Rutgers University Institutional Biosafety Committee (IBC) – North Campus Meeting for NIH Guidelines Materials Minutes of September 9, 2025

1. ATTENDEES

\boxtimes	Preeti Bharaj		Bhupinder Singh	\boxtimes	Aimee Beaulieu - Co- Chair
\boxtimes	Theresa (LiYun) Chang		Shaun Shahani	\boxtimes	Ryan McAllister - REHS
\boxtimes	Nancy Connell		Lanbo Shi	\boxtimes	Brian Eggert - REHS
	Roberto Colangeli		Jason Weinstein	\boxtimes	Blas Peixoto - REHS
\boxtimes	Carla Cugini		Lai-Hua Xie	\boxtimes	Jacquelyn Vidal - REHS
	Dominic Del Re	\boxtimes	Amanda Hueting - Local Non-Affiliated	\boxtimes	Robert Adcock - REHS
\boxtimes	Jean-Pierre Etchegaray		Michael Ricker - Local Non-Affiliated	\boxtimes	Sophia Cheng - REHS
\boxtimes	Yosuke Kumamoto		Sonia Solano - Local Non-Affiliated	\boxtimes	Sivarchana Boada-REHS
\boxtimes	Deborah Lazzarino		Jeetendra Eswaraka - Ex Officio		
	Latisha Moody		Alejandro Ruiz - Ex Officio		
\boxtimes	Dane Parker		Bryan Bocco - Ex Officio		
\boxtimes	Lidya Sanchez				

2. MEETING LOGISTICS

CURRENT MEETING					
Called to Order: 10:01 AM	Adjourned: 10:59 AM	Location: WebEx			
PREVIOUS MEETING					
Previous Minutes for NIH Guidelines Materials from July 8, 2025 Approved (18:0:1) ¹					
NEXT MEETING					
Date: November 11, 2025Time: 10:00 AMLocation: WebEx					

CONFLICT OF INTEREST STATEMENT

Committee members with a conflict of interest related to the review of a specific registration may not be involved in the review or approval of a project in which they have been or expect to be engaged or have a direct financial interest.

3. PRE-AGENDA

TOPIC	SUMMARY		
	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-		
	<u>25-082.html</u>		
	 Communication received March 28, 2025 		
	 To maximally meet the transparency aims of the 		
	NIH Guidelines on June 1st 2025:		
	 The NIH OSP will publicly post the rosters of 		
IDC Mambar	all active IBCs registered with OSP via the		
IBC Member	IBC-Registration Management System		
Education:	 NIH expects that approved meeting minutes 		
NIH Implementation	from all IBC meetings occurring on, or after		
NIH Implementation	this date will be posted publicly on an		
Update: Promoting Maximal Transparency	institutional website.		
Under the NIH	 NIH's expectation that minutes will be 		
Guidelines for	posted immediately after approval and		
Research Involving	once all appropriate and allowable		
Recombinant or	redactions have been made		
Synthetic Nucleic Acid	 Minutes must remain publicly 		
Molecules	available for 5-years		
morodato	The June IBC minutes will be the first document posted		
	to the Rutgers IBC website after approval by the IBC.		
	July IBC minutes will be the first document posted from		
	the IBC-N (presuming approval at today's meeting)		
	REHS will be asking PI to provide a submission		
	summary that meets the NIH expectations and to assist		
	reviewers in providing their review summary		
	https://www.whitehouse.gov/presidential-		
	actions/2025/05/improving-the-safety-and-security-of-		
IBC Member	biological-research/		
Education:	Expected New/Revised Executive Orders		
	Framework for Nucleic Acid Synthesis Screening		
Presidential Executive	 Within 90 days of the date of this order 		
Order: Improving the	(8/3/25), the Director of OSTP, in		
Safety and Security of	coordination with the APNSA and the heads		
Biological Research	of relevant agencies, shall revise or replace		
	the previous EO		
	Dual Use Research of Concern Policy		

	 #4a) Within 120 days of the date of this order (9/2/25), the Director of OSTP, pursuant to 42 U.S.C. 6627 and in coordination with the APNSA and the heads of relevant agencies, shall revise or replace the previous EO Within 180 days of the date of this order (11/1/25), the Director of OSTP, in coordination with the Director of the Office of Management and Budget, the APNSA, the Assistant to the President for Domestic Policy, and the heads of the other relevant agencies, shall develop and implement a strategy to govern, limit, and track dangerous gain-of-function research across the United States that occurs without Federal funding and other life-science research that could cause significant societal consequences Framework for Nucleic Acid Synthesis Screening No updates provided as of 9/8/2025 Updates will be provided at a future IBC meeting once the new Executive Order becomes available Dual Use Research of Concern No updates provided as of 9/8/2025 Updates will be provided at a future IBC meeting once the new Executive Order becomes available
New Business: REHS Staff Update	 Ryan McAllister is leaving Rutgers. Sivarchana Boada has joined REHS as a senior biosafety officer.
	allocatory childer.
New Business: IBC Membership Updates	 Departures: Ryan McAllister Aimee Beaulieu Bhupinder Singh Additions: Sivarchana Boada Roseann Kehoe
New Business: July 2025 Newsletter	 Anticipated release dates (quarterly) January April July October

	 Sent out via RAIN List and BPMS-registered PIs and Administrators
	IBC members mistakenly left off the list, this has been
	corrected for future distributions
	October 2025 Newsletter Will Include
	 NIH Implementation Update: Promoting Maximal
	Transparency Under the NIH Guidelines for
	Research Involving Recombinant or Synthetic
	Nucleic Acid Molecules
	 IBC Submission Summaries from PIs
	Updated IRE (aka DURCom) responsibilities from the
	IBC Handbook
	 DURC reviews will happen by the PI & Biosafety
	Office through the Grant Submission and IBC
	Pre-Review
	 IBC will only review DURC-identified projects once Risk-Benefit Analysis and Risk Mitigation
	Plan are reviewed and approved by the funding
	agency
	 The IBC can require enhancements beyond the
New Business:	Risk Mitigation Plan
	 The IBC will not be involved in the Risk
IBC Handbook	Mitigation Plan, research findings,
Updates	communications aspects
	Details related to Roles and Responsibilities are
	developed
	 Approved by the Rutgers Office for Research on
	8/13/25
	Agreed to by the DURCom on 8/20/25
	Expect the distribution of these changes and others in the IBC handhard to be distributed in the Continue of
	the IBC handbook to be distributed in the Spring of
	2026 IBC Charge (ake Charter) is being developed based on
	 IBC Charge (aka Charter) is being developed based on IBC handbook language
Old Business:	• None

PROTOCOL REVIEWS

The following protocols were reviewed according to the risk assessment guidelines published in the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*. The risk assessment is documented in the REHS Biosafety Protocol Management System and includes a review of the engineering controls, work practices, safety training, and medical surveillance of project personnel. Individual protocols are evaluated on the following matters as appropriate: the proposed biosafety level

and safety practices, agent characteristics, source and nature of agents, host animals/cells to be used, and the type of manipulations planned.

Note: Protocols were not necessarily reviewed in the order they appear below.

1. ADMINISTRATIVE APPROVALS					
PROTOCOL	PI	MATERIAL(S) OF INTEREST	BSL		
20-084	Hu, William	Amendment to update locations and answer new Materials Used question	2		
23-042	Zhang, Xuesong	Amendment to add another IRB study	2		
21-016	Bergey, Christina	Renewal with minor changes	2		
23-017	Miller, Shoreh	Amendment to add human tumor cell lines	2		
23-035	Wong, Lok Yin Roy	Amendment – Updates of experimental outcomes (to address clerical error). Details are uploaded in the File Cabinet section	3		
15-089	Guo, Yanxiang	Amendment to answer new synthetic nucleic acid questions	2		
23-035	Wong, Lok Yin Roy	Renewal without changes	3		
12-190	Verzi, Michael	Renewal without changes	2		
12-242	Carman, George	Renewal with completion of new Addendum K	1		

2. ADMINISTRATIVE TERMINATIONS				
PROTOCOL	PI	TITLE OF PROTOCOL	EXPIRY DATE	
None				

3. BIOSAFETY OFFICER REPORT (BSO) Approved (18:0:0) ¹					
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL / GUIDELINES		
		Title: Roles of several p53 regulated genes in tumorigenecity in nude mice			
13-097	Feng, Zhaohui	Materials: Lentiviral vector, CRISPR/Cas9, Cell lines, Mice	2 / III-D-1, III-D- 4		
		Submission Summary: The primary objective of this project is to investigate the role of TRIM6 in colorectal tumorigenesis. The original protocol (10/11/18 amendment) was approved for TRIM6			

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		knockout using lentiCRISPR vectors in various cell lines. This amendment requests approval to use an alternative lentiviral vector for conditional TRIM6 knockout, employing a doxycycline-inducible Cas9 (iCas9) system (TRIM6 iKO). Specifically, the Lenti-iCas9-neo plasmid (#85400, Addgene) will be used to enable temporal control of TRIM6 deletion. Tripartite motif-containing protein 6 facilitates growth and migration of breast cancer.	
		To assess whether established colorectal tumors require sustained TRIM6 expression for maintenance, subcutaneous xenograft tumors will be generated in 8-week-old BALB/c nude mice using control or TRIM6 iKO cells. Once tumors reach approximately 100 mm³, doxycycline (2 mg/mL in drinking water for 6 days) will be administered to induce TRIM6 knockout. Tumor growth will be monitored, and progression will be compared across experimental groups (with or without Dox) based on tumor size measurements.	
		The laboratory use Trans-Lentiviral Packaging System, which offers a superior safety profile compared to other commercially available lentiviral vector systems. The packaging components are separated onto five plasmids. Additionally, expression of gag-pro and tat-rev are under the control of the conditional tetracycline responsive promoter element (TRE), limiting expression of these viral components strictly to the packaging cell line. Occupational Health: In Place	
		Training: In Place BioAudit: Facilities are Acceptable	
		Title: Engineered T-cell Therapy for Human Cancers-Hinrichs Lab Materials: rDNA, Retroviral vector (MSGV-based), Human cells, Mice	
20-083	Hinrichs, Christian	Submission Summary: This amendment proposes studies to evaluate the impact of PD-L1 chimeric receptor—engineered murine T cells on tumor growth. Programmed cell death ligand 1 (PD-L1) is a protein found on the surface of cancer cells and immune cells. It plays a role in regulating the immune system. The laboratory is previously approved to	2 / III-D-1, III-D- 4

generate 2nd generation (TAT) replication-deficient lentiviral vectors in 293 T-cells

Primary murine T cells will be transduced with replication-incompetent MSGV-based gammaretroviral vectors produced in Plat-E packaging cells (latinum Retroviral Packaging Cell Lines are based on the 293T cell line. They exhibit longer stability and produce higher yields of retroviral structure) using plasmids encoding a PD-L1 chimeric receptor (and TCR as needed) with the pECO envelope protein (It interacts on the host cell surface with the ecotropic receptor protein, murine aminoacidtransporter-1(MCAT-1)which facilitates rat or mouse host cell infection). The viral vector will not be administered directly to animals. Instead, transduced T cells will be used for both in vitro and in vivo analyses. In vitro studies will assess T cell proliferation, receptor activation, and function by ELISA and flow cytometry following treatment with a PD-L1 dimerizing small molecule agonist. In vivo experiments will involve adoptive transfer of transduced T cells into syngeneic mice (via intravenous or intraperitoneal injection) to monitor their effects on tumor growth. At experimental endpoints, spleens will be harvested under BSL-2 containment, processed into single-cell suspensions, stained with fluorescent antibodies, and analyzed by flow cytometry. All tissues will be fixed with 4% paraformaldehyde prior to intracellular staining.

The replication-incompetent gammaretroviral vectors used in this work are restricted to in vitro T cell transduction, minimizing exposure risks. Transduced cells, not viral vectors, will be administered to mice. Standard ABSL-2 and BSL-2 precautions will be followed for vector handling, tissue culture, and animal procedures. No enhanced pathogenicity, oncogenes, or toxins are introduced beyond the chimeric receptor construct.

Occupational Health: In Place

Training: In Place

BioAudit: Facilities are Acceptable

4. AD HOC MEETING APPROVALS					
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL/ GUIDELINES		

5. NEW PROTOCOLS					
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL/ GUIDELINES		
		Title: human pluripotent stem cells for cancer immunotherapy Materials: rDNA, Lentiviral Vectors, CRISPR, Escherichia coli, Human cells			
		Submission Summary: This new protocol describes the generation of human induced pluripotent stem cell (iPSC)-derived lymphocytes and their functional testing against tumor cell lines. The lab studies the differentiation of immune cells from human iPSCs. They use 3rd generation lentiviral vectors to deliver CRISPR-based gene knockdown components and chimeric antigen receptors. The main target of gene knockdown includes epigenetic regulators such as G9a and GLP. They also culture human cancer cell line as the target of the CAR receptors. No animal experiment will be performed.			
25-025	Jing, Ran	Agents and Materials: The work involves human iPSC lines differentiated into lymphocytes, along with replication-incompetent, third-generation lentiviral vectors used to introduce synthetic receptor constructs. Tumor cell lines, maintained at BSL-2, are used as targets for in vitro assays.	2 / III-D-1, III-D- 2		
		Modifications and Characteristics: The lentiviral vectors are engineered with deletions to prevent replication and contain only synthetic receptor sequences, with no oncogenes, toxins, or elements known to enhance virulence or environmental stability.			
		Experimental Manipulations: Planned experiments include iPSC differentiation, lentiviral transduction, and in vitro assays where stem cell-derived lymphocytes are tested for activity against tumor cells. Analyses will include cell phenotype, cytotoxicity, and cytokine production.			
		Risks and Mitigation: Risks are limited to BSL-2 work with human cells and lentiviral vectors. Mitigation measures include conducting all viral manipulations in biosafety cabinets, regular testing for replication-			

25-022	Wong, Lok Yin Roy	Title: Select agent SARS-CoV Materials: rDNA, SARS-CoV, Escherichia coli, Mice Submission Summary: This is a new protocol for SARS-CoV (IBC 25-022). The main goal of this project is to study SARS-CoV pathogenesis and develop therapeutic interventions for SARS-CoV infection. Risks associated with the work is minimal as all the work performed will strictly adhere to the measures described in this protocol and standard A/BSL3 practices for select agents. SARS-CoV will be used to infect mice, cell lines or primary human cells. SARS-CoV replicates efficiently in mice and cell lines, less so in primary human cells. SARS-CoV is pathogenic to human and mice. Endpoints include conclusion of tissue culture experiments, typically would not exceed 120 hours. End points for anima experiments include humane endpoints that reflect severe disease after infection as detailed in the IACUC protocol or designated time points, typically include 2, 4 and 6 days post infection. Long-term experiments that involve housing infected animal for more than 3 months are possible but not frequent. All infected animals will be euthanized when endpoint is reached. All infected samples (tissue culture and animals) will be stored at certified A/BSL3 facilities for select agent work. Infected samples will be inactivated and destroyed immediately when analysis or data collection is completed. Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable IBC Vote: Approved (18:0:0)¹	3 / III-D-1, III-D- 2, III-D-3, III-D- 4
		disinfection protocols. No animal work is included. Endpoints: The main endpoints are evaluation of lymphocyte phenotype, tumor cell killing activity, and molecular markers of immune function. Occupational Health: In Place Training: In Place BioAudit: Required before commencing work (Provision of approval) IBC Vote: Approved (18:0:0)¹	
		competent lentivirus, and use of validated	

6. AMENDMENTS			
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL/ GUIDELINES
19-053	Schuster, Benjamin	Title: Schuster Lab Recombinant DNA and Protein Biosafety Protocol Materials: rDNA, Escherichia coli, Saccharomyces cerevisiae, C. elegans Submission Summary: This is a renewal with changes of IBC Protocol #19-053. The protocol is for recombinant DNA research focused on studying the biophysics and bioengineering of biomolecular condensates and proteins that exhibit liquid-liquid phase separation. Research is at the level of BSL-1 and BSL-2. Hosts include non-pathogenic E. colistrains, yeast strains, C. Elegans, and standard human cell lines. Nucleic acid sequences code for phase-separating proteins as well as enzymes from various species, including C. elegans and humans, where mutations are introduced to study the biophysics of these proteins, and also to improve their enzymatic activity for translation to industrial applications. Experimental manipulations include microbial and tissue culture, centrifugation (with aerosol containment), and standard analytical assays. Specific changes being made in this submission include adding C. elegans work, as well as adding new gene targets (e.g., P granule protein PGL-3, mitochondrial transcription factor TFAM, and ligand-activated transcription factor androgen receptor). The new gene targets, like our previously approved ones, are intrinsically disordered proteins that undergo liquid-liquid phase separation. Other new gene targets are enzymes (e.g., microbial transaminases) that we will use to generate enzymatically active fusion proteins for incorporation into biomolecular condensates, which is also an extension of previously approved work. Occupational Health: In place Training: In Place BioAudit: Facilities are Acceptable IBC Vote: Approved (18:0:0)¹	2 / III-D-4, III-E

Materials: rDNA, AAV, Mice Submission Summary: The Daniels Lab studies how viral infections impact inflammation in the central nervous system. Our research uses established models of viral encephalitis caused by Zika virus, Langat virus, and West Nile virus, together with genetic models of disease in mice and primary neural and glial cell cultures. This amendment expands our toolkit to include adeno-associated virus (AAV) vectors, which will be used for targeted expression of fluorescent proteins or other transgenes to allow higher-resolution analyses of brain function and host-pathogen interactions. The principal risks associated with this work relate to accidental laboratory-acquired infection through blood or mucous membrane exposure to infected fluids or tissues. While the viruses used in these studies are not typically transmitted by aerosols, inadvertent aerosol exposure is a theoretical possibility. All personnel will use standard personal protective equipment and perform all experimental manipulations in certified biosafety cabinets. All waste materials and animal tissues will be sterilized or chemically disinfected prior to disposal. The hazards and safety requirements for these agents are well described in the literature and by Rutgers REHS, and our proposed practices are consistent with or more stringent than those employed at peer institutions. Importantly, these viruses pose limited risk to healthy adult humans when appropriate biosafety practices are followed. The viral agents used are unmodified circulating strains; no changes are made to virulence, host range, or antiviral susceptibility. AAV vectors will only encode fluorophores or other proteins of interest and will not contain oncogenes, toxins, or other sequences that would increase pathogenicity. Experimental manipulations include infection of primary cells and animal models. Endpoints include standard assays such as plaque assay, immunofluorescence microscopy, and qPCR. These approaches together will advance our understandling of neuroi			Title: USDA Daniels Lab Biosafety Protocol	
how viral infections impact inflammation in the central nervous system. Our research uses established models of viral encephalitis caused by Zika virus, Langat virus, and West Nile virus, together with genetic models of disease in mice and primary neural and glial cell cultures. This amendment expands our toolkit to include adeno-associated virus (AAV) vectors, which will be used for targeted expression of fluorescent proteins or other transgenes to allow higher-resolution analyses of brain function and host–pathogen interactions. The principal risks associated with this work relate to accidental laboratory-acquired infection through blood or mucous membrane exposure to infected fluids or tissues. While the viruses used in these studies are not typically transmitted by aerosols, inadvertent aerosol exposure is a theoretical possibility. All personnel will use standard personal protective equipment and perform all experimental manipulations in certified biosafety cabinets. All waste materials and animal tissues will be sterilized or chemically disinfected prior to disposal. The hazards and safety requirements for these agents are well described in the literature and by Rutgers REHS, and our proposed practices are consistent with or more stringent than those employed at peer institutions. Importantly, these viruses pose limited risk to healthy adult humans when appropriate biosafety practices are followed. The viral agents used are unmodified circulating strains; no changes are made to virulence, host range, or antiviral susceptibility. AAV vectors will only encode fluorophores or other proteins of interest and will not contain oncogenes, toxins, or other sequences that would increase pathogenicity. Experimental manipulations include infection of primary cells and animal models. Endpoints include standard assays such as plaque assay, immunofluorescence microscopy, and qPCR. These approaches together will advance our understanding			·	
of fledfollillidite fledfallishs while flathtailing the	18-076	Daniels, Brian	Submission Summary: The Daniels Lab studies how viral infections impact inflammation in the central nervous system. Our research uses established models of viral encephalitis caused by Zika virus, Langat virus, and West Nile virus, together with genetic models of disease in mice and primary neural and glial cell cultures. This amendment expands our toolkit to include adeno-associated virus (AAV) vectors, which will be used for targeted expression of fluorescent proteins or other transgenes to allow higher-resolution analyses of brain function and host–pathogen interactions. The principal risks associated with this work relate to accidental laboratory-acquired infection through blood or mucous membrane exposure to infected fluids or tissues. While the viruses used in these studies are not typically transmitted by aerosols, inadvertent aerosol exposure is a theoretical possibility. All personnel will use standard personal protective equipment and perform all experimental manipulations in certified biosafety cabinets. All waste materials and animal tissues will be sterilized or chemically disinfected prior to disposal. The hazards and safety requirements for these agents are well described in the literature and by Rutgers REHS, and our proposed practices are consistent with or more stringent than those employed at peer institutions. Importantly, these viruses pose limited risk to healthy adult humans when appropriate biosafety practices are followed. The viral agents used are unmodified circulating strains; no changes are made to virulence, host range, or antiviral susceptibility. AAV vectors will only encode fluorophores or other proteins of interest and will not contain oncogenes, toxins, or other sequences that would increase pathogenicity. Experimental manipulations include infection of primary cells and animal models. Endpoints include standard assays such as plaque assay, immunofluorescence microscopy, and qPCR. These approaches together will advance our understanding	_ `

23-005 Cuesta, Santiago	Occupational Health: In Place Training: Required before commencing work (Provision of approval) BioAudit: Facilities are Acceptable IBC Vote: Approved (18:0:0)¹ Title: Gut microbiome modulation of brain responses Materials: rDNA, Bacteroides fragilis, Lactobacillus gasseri Submission Summary: This amendment pertains to a protocol involving animal work designed to investigate gut microbiome—brain interactions. The original protocol was approved under the IBC registration # 23-005, and this amendment introduces additional microbial strains for further mechanistic studies. Both added strains (the non- enterotoxigenic Bacteroides fragilis and Lactobacillus gasseri) are generally considered low- risk under BSL-2 conditions and do not exceed standard BSL-2 requirements. B. fragilis: Non- enterotoxigenic anaerobic, opportunistic pathogen, antibiotic-sensitive, moderate environmental stability. L. gasseri: Probiotic, non-pathogenic, antibiotic-sensitive, low environmental persistence Microbial strains have or will be modified to include deletions in metabolic pathway genes not associated with virulence or pathogenicity. Animal work includes oral gavage of modified strains, behavioral testing, and tissue collection for transcriptomic and metabolomic analysis. Primary endpoints include changes in behavior, neuroinflammation markers, and microbial colonization patterns. Endpoint methods include qPCR, immunohistochemistry, metabolomic protein expression and 16S rRNA sequencing. Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable IBC Vote: Approved (18:0:0)¹	2 / III-D-1, III-D- 2, III-D-4
20 020	Title: Bacterial sphingolipids	2 / III-D-1, III-D-
20-020 Klein, Eric	Materials: rDNA, Uropathogenic E. coli, Mice	4

		Submission Summary: The main goal of this project is to investigate the regulation of sphingolipid synthesis in E. coli and the role of these lipids in gut colonization. The protocol was previously approved for gene knockout and reporter studies in E. coli to identify regulatory pathways controlling the expression of sphingolipid genes. This amendment adds mouse infection models to test whether sphingolipids help promote uropathogenic E. coli (UPEC) gut colonization. Specifically, they are requesting approval to inoculate mice with wild-type and spt knock-out strains. These bacteria are Biosafety Level-2 organisms that were previously approved. Mice will be treated with antibiotics to remove the endogenous microbiome prior to inoculation with UPEC. Feces will be collected over two weeks and bacterial levels will be measured by colony forming units on agar plates. They will also assess gut inflammatory markers by immunohistochemistry, qRT-PCR, and/or ELISA. Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable IBC Vote: Conditionally Approved (18:0:0)¹ 1. The location for bacteria plating and fecal pellet homogenization will be changed from a chemical fume hood to a certified biosafety cabinet.	
19-027	Boison, Detlev	Title: Therapies for epilepsy prevention Material: rDNA, AAV, Mice The long-term objective of the project is to determine the convergent mechanisms by which seizures and alcohol poisoning affect breathing to enable the rational development of novel treatment strategies. The overarching hypothesis is that adenosinergic inhibition of serotonergic and/or noradrenergic neurons contributes to the effect of seizures and alcohol poisoning on breathing. The approach utilizes virally transducable G-protein-coupled receptor-activation-based (GRAB) sensors, a cutting-edge fiber photometry technique in rodent models along with more conventional virally transducable intracellular calcium sensors. All vial injections will be intracranial in mice and <1 ul. All the viruses that will be used are commercially available, Biosafety Level 1, without helper virus, replication incompetent, and non-pathogenic (AAV9-hsyn-NES-	1 / III-D-1, III-D- 4

		jRGECO1a, AAV9-hsyn-Ado1.1m, AAV9-TN-Ado1.1m, AAV9-hsyn-r5HT1.0, and AAV9-hsyn-mRuby3-NE2h). All of these viruses induce the expression of florescent sensors and ostensibly have no effect on cell health. The virus, the animals, and their bedding will be handled in accordance with Rutgers Environmental Health and Safety Standard Operating Practices (https://ipo.rutgers.edu/rehs/biosafety-program/sops/adeno). Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable IBC Vote: Approved (18:0:0)¹	
22-041	Brooke Herrera, Bobby	Materials: Pegivirus, E. coli, human cells, Lentiviral vectors Submission Summary: This amendment adds human pegivirus (HPgV-1; formerly GBV-C/HGV) to an existing protocol that investigates adaptive immune mechanisms across multiple human viruses. HPgV-1 is a positive-sense, single-stranded RNA virus in the family Flaviviridae (genus Pegivirus); it is widely prevalent, lymphotropic, and not causally linked to human disease. Work will evaluate antibody and T-cell responses to pegivirus antigens using in vitro infection assays (BSL-2 enhanced practices), recombinant protein expression, and ex vivo immunology. Where needed to support mechanistic readouts, the laboratory will generate non-replicating recombinant cell lines expressing select pegivirus proteins (e.g., E2 glycoprotein and nonstructural proteins such as NS3/NS5A) in HEK293/CHO/E. coli expression systems or via third-generation, self-inactivating lentiviral vectors; no infectious pegivirus clones will be constructed or rescued. Experiment endpoints include quantification of viral RNA by qRT-PCR in cell culture supernatants/lysates, serologic assays (ELISA, neutralization/surrogate neutralization), and T-cell readouts (ELISpot/flow cytometry). For any animal studies referenced in the parent protocol, pegivirus-related work will be limited to exposure to inactivated materials or recombinant proteins to profile immune responses; animals will be monitored per IACUC-approved criteria with standard clinical and humane endpoints.	2 / III-D-1, III-D- 2, III-D-4

Risk assessment: HPgV-1 is handled at BSL-2; the laboratory will employ BSL-2 enhanced controls that exceed the standard for the assigned level, including exclusive BSC use for all manipulations, restrictedaccess space, no sharps/glass, sealed rotors/locking gaskets for centrifugation, double-containment for transport, and chemical decontamination (fresh 10% bleach followed by 70% ethanol; ?20-minute contact for disposables). Lentiviral work follows Rutgers SOPs (third-gen SIN vectors, VSV-G envelope, minimal volumes, and RCL mitigation/testing per SOP). No live virus will be isolated or propagated from acute clinical samples. These measures align with NIH's public-minutes transparency requirements for IBC oversight while maintaining biosafety and privacy safeguards.

Occupational Health: In Place

Training: In Place

BioAudit: Facilities are Acceptable

IBC Vote: Approved (17:0:0)^{1,3}

¹ Voting Decision (Yay: Nay: Abstain)

² Member(s) joined the meeting

³ Member(s) left the meeting