Rutgers University
Institutional Biosafety Committee (IBC) – Central Campus
Meeting for NIH Guidelines Materials
Minutes of June 4, 2025

1. ATTENDEES

☐ Carol Bagnell	☒ Bhupinder Singh	☒ Blas Peixoto - REHS
☒ Nada Boustany	☐ Milind Shah	☒ Robert Adcock - REHS
☒ Jeffrey Boyd	☒ Matthew Ferguson – Local Non-Affiliated	☒ Jacquelyn Vidal - REHS
☒ Qian Cai	☐ Ellen Welch – Local Non-Affiliated	☒ Sophia Cheng - REHS
☒ Julie Caruth	☒ Thomas Boyle – Local Non-Affiliated	☒ Shaun Shahani
☒ Richard Ebright	☐ James Clancy – Local Non-Affiliated	☒ Elizabeth Minott – Guest, RU Legal
☒ Zhaohui Feng	☐ Jeetendra Eswaraka – Ex Officio	☐
☒ John Hershey	☐ Alejandro Ruiz – Ex Officio	☐
☒ Peng Jiang	☐ Bryan Bocco – Ex Officio	☐
☒ Eric Klein	☒ Ron Hart – Co- Chair	☐
☒ John McLaughlin	☒ Ryan McAllister - REHS	☐
☒ Donald Schaffner	☒ Brian Eggert - REHS	☐

2. MEETING LOGISTICS

CURRENT MEETING		
Called to Order: 12:02 pm	**Adjourned:** 1:09 pm	**Location:** WebEx
PREVIOUS MEETING		
Minutes from April 2, 2025		**Approved (18:0:0)**[1]
NEXT MEETING		
Date: August 6, 2025	**Time:** 12:00pm	**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
Introduction of Ex-Official Attendee	Elizabeth Minot (Rutgers Office of General Counsel, Senior Associate General Counsel) is the IBC legal advisor who is working with IBC chairs and biosafety staff in relation to the recent White House Executive Orders and NIH Implementation Update: "Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules"
Introduction of New IBC Member	New local non-affiliated member joining IBC. Matt serves on the New Brunswick City Council.

IBC Member Education
 	
Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
	Communication was received on March 28, 2025 to maximize transparency of IBC Meetings in relation to the NIH Guidelines starting after June 1st, 2025:
	• https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-082.html
	• The NIH OSP will publicly post the rosters of all active IBCs registered with OSP via the IBC-Registration Management System
	  ○ These rosters will include all members identified by name and role on the committee
	  ○ In addition, NIH will be posting the contact information for the:
	  ▪ IBC Chair
	  ▪ Biological Safety Officer
	  ▪ IBC Contact
	• NIH expects that approved meeting minutes from all IBC meetings occurring on, or after this June 1st, 2025 will be posted publicly on an institutional website
	  ○ NIH's expectation that minutes will be posted immediately after approval and once all appropriate and allowable redactions have been made.
	  ○ Please note that the provisions of this memo only apply to meetings taking place on, or after June 1st, 2025. Minutes from meetings before June 1st, 2025 are not required to be posted but must be provided to members of the public upon request.
	  ○ Minutes must remain publicly available for 5 years

IBC Member Education **NIH IBC Minutes Template**	• NIH released a guidance template for IBC minutes: https://osp.od.nih.gov/wp-content/uploads/2025/05/Minutes-PtoC-and-Template.pdf

	• Updates to Rutgers IBC minutes will be specific to what has been ongoing in our IBC meeting and will include the following to formalize our IBC process to the public:
	  ○ Confidentiality Statement
	  ○ Submission Summaries for proposals that require full IBC review
	  ○ Occupational Health Component
	  ▪ Vaccination requirements
	  ▪ Respiratory protection (with REHS)
	  ▪ Periodic review of any medical surveillance
	  ▪ Post-exposure response procedures
	  ○ REHS Component: Training and Facilities
	• Separating Committee Minutes: recombinant from non-recombinant work

IBC Member Education
 	
Presidential Executive Order: Improving the Safety and Security of Research
	• https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/
	• Two sections of importance are #3 & #4
	  ○ Section 3 Stopping of Dangerous Gain of Function Research
	  ▪ "(a.i) end Federal funding of dangerous gain-of-function research conducted by foreign entities in countries of concern (e.g., China) pursuant to 42 U.S.C. 6627(c), or in other countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies"
	  ▪ "(a.ii) end Federal funding of other life-science research that is occurring in countries of concern or foreign countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies and that could reasonably pose a threat to public health, public safety, and economic or national security, as determined by the heads of relevant agencies."
	  ▪ "(b) shall establish guidance for the Secretary of Health and Human Services and the heads of other relevant agencies with respect to suspension of federally funded dangerous gain-of-function research, pursuant to the terms and conditions of the relevant research funding, at least until the completion of the policy called for in section 4(a) of this order."
	  ○ Section 4 Secure Future Research Through Commonsense Frameworks
	  ▪ Expect New/Revised Executive Orders
	  • Framework for Nucleic Acid Synthesis Screening

	• https://aspr.hhs.gov/S3/Documents/OSTP-Nucleic-Acid-Synthesis-Screening-Framework-Sep2024.pdf • Online/Offline since 01/22/25 • Initial implementation date was 04/29/25 • "Within 90 days of the date of this order (08/03/25), the Director of OSTP, in coordination with the APNSA and the heads of relevant agencies, shall review or replace the previous EO" • Dual Use Research of Concern Policy • https://aspr.hhs.gov/S3/Documents/USG-Policy-for-Oversight-of-DURC-and-PEPP-May2024-508.pdf • Offline on 05/05/25 • Initial implementation date was 05/06/25 • "(a) Within 120 days of the date of this order, 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 2024 "United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" ○ Section 5 Manage Risks Associated with Non-federally Funded Research • "Within 180 days of the date of this order (11/01/25), 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 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."
Old Business **Updated Guidance Regarding Risk Group of SARS-CoV-2 under the NIH Guidelines and Biosafety Guidance under the CDC**	In conjunction with each other, the NIH and CDC have updated classification and guidance for SARS-CoV-2 IBC risk assessments and research controls • The NIH has updated the minimum risk group classification for SARS-CoV-2 from Risk Group (RG) 3 to RG2 as a starting point when conducting risk assessments (https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/biosafety-considerations-for-research-involving-sars-cov-2/) • The CDC has updated their laboratory guidance updating the minimum containment level for SARS-CoV-2 from Biosafety Level (BSL) 3 to BSL2

	(https://www.cdc.gov/covid/php/lab/index.html) • The Rutgers Office for Research (OfR) will set the university policy to allow or not allow the IBC to begin accepting research proposals for SARS-CoV-2 research at BSL2. The IBC is awaiting a decision from the OfR. Rutgers North and Central IBC have agreed on a protocol review triage approach and will revisit BSL2 enhancements for SARS-CoV-2 if/when Rutgers OfR decides to allow PI to submit IBC proposals for work at BSL2.

Old Business
 	
Biosafety Protocol Management System Updates
	Addendum B – Microorganism List
	• Harmonized list of microorganisms
	  ○ Standardized to ensure uniform formatting, nomenclature, and spelling
	  ○ Facilitating communication across Rutgers systems and the ability to identify pathogens across campus more effectively
	
	Addendum K – Synthetic Nucleic Acids [sNA]
	• Legitimacy approval for use letter
	  ○ To submit with orders related to Synthetic Nucleic Acid Sequences of Concern (SOC)
	  ○ Driven by IBC approvals for pathogen work
	  ○ Facilitates ordering allowance without case-by-case congruency review
	  ○ Supports verifying legitimacy during the ordering and procurement process
	
	Dual Use Research
	• Dual Use Section: Making congruent with the grant submission system
	  ○ Experimental outcome list is update per the 2024 Executive Order
	  ○ Capability to list pathogen associated with the experimental outcome
	  ○ Categories of work
	  ○ Justification (box 1)

New Business
 	
Communication Updates
	2025 Biosafety Newsletter
	• Anticipated 2025 release dates (quarterly)
	  ○ January
	  ○ April
	  ○ July
	  ○ October
	• Published on Biosafety website

New Business
 	
Communication Updates
	REHS Website Updates
	  ○ Dual Use Research of Concern
	  ○ Synthetic Nucleic Acid Synthesis Framework

New Business
 	
Training Updates
	• Dual Use Research of Concern
	  ○ In-person training slides updated
	  ○ Online training slides updated

	○ Will revisit when updates are provided in September 2025 • Synthetic Nucleic Acid Synthesis Screening Framework ○ "Providers" training meeting on 04/24/25 ○ Will revisit when updates are provided in August 2025

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	SUMMARY	BSL
22-025	Monahan, Kevin	Renewal without changes	2
13-401	Gelinas, Celine	Renewal with minor changes	2e
13-376	Xue, Chaoyang	Amendment to add CryoEM location	2
19-011	Kim, Hee-Sook	Renewal with minor changes	2
19-015	Etchegaray, Jean-Pierre	Amendment to add personnel	2
19-048	Alland, David	Amendment – Updates of experimental outcomes (to address clerical error) and updates of inactivation methods (to add heat inactivation of Chikungunya virus at 60C for 90 minutes; verification of method has been performed). Details are uploaded in the File Cabinet section.	3
13-555	Bhanot, Purnima	Renewal without changes	2
14-114	Denzin, Lisa	Renewal without changes	2
22-022	Hinrichs, Christian	Renewal with personnel changes	2
19-027	Boison, Detlev	Renewal with minor changes	2
16-035	Abdellatif, Maha	Renewal without changes	2
18-028	Lin, Hao	Renewal with changes	2
19-032	Price, Dana	Renewal with minor changes	2
21-020	Price, Dana	Renewal with minor changes	2
23-006	Martinez Zamudio, Ricardo	Amendment to remove personnel	2

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

3. BIOSAFETY OFFICER REPORT (BSO) – IBC Vote: Approved (18:0:0)[1]			
PROTOCOL	**PI**	**SUMMARY**	**BSL / GUIDELINES**
14-150	Di, Rong	**Title:** Improvement of crop stress tolerance and disease resistance by gene editing **Materials**: CRISPR editing, Plants (creeping bentgrass), Burkholderia vietnamiensis, Azoarcus communis, and Gluconacetobacter diazotrophicus **Submission Summary:** The main goal of this project is to develop the platform of CRISPR/Cas-based gene editing for both dicot and monocot plants to engineer disease resistance and stress tolerance using creeping bentgrass as a model plant. Previously approved for CRISPR/Cas9 stress response gene knock-in or knock-out studies in various plants. This amendment adds CRISPR knock-out gene targets for creeping bentgrass in the previously approved gene family (negative regulators of stress) with a goal of enhancing the ability of the plant to attract nitrogen-fixing diazotrophic endophytic bacteria. Specifically, they are requesting approval to knock-out the CYP75B3/B4 genes using CRISPR/Cas9. The mutations in these two genes will result in plants secreting compounds that act as attractants for the adherence and internalization of nitrogen-fixing diazotrophic endophytic Risk Group 1 bacteria (all new non-recombinant bacteria to the protocol). These bacteria will be purchased from ATCC, grown in the lab and tested on the wild type and CYP75B3/B4 mutant plants in lab growth chambers. Testing on plants will be done by direct application of bacterial suspension to the root zones of the plants using pipets or pipet tips. These bacteria are expected to enhance the capability of mutant plants to absorb and retain more nitrogen, thus helping to reduce the application of nitrogen fertilizer. The end points for newly proposed endophytic bacterial study will be: 2 weeks after inoculation, we will harvest the grass plants' leaves and roots to isolate DNAs and to measure the N_2 levels. The rest of the plants will be collected and autoclaved before disposal. **Occupational Health:** Not Applicable **Training:** In Place **BioAudit:** Facilities are Acceptable	1/ III-E-2

4. NEW PROTOCOLS			
PROTOCOL	**PI**	**SUMMARY**	**BSL / GUIDELINES**
25-014	Hargarten, Jessica	**Title:** Hargarten Biosafety Protocol **Materials**: Escherichia coli, Cryptococcus neoformans, Cryptococcus gatti, Candida albicans; human iPSCs, Sendai virus (virus kit for iPSC reprogramming), rDNA, Animals **Submission Summary:** Protocol covers (i) culture, CRISPR-Cas9 gene editing, and mouse infection studies with non-recombinant Risk Group 2 fungal pathogens; (ii) cell reprogramming with Sendai virus; (iii) gene editing with lentivirus; (iv) culture and human patient-derived primary cell cultures and patient-derived iSPC lines; and (v) rDNA with E. coli. Risk Assessment has been revised to correct erroneous statements, to provide missing information on routes of infection and on lentivirus, and to call for use of a BSC for in vitro work with Crytptococcus spp., Candida spp., or lentivirus.. **Occupational Health**: Complete **Training**: In place **BioAudit**: Required before commencing work (Provision of Approval) **IBC Vote: Approved (18:0:0)**[1]	2 / III-D-1, III-D-3, III-E-1

5. AMENDMENTS			
PROTOCOL	**PI**	**SUMMARY**	**BSL / GUIDELINES**
21-041	Grosso Jasutkar, Hilary	**Title:** Synaptic Autophagy **Materials:** rDNA, AAV, Animals **Submission Summary:** The amendment aims to test the hypothesis that improving efficiency of synaptic protein turnover by autophagy can be protective against normal cognitive aging and neurodegeneration. The PI will over express autophagy-related genes using AAV vector delivery to increase autophagic efficiency. The autophagy-related genes will be delivered using retro-orbital injection of the AAV. PHP.eB vector. These vectors are obtained	1 / III-D-4

		from the company Vector Builder and do not include a helper virus. The biosafety procedures of AAVs were in place and had been previously approved. In addition, the PI updated the literature review, assigned the AAV vector training to her staff, and shared the AAV SOP with them. The PI will upload the signed SOP to the file cabinet once the staff are comfortable with their understanding and have signed it. I have no concerns and recommend approval. **Occupational health:** Required before commencing work (Provision of approval) **Training:** In Place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (18:0:0)[1]**	
14-068	Cugini, Carla	**Title:** Analysis of oral bacteria species **Materials:** rDNA, Veillonella parvula **Submission Summary:** This amendment proposes to make one mutant in an organism that the authors have previously been approved to work with (Veillonella parvula). The mutant will likely make the organism less virulent. They will also use a series of plasmids to try to make a transposon mutant library. no additional risk was noted. I recommend approval. **Occupational Health:** Complete **Training:** In place **BioAudit:** Facilities are Acceptable **IBC Vote: Approved (18:0:0)[1]**	2 / III-D-1
19-058	Solesio Torregrosa, Maria	**Title:** Inorganic polyphosphate as a chaperone in aging and in neurodegenerative diseases **Materials:** rDNA, Lentivirus vector, Human cells, BBP **Submission Summary:** This amendment will use lentivirus to infect mammalian cells for mitochondria isolation and analysis. Lentivirus will be prepared and provided by the other lab. The amendment is clearly written. Hepatitis B vaccination is required. **Occupational Health:** Complete **Training**: Required before commencing work (Provision of Approval) **BioAudit:** Facilities are Acceptable	2 / III-D-1

		IBC Vote: Approved (18:0:0)[1]	

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