Requested Additions/Changes:										
	immunodeficien	t anima	ls engrafted	l with function	onal hur	man hiological				
	dministration of				onai mui	man biblogicai				
_	nammalian tissue									
New rooms	iaiiiiiaiiaii tissuc	Cultule	CCIIS							
	fectant and safet	v inform	nation							
opuated disin	ircciant and saict	y IIIIOII	iiatioii							
Function/Nature of R	ecombinant Gen	es to be	Expressed:							
N/A □ Oncogene			-		nalino	☐ Antimicrobial				
☐ Immunomodulatory				-	_					
minimumoniodalatory		monome	Resistance	ш керопе		Ci				
Species of Recombin	ant Genes to be I	Express	ed:							
\boxtimes N/A \square Human				Other						
Committee Commen	nts:									
 Administrativ 	e edits									
 Please confirm 	n cell lines BSL	with su	pplier, work	may potenti	ially be	used at a lower				
BSL/ABSL.		-		• 1	•					
 Clarify location 	on of inactivation	steps f	or BSL1 vs	. BSL2 items	S					
Facilities, Procedure	es, and Safety Pi	ractices	Reviewed	(Y/N):						
⊠ Yes □ No										
PI/Supervisor Train	ing (Y/N):			Handler T	raining	(Y/N):				
⊠ Yes □ No				⊠ Yes	□ No					
Motion Approval:		For:	A gainst.	Abstain:	Recus	e: Not Present:				
Approved w/ Admin	istrative	11	Against:	Abstain.	necus 0	e. Not i resent.				
Revisions		11	U	U	U	U				
Dagia Dagaguak	Duoto sal ID:	1	DI.	Diagar.	4	MIII Cata				
Basic Research Amendment #16	Protocol ID: IBC 2205		PI:	Biosafe Level:		NIH Cat.:				
Amenument #10	IBC 2203		Xie	BSL2, AB		III-D-1-a, III-D-				
Project Titles:				DSLZ, AB	SL2	3-a, III-D-4-b				
Organization, Dynam	nice and Machani	eme of	Extrachrom	ocomal DN/	\ in Uur	nan Cancer				
organization, Dynam	nes and Meenall	SIIIS UI .	LAHACIII OIII		7 III 11Ul					

Associated Grant Numbers:								
Non-NIH Funding								
Summary of Approved Items:								
Generation of replication defective lentiviral and adeno-associated viral (AAV) particles,								
transduction of tissue culture cells and administration in vivo; Transfection of tissue culture								
cells; Human-derived materials.								
Requested Additions/Changes:								
Mammalian expression plasmi	ds							
 Gene targets and genes for edit 	ing							
Administration route for AAV	_							
Function/Nature of Recombinant Gene	es to be	Expressed:						
□ N/A □ Oncogene ⊠ Tumor Suppre	essor Ge	ene 🗵 Struc	ctural 🛛 Si	ignaling [l Antimicrobial			
☐ Immunomodulatory ☐ Toxin ☐ Ar	tibiotic	Resistance	⊠ Reporters	s ⊠ Other				
·			-					
Species of Recombinant Genes to be E	Expresse	ed:						
□ N/A ⊠ Human □ Murine ⊠ Bac	terial [□ Viral 🖂 🤇	Other					
Committee Comments:								
N/A								
Facilities, Procedures, and Safety Pr	actices	Reviewed ((Y/N):					
⊠ Yes □ No								
PI/Supervisor Training (Y/N):			Handler T	raining (Y	/N):			
⊠ Yes □ No			⊠ Yes	□ No				
Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:			
Approved	11	0	0	0	0			

V. Other Business

None