# Rutgers University Institutional Biosafety Committee (IBC) – Central Campus Meeting for NIH Guidelines Materials Minutes of October 1, 2025

# 1. ATTENDEES

$\boxtimes$	Carol Bagnell	□ в	Bhupinder Singh		Blas Peixoto - REHS
	Nada Boustany	⊠ N	/lilind Shah	$\boxtimes$	Robert Adcock - REHS
	Jeffrey Boyd		Matthew Ferguson Local Non-Affiliated		Jacquelyn Vidal - REHS
$\boxtimes$	Qian Cai		Ellen Welch Local Non-Affiliated		Sophia Cheng - REHS
$\boxtimes$	Julie Caruth		homas Boyle Local Non-Affiliated		Sivarchana Boada - REHS
	Richard Ebright		ames Clancy Local Non-Affiliated		Latisha Moody
$\boxtimes$	Zhaohui Feng		eetendra Eswaraka <sup>Ex Officio</sup>		
$\boxtimes$	John Hershey		Nejandro Ruiz Ex Officio		
	Peng Jiang		Bryan Bocco Ex Officio		
$\boxtimes$	Eric Klein	⊠ R	Ron Hart – co-Chair		
$\boxtimes$	John McLaughlin	⊠ R	Ryan McAllister - REHS		
$\boxtimes$	Donald Schaffner	⊠в	Brian Eggert - REHS		

# 2. MEETING LOGISTICS

CURRENT MEETING					
Called to Order: 12:04 PM	<b>Adjourned:</b> 12:39 PM	<b>Location:</b> WebEx			
PREVIOUS MEETING	PREVIOUS MEETING				
Minutes from August 6, 2025 Approved (15:0:0)¹					
NEXT MEETING					
Date: December 3, 2025	Time: 12:00 PM	Location: 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 he or she has been or expects to be engaged or has a direct financial interest.

# 3. PRE-AGENDA

TOPIC	SUMMARY
Old Business: Newsletter Update	<ul> <li>July 2025 Newsletter</li> <li>Anticipated release dates (quarterly)         <ul> <li>January</li> <li>April</li> <li>July</li> <li>October</li> </ul> </li> <li>Sent out via RAIN List &amp; BPMS registered PIs and Administrators</li> <li>IBC members mistakenly left off the list; this has been corrected for future distributions</li> </ul>
New Business:  New NIH Initiative -  Modernizing and  Strengthening  Oversight of Biosafety	<ul> <li>On 9/9/25, the NIH launched a new initiative for comprehensive changes to modernize and strengthen biosafety policies, practices, and oversight. The effort aims to revamp biosafety oversight to address biosafety risks in a climate of rapidly advancing science and technology. A secondary aim is to empower Institutional Biosafety Committees (IBCs) and reinforce their positions as a front line for biosafety oversight and ensure that IBCs receive comparable support to committees for human subjects and research animals.</li> <li>Main website: <a href="https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/">https://osp.od.nih.gov/policies/biosafety-modernize-and-strengthen-the-oversight-of-biosafety/</a></li> </ul>
New Business: CDC Inspection	<ul> <li>The CDC inspected our select agent program and the Regional Biocontainment Laboratory on September 23 and 24.</li> <li>A few minor departures and observations were noted.</li> <li>REHS is working with the researchers and BSL3 operations group to address the findings.</li> </ul>

New Business:	Ryan McAllister is leaving Rutgers.
REHS Staff Update	Sivarchana Boada has joined REHS as a senior biosafety officer.
New Business: IBC Membership Updates	<ul> <li>Departures:         <ul> <li>Ryan McAllister</li> <li>Aimee Beaulieu</li> <li>Bhupinder Singh</li> </ul> </li> <li>Additions:         <ul> <li>Sivarchana Boada</li> <li>Roseann Kehoe</li> </ul> </li> </ul>
IBC Member Education: Presidential Executive Order: Improving the Safety and Security of Biological Research	<ul> <li>Framework for Nucleic Acid Synthesis Screening         <ul> <li>Within 90 days of the date of this order (8/3/25), the Director of OSTP, in coordination with the APNSA and the heads of relevant agencies, shall revise or replace the previous EO</li> </ul> </li> <li>Dual Use Research of Concern Policy         <ul> <li>#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</li> <li>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 lifescience research that could cause significant societal consequences</li> <li>Framework for Nucleic Acid Synthesis Screening</li> <li>No updates provided as of 10/1/2025</li> <li>Updates will be provided at a future IBC meeting once the new Executive Order becomes available Dual Use Research of Concern</li> <li>No updates provided as of 10/1/2025</li> </ul></li></ul>

 Updates will be provided at a future IBC meeting once the new Executive Order becomes available <a href="https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/">https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/</a>

### **PROTOCOL REVIEWS**

The following protocols were reviewed according to the risk assessment guidelines published in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and 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 or recombinant/synthetic nucleic acid sequences and resulting effects of expressed proteins, host animals/ cells, and cloning vectors to be used, and the type of manipulations planned.

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

1. ADMIN	1. ADMINISTRATIVE APPROVALS				
PROTOCOL	PI	MATERIAL(S) OF INTEREST	BSL		
20-087	Buettner, Christoph	Amendment – addition of personnel	2		
13-455	Roth, Monica	Amendment – updates of experimental outcomes (to address clerical error). Details are uploaded in the File Cabinet section. Also completed new Addendum K.	2		
13-494	Freundlich, Joel	Amendment – removing selection markers to amend experimental outcomes. Details are uploaded in the File Cabinet section.	3		
19-072	Freundlich, Joel	Amendment – removing selection markers to amend experimental outcomes. Details are uploaded in the File Cabinet section.	2		
19-061	Alland, David	Renewal with minor changes	2e		
19-043	Cao, Jian	Renewal with minor changes	2		
19-064	Chiou, Shin- Heng	Renewal with minor changes	2		
13-290	Fraidenraich, Diego	Renewal without changes	2		
13-586	Alder-Suss, Janet	Renewal without changes	2		
19-049	Izgu, Enver	Renewal with minor changes	2		
19-023	Izgu, Enver	Renewal with minor changes	2		
13-022	Matise, Michael	Renewal without changes	2		
13-340	Rivera-Medina, Amariliz	Renewal without changes	2e		

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

3. BIOSA	3. BIOSAFETY OFFICER REPORT (BSO) Approved (15:0:0) <sup>1</sup>			
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL / GUIDELINES	
19-034	Miller, Shoreh	Materials: rDNA, luciferase expressing mouse, tumor cell lines  Submission Summary: This amendment includes the addition of two luciferase-expressing mouse tumor cell lines obtained from ATCC: 4T1-luc2 (mammary tumor) and B16-F10-luc2 (melanoma). Both lines have been stably engineered to express the luciferase gene, permitting in vivo imaging by IVIS. The proposed in vivo procedures involve a single subcutaneous injection of tumor cells per mouse: B16-F10-luc2 cells will be administered by manual restraint into the dorsal skin, while 4T1-luc2 cells will be administered under light anesthesia near the fourth nipple. Animals will undergo IVIS imaging at defined intervals to assess tumor growth, and three weeks post-injection will be euthanized for collection of blood and bone marrow cells. All work will be conducted under BSL-2 conditions with standard precautions. Risk mitigation includes use of a biosafety cabinet for all manipulations, chemical disinfection of waste with 10% bleach, sharps disposal in designated containers, and housing of mice in negatively pressurized ventilated cages. Carcasses will be disposed of as regulated medical waste. These procedures are consistent with the previously approved scope of tumor cell line injections under this protocol and build upon established IVRS practices. The addition of luciferase-expressing 4T1 and B16-F10 models provides a non-replicative, non-oncogenic reporter modification for imaging purposes and does not increase risk beyond standard BSL-2 containment that the lab has previously been approved to work under.	2 / III-D-4	

23-058	Sahoo, Pabitra	Training: In Place BioAudit: Facilities are Acceptable  Title: Local Protein Synthesis  Materials: rDNA, primate cell line  Submission Summary: The main goal of this project is to investigate axonal protein synthesis in nerve regeneration, focusing on why peripheral nerves regenerate while the ones belonging to the central nervous system do not. The protocol was previously approved for the use of replication-incompetent AAV2/5 and lentiviral vectors to manipulate genes involved in mRNA transport and stress granule dynamics (e.g., G3BP1, G3BP2, casein kinase 2) in rodent primary neurons, human cell lines (HEK293, HeLa), and rodent models. This amendment adds the use of Cos7 cells for in vitro studies. Cos7 cells are widely used fibroblast-like cell lines derived from African green monkey kidney cells. We obtained these cells from our collaborator at the University of South Carolina. Recombinant DNA Technology will be used to overexpress our gene of interest in cell lines and primary neurons isolated from rats or mice. All work with recombinant DNA will be performed in a BSC with appropriate PPE (labcoat, gloves, eye protection).  Nucleofections or lipid-based reagents (Lipofectamine 2000) will be used to transfect the cells with recombinant DNA. Monolayer cultures will be fixed with paraformaldehyde (PFA) for 20 minutes then removed form the BSC for immunostaining and futher analysis via confocal microscopy and cellomics.	2 / III-E, III-F-8
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4. AD HC	4. AD HOC MEETING APPROVALS				
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL		
None					

5. NEW F	5. NEW PROTOCOLS					
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL / GUIDELINES			
None						

6. AMEN	DMENTS		
PROTOCOL	PI	TITLE & MATERIAL(S) OF INTEREST	BSL / GUIDELINES
13-546	Tao, Yuanxiang	Materials: rDNA, AAV vectors, mice  Submission Summary: The goal of this project is to examine epigenetic mechanisms underlying neuropathic pain. Previously approved epigenetics-related genes have been associated with nerve trauma-induced neuropathic pain. One amendment adds a diabetes-specific circular RNA in diabetic neuropathic pain. We propose that this circular RNA is controlled by HNRNPL and PUM2 and regulates the expression of the downstream CCL2 in neurons of dorsal root ganglion under the conditions of type 1 and type II diabetics mellitus. We will use AAV5 to overexpress CCL2, HNRNPL and PUM2 in mouse dorsal root ganglion (DRG) through DRG microinjection of AAV5-CCI2, AAV5-Hnrnpl and AAV5-PUM2, respectively. Another amendment adds a human NIS-IncRNA ASO in human NIS-IncRNA-overexpressed mice. We propose that this ASO attenuates DRG human NIS-IncRNA overexpression-induced nociceptive hypersensitivity. We will overexpress human NIS-IncRNA in the DRG through microinjection of AAV5-hNIS into the unilateral L3/4 DRGs. AAV5-GFP will be used as a control. 7 or 8 weeks after DRG microinjection, the mice will be euthanized and microinjected DRGs be collected for real-time RT-PCR assay of the targeted genes. The rest of the body will be treated with 10% bleach before disposal.	1 / III-D-1, III-D-4

		Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable  IBC Vote: Approved (15:0:0)¹	
25-001	Lear, Travis	Title: Study of Nutrient Sensing and Lysosomal Activity in Aging and Neurodegeneration  Materials: Bloodborne pathogens, CRISPR, primary human cells, iPSC, Sendai virus vector  Submission Summary: The main goal of this project to evaluate the mechanism and biologic effect of the regulation of the protein KPTN by the E3 ubiquitin ligase PDZRN3, particularly with concern to effects on lysosomal activity, and on clearance of toxic protein aggregates. This protocol was previously approved for cloning, CRISPR Cas9 gene editing, cell culture expression, and tau aggregate treatment. This amendment expands the protocol to include inducible pluripotent stem cell (iPSC) experiments. Specifically, this includes details on iPSC culturing, re-programming, gene editing, differentiation, and experimental testing to measure the effect of the PDZRN3-KPTN axis on more biologically relevant cell models for neurodegeneration. Work with iPSC will utilize commercially available or Rutgers Alzheimer's Institute-derived patient samples for cell culture. Re-programming iPSC will be conducted using a commercially procured Sendai Virus vector system which encodes the Yamanaka factors (Oct3/4, Klf4, Sox2, c-Myc); while this method is virally-derived, the biohazard risk for its use is minimal to humans, with no documented lab-acquired infection. Further, we will utilize biosafety cabinets and BSL2 precautions for all Sendai Virus work. Additionally, this amendment updates the gene knockout (KO) strategy to include lentiviral-based CRIPSR Cas9 experiments, including biosafety steps and potential hazards. These experiments will include the cloning of sgRNA targeting sequences to a lentiviral transfer vector, and subsequent viral prep and transduction to cell lines such as SH-SY5Y. Cloning materials will be procured from commercial vendors such as IDT. Third generation lentiviral system will be used, which significantly reduces the risk of generating replication competent virus. We will also conduct all	2 / III-D-1, III-D-2

		IBC Vote: Approved (15:0:0) <sup>1</sup>	
14-118	Neiditch, Matthew	Materials: rDNA, Escherichia coli, Bacillus subtilis, Geobacillus stearothermophilus  Submission Summary: The overall goal of this project is to define, at atomic detail, the molecular mechanisms regulating bacterial cell-cell communication, genetic competence and transformation, cytidine deaminase function, and the mechanism of action of TB drugs. This protocol and its amendments describe workflows to overexpress proteins in E. coli or M. smegmatis, lyse the cells to obtain the proteins, and purify them for downstream structural biology and biochemical analyses. We are adding three orthologs of metallobeta-lactamase domain-containing proteins, Bacillus species competence proteins (two orthologs each of ComFA and ComFC or ComEC), and an iron-dependent repressor protein, as detailed in the protocol. All of these proteins will be synthesized by Genewiz or an equivalent company and overexpressed in E. coli. Proteins purified from E. coli and M. smegmatis will be used for in vitro biochemical assays, such as ATPase, and for structural biology studies. While E. coli is our primary expression system, M. smegmatis is used mainly for the overexpression of KasA and MenG.  Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable	2 / III-D-1, III-D-2
		with BSL2 precautions to reduce biohazard risk.  Occupational Health: In Place Training: In Place BioAudit: Facilities are Acceptable  IBC Vote: Approved (15:0:0)¹	
		virus work and preparation in a biosafety cabinet	

Voting Decision (Yay: Nay: Abstain)
 Member(s) joined the meeting
 Member(s) left the meeting