Rutgers University
Institutional Biosafety Committee (IBC) – North Campus
Meeting for NIH Guidelines Materials
Minutes of January 13, 2026

1. ATTENDEES

☒ Preeti Bharaj	☐ Roseann Kehoe	☒ Sergei Kotenko – Co- Chair
☒ Theresa (LiYun) Chang	☒ Shaun Shahani	☒ Brian Eggert - REHS
☒ Nancy Connell	☐ Lanbo Shi	☒ Marija Borjan - REHS
☒ Roberto Colangeli	☐ Jason Weinstein	☒ Sivarchana Boada - REHS
☒ Carla Cugini	☒ Lai-Hua Xie	☒ Blas Peixoto - REHS
☐ Dominic Del Re	☒ Amanda Hueting – Local Non-Affiliated	☒ Robert Adcock - REHS
☒ Jean-Pierre Etchegaray	☐ Michael Ricker – Local Non-Affiliated	☒ Jacquelyn Vidal - REHS
☒ Yosuke Kumamoto	☐ Sonia Solano – Local Non-Affiliated	☒ Sophia Cheng - REHS
☒ Deborah Lazzarino	☐ Jeetendra Eswaraka – Ex Officio	☐
☒ Latisha Moody	☐ Alejandro Ruiz – Ex Officio	☐
☒ Dane Parker	☐ Bryan Bocco – Ex Officio	☐

2. MEETING LOGISTICS

CURRENT MEETING		
Called to Order: 10:01 AM	**Adjourned:** 11:00 AM	**Location:** WebEx
PREVIOUS MEETING		
Minutes from November 11, 2025		**Approved (16:0:0)**[1,2]
NEXT MEETING		
Date: March 10, 2026	**Time:** 10:00 AM	**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: **Meeting Schedule for 2026**	The IBC-North will continue meeting on the 2nd Tuesday of every other month from 10:00 am - 12:00 pm.
Old Business: **NIH Initiative: Modernizing and Strengthening Oversight of Biosafety**	NIH has renewed their efforts to complete Phase I of their initiative and listening sessions for regions two through six have either occurred or have already been scheduled. Next upcoming listening session will be for Region 3. While active commenting during the session is only open to those who reside in the region, individuals are encouraged to listen in and offer offline commentary. The final listening session is currently scheduled for the end of February 2026. Details for the NIH initiative can be found at this NIH website: https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/ Individual comments can be submitted at the following link: https://osp.od.nih.gov/help-modernize-and-strengthen-the-oversight-of-biosafety/ Organizations have also submitted comments, including the comments from COGR: https://www.cogr.edu/blog/cogr-submits-comments-reponse-nihs-strenthening-and-modernizing-biosafety-oversight
New Business: **IBC Membership Updates**	Welcome to the new IBC-North co-chair Dr. Sergei Kotenko! We look forward to your experience and leadership for this committee. Thank you to all who have agreed to serve on the IBC for another term. The Office of Academic Affairs will be sending official appointment letters soon.

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. ADMINISTRATIVE APPROVALS

PROTOCOL	PI	MATERIAL(S) OF INTEREST	BSL
14-023	Babu, Gopal	Renewal with minor changes	2
22-014	McClenaghan, Conor	Renewal without changes	2
22-031	Montagna, Cristina	Renewal with minor changes	2
16-077	Sampath, Harini	Renewal without changes	2
16-009	Fong, Dunne	Renewal without changes	2
12-286	Rongo, Christopher	Renewal with minor changes	1
20-001	Barber, Annika	Renewal with minor changes	2
13-350	Ramasubbu, Narayanan	Renewal without changes	2
15-005	Ploss, Alexander	Renewal without changes	3
19-057	Li, Shaohua	Renewal with minor changes – added use of commercially bought synthetic CREG1	2
19-082	Pierce, Robert	Renewal without changes	2
25-024	Zhang, Xiyuan	Amendment – Additional workers added	2
20-014	Pinter, Abraham	Renewal without changes	2
19-061	Alland, David	Amendment – Added a new instrument (spectrophotometer)	2e
21-040	Chan, John	Renewal without changes	3
12-336	Hatefi, Arash	Renewal with minor changes – updated	1
15-080	Anderson, Stephen	Renewal without changes	1
17-003	Gormley, Adam	Renewal without changes	2

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

3. BIOSAFETY OFFICER REPORT (BSO) Approved (16:0:0) [1]			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
18-028	Lin, Hao	**Title:** Evaluation of transdermal gene delivery and gene expression **Materials:** rDNA, E. coli **Submission Summary:** The main goal of this protocol is to investigate the efficacy of various DNA plasmids after delivery into either cells (in vitro) or animal models (in vivo). This amendment expands the testing of plasmids expressing luciferase and a human protein with therapeutic potential, including a few commonly used plasmid backbones (pALD, pUK21, pcDNA3) and promoters (CMV or tissue-specific promoters). Luciferase was previously approved as a gene target, and the secreted polypeptide is endogenous to the human body. Plasmids will be administered to rodents by intramuscular injection. For luciferase studies, the rodents will be observed by IVIS luminescence imaging at set days post injection. For polypeptide studies, the rodent blood will be analyzed at set days post injection. A proprietary chemical formulation consisting of inorganic ions and synthetic surfactants will be co-administered with the plasmids to evaluate transfection enhancement compared to plasmid DNA alone. Biosafety level 2 containment practices will be followed including use of personal protective equipment, decontaminating surfaces with 10% bleach or 70% ethanol, and autoclaving waste materials before disposal in medical waste boxes. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable	2 / III-E, III-D-4

4. AD HOC MEETING APPROVALS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL**
None			

5. NEW PROTOCOLS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
25-032	Kaur, Tejbeer	**Title:** Human iPSC-derived inner ear-like macrophages (IIEMs) as a platform for modeling hearing and hearing loss **Materials:** rDNA, Mice, Human cells **Submission Summary:** This project investigates the function and behavior of human-induced pluripotent stem cell (hiPSC)-derived primitive macrophage progenitors (PMPs) within the mouse inner ear. The study will assess survival, colonization, immune response, and therapeutic potential after transplantation into neonatal immunodeficient (Rag2-/- hCSF1 knock-in) mice. Follow-up studies include histology, auditory function testing, macrophage activity via cochlear explants and live imaging, cytokine response evaluation, and human macrophage depletion using CSF1R inhibitors. Work will be performed at BSL-2 with standard PPE, biosafety cabinet procedures, sharps disposal, and autoclaving animal waste. **Occupational Health:** In Place **Training:** Required before commencing work (Provision of approval) **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (16:0:0)[1]** Conditions for approval: 1. Clarify the method used to differentiate iPSCs into macrophages	2 / III-D-4, III-E-1
25-037	Neisch, Amanda	**Title:** Use of Drosophila to study axonal transport regulation **Materials:** rDNA, E. coli, Drosophila melanogaster	1 / III-D-4

		Submission Summary: This project aims to identify regulators of intracellular transport using Drosophila melanogaster as a model system to study the process. Drosophila genetic crosses will be conducted for expression of transgenes. These transgenic animals will be used for tissue dissections for live imaging, immunofluorescence, and protein lysates for Western blot analysis. Drosophila melanogaster cell lines, S2 and BG3, will be used for protein expression. Recombinant DNA (rDNA) constructs of fly genes or their human orthologue will be generated in E. coli strains DH5alpha or XL1-Blue. The following vectors: pUAST, pUASp, pBid, pOT2, pBSK+ will be used. Transgenes will be incorporated into the Drosophila for expression using the UAS-Gal4 system, expressed in Drosophila cells using the pActin-Gal4 vector, or expressed in the E. coli bacterial strain BL21. Synthetic ssDNA oligos will be used for CRISPR/Cas genome editing to add epitope tags or mutagenize domains or amino acids within endogenous Drosophila genes to probe the function of these domains/amino acids. placed throughout the lab to prevent escape. E. coli will be inactivated with 10% bleach. Drosophila and cultured cells will be collected as biohazard waste and autoclaved prior to disposal. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (16:0:0)[1]** Conditions for Approval: 1. Update the locations section to include the autoclave room and notation of which rooms are shared spaces. 2. Update the transportation section to include use of a secondary container	
25-035	Firestein, Morgan	**Title:** Extracellular Vesicles, Hormones & Neurodevelopment **Materials:** rDNA, Human cells, Human tissue **Submission Summary:** The Lab investigated child neurological development. Project # 1. Examines extracellular vesicles (EVs) in relation to maternal metabolic conditions. EVs will be isolated from	2 / III-F-8

		plasma and placental tissue via ultracentrifugation and characterized using NTA, flow cytometry, ELISA, and RNA sequencing. Placental tissue will be stabilized in RNAlater, frozen, and used for RNA extraction and RT-qPCR analysis. Project #2. Evaluates infant neurodevelopment and NICU exposure to endocrine disrupting chemicals (EDCs). Urine and buccal swabs will be collected from neonates and infants, stored at -80°C, and assayed using LC/MS for EDC metabolites, estradiol, and testosterone. Project #3. Investigates the effects of placenta-derived EVs directly on neural progenitor cells and microglia cells iPSCs (previously derived) will generate trophoblast cells (iTCs), neural progenitor cells (iNPCs), and microglial cells (iMGLs). EVs from iTCs and fresh placental tissue will be co-cultured with iNPCs and iMGLs. RNA will be isolated for bulk and small RNA sequencing to assess transcriptional changes. BSL-2 work practices will be followed, including use of biological safety cabinets and PPE. Solid and liquid biological waste will be inactivated with 10% bleach and/or autoclaved before disposal. All equipment, surfaces, and spills will be disinfected with 10% bleach followed by 70% ethanol. **Occupational Health:** In Place **Training:** Required before commencing work (Provision of approval) **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (16:0:0)**[1] Conditions for Approval: 1. Clarify whether pathogen status of human specimens will be known 2. Outline specific safety procedures for sample processing & sharps	
25-041	Wang, Yuan	**Title:** Wang Lab Protocol **Materials:** rDNA, Retrovirus vector, Human cells **Submission Summary:** The main goal of this project is to characterize the functions of the C-terminus SAP domain of Ku70 in DNA repair pathways of established mammalian cell lines. We will generate different versions of exogenous Ku70, including wild-type and mutant constructs targeting the SAP domain. Procedures include E. coli-based	2 / III-D-1

		cloning, PCR, cell culture, viral vector transfection, protein extraction, immunoprecipitation, immunostaining, and DNA damage response assays (e.g., comet assays) and reporter systems. Established cell lines will be transduced with replication-deficient retroviral vectors expressing genes related to DNA damage and repair, cell cycle regulation, and apoptosis. When working with biological agents (plasmids, cell culture, viral vectors), lab personnel will follow standard BSL-2 containment procedures to prevent aerosolization or environmental release. This includes working within biological safety cabinets and wearing PPE (lab coats, gloves, eye protection. Biological waste materials, including cell culture supernatants, lysates, and contaminated consumables, will be treated by autoclaving or chemical disinfection before disposal. Spills and surfaces will be decontaminated with 10% bleach or another approved disinfectant. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Required before commencing work (Provision of approval) **IBC Vote: Approved (16:0:0)**[1]	

6. AMENDMENTS			
PROTOCOL	**PI**	**TITLE & MATERIAL(S) OF INTEREST**	**BSL / GUIDELINES**
15-003	Pinter, Abraham	**Title:** CDC – Cloning and expression of anti-LAM antibodies, TB genes, and assays of LAM present in various bodily fluids from TB patient **Materials:** rDNA, *Mycobacterium tuberculosis* auxotroph strains **Submission Summary:** The goal of this project is to define the structural differences between lipoarabinomannan (LAM) detected in the urine of patients with active tuberculosis (uLAM) and LAM purified from cultured Mycobacterium tuberculosis (bLAM). Our prior work demonstrated that uLAM and bLAM display distinct antigenic epitopes, enabling development of a more sensitive urine-based TB diagnostic assay than currently WHO-approved tests. However, further improvement in	2e / III-D-1

		diagnostic sensitivity requires a better understanding of the origin and structure of uLAM.To address this, THP-1 macrophages will be infected with auxotrophic M. tuberculosis strains under enhanced BSL-2 conditions to characterize LAM secreted from infected host cells and compare it with patient-derived uLAM. In parallel, the protective activity of candidate antibodies will be evaluated by measuring intracellular growth of Mtb auxotrophs in THP-1 cells in the presence or absence of plasma from BCG-vaccinated or Mtb-infected individuals and monoclonal antibodies targeting Mtb cell-wall antigens. All work with Mycobacterium tuberculosis auxotroph mutant strains will be conducted under BSL-2 Plus containment using appropriate PPE, including laboratory coats, gloves, and eye protection. All manipulations of liquid cultures are performed exclusively within a certified biosafety cabinet (BSC), with Vesphene used inside the BSC for immediate decontamination and inactivation of cultures, pipettes, and work surfaces. Microcentrifuge tubes, pipette tips, micropipette tips, and liquid cultures are chemically inactivated with Vesphene prior to disposal, and Vesphene-containing waste bottles are sealed and discarded in accordance with institutional biosafety and hazardous waste disposal procedures. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (16:0:0)[1]**	
20-003	Monahan, Kevin	**Title:** Molecular mechanisms controlling gene expression in the mouse olfactory system **Materials:** rDNA, *E. coli* **Submission Summary:** The main goal of this project is to investigate the development of the mouse olfactory system. This protocol was previously approved for gene knockout and transgenic mouse studies to determine how olfactory stem cells become many different types of specialized olfactory neurons. Our aim is to understand the mechanisms that allow these cells turn on the appropriate genes at the appropriate times. These experiments include	1 / III-E

		immunohistochemistry, qRT-PCR, and fluorescence activated cell sorting to collect cells for various genomics assays. Through this work we hope to gain insights into how neurons mature and differentiate that are applicable throughout the nervous system. This renewal seeks approval to continue these studies, which involve the use of transgenic mice and E.coli, which are use for preparing recombinant DNA vectors. We are also seeking approval of new experiments in which we will clone candidate gene regulatory sequences into a zebrafish reporter vector, which will then by collaborators to test these sequences for activity in the zebrafish olfactory system. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (16:0:0)[1]**	
23-005	Cuesta, Santiago	**Title:** Gut microbiome modulation of brain responses **Materials:** rDNA, *Clostridioides difficile* **Submission Summary:** The main goal of this protocol is to investigate gut microbiome-brain interactions (in vitro and in vivo). This amendment introduces 2 additional microbial strains for further mechanistic studies. Both strains being added (Clostridioides difficile strains 630 and 60556/M6) are considered BSL-2 strains. The C. difficile 630 strain is a toxigenic anaerobic, opportunistic pathogen with moderate virulence (TcdA+/TcdB+) and moderate environmental stability with spore formation, and it is relatively antibiotic-sensitive (compared to hypervirulent strains). The C. difficile 60556/M6 strain is a hypervirulent toxigenic anaerobic pathogen with high toxin production (TcdA+/TcdB+/binary toxin+), increased antibiotic resistance, and high environmental persistence due to robust spore formation. The new microbial strains have or will be modified to include deletions in metabolic pathway genes not associated with virulence or pathogenicity (e.g., genes involved with metabolism, macromolecule biosynthesis, sensing metabolites, and extracellular appendage synthesis). The strains will be handled with strict	2 / III-D-1, III-D-4

		adherence to BSL-2 containment measures (ABSL-2 for animals) including use of biosafety cabinets and PPE. Waste materials will be inactivated by autoclaving, and following termination of every experiment, the bacteria will be subjected to 10% bleach for at least 20 minutes to kill the biological agent. **Occupational Health:** In Place **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Conditionally Approved (16:0:0)[1]** Conditions for Approval: 1. Clarify whether an anaerobic chamber will be used for growing *Clostridioides difficile*	

[1] Voting Decision (Yay: Nay: Abstain)
[2] Member(s) joined the meeting
[3] Member(s) left the meeting