COMS meeting on 10/3/2025
Minutes

Location: ZOOM
Time: 10AM - 12PM

Harvard University Committee on Microbiological Safety (COMS)
COMS@hms.harvard.edu

Documentation of Quorum

Total Voting Members on Committee Roster: 29
Total Needed for Quorum: 10
Total Present at Call to Order: 30
Members Arriving After Call to Order: 3

ATTENDEES PRESENT		
Committee Chair	**Committee Vice Chair**	
• S. Helaine	• M. Nibert	
Members		
• A. Baptista (IBC Member) • D. Barbeau (IBC Member) • S. Bhalchandra (IBC Member) • M. Dorf (IBC Member) • L. Gamer (IBC Member) • R. Lee (IBC Member) • Y. Lu (IBC Member)	• R. Rasmussen (IBC Member) • B. Neugeboren (IBC Member) • M. Nilsen (IBC Member) • J. Park (IBC Member) • R. Polak (IBC Member) • K. Pritchett-Corning (IBC Member) • M. Melisi (BSO Officer)	• A. Reid (BSO Officer) • S. Santra (IBC Member) • J. Sixsmith (IBC Member) • M. Super (IBC Member) • D. Tipper (IBC Member) • T. Winters (IBC Member)
Ex-Officios		
• B. Corning	• M. Corrigan	• S. Estime
• M. Schatz		

Call to Order

The meeting was called to order at 10am.

Introduction of Guests

None

Meeting Minutes for Approval

Meeting	Minutes Approved	Link to Minutes
COMS meeting on 7/25/2025	Yes	Link

Scheduled Business

Type	COMS #	Title	PI	Institution	Motion
Appointed Review Protocols Involving Recombi	25-082	Innate Immunity to RNA Viruses in C. elegans and human	Jérémie Le Pen	Harvard T.H. Chan School of Public Health (HSPH)	Approved This is a new COMS protocol. Researchers will investigate the mechanisms underlying host innate immunity to RNA viruses, utilizing both Caenorhabditis elegans (Caenorhabditis elegans) and human cell models. Research involves recombinant RNA viruses (e.g., SINV, VSV, CHIKV-181/25 attenuated vaccine strain, HSV-1-GFP, and other reporter-tagged viral clones) that are not further

nant DNA		cell models			engineered. High-risk procedures include viral RNA transfection, virus amplification, and titration in permissive mammalian cells. Host cells are genetically modified (CRISPR knockouts, siRNA-mediated knockdown, or overexpression) to study innate immune genes. This falls under sections III-D, III-E and III-F of the NIH Guidelines, and will be conducted under BL1, BL1-N and BL2 containment per COMS policies and institutional biosafety manuals. Some agents require a consultation with occupational health be offered. The lab is responsible for obtaining any CDC/USDA VS-16 permits needed for the purchase and transport of agents. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 16 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	22-082-A28	Life Lab at Longwood Project II	Mark Namchuk	Harvard Medical School (HMS)	Approved This amendment adds a new project involving human cell lines and lentiviral vectors to study differentiation of ovarian cells. The prepackaged lentiviral vectors will use CRISPR technology to target a variety of genes (some potential oncogenes) and including fluorescent markers. This work falls under NIH Guidelines category III-E and will be conducted at BL2 and BL2 with additional stipulations per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	23-051-A13	Undercovering the antigenic landscape of endemic coronaviruses	Kizzmekia Corbett-Helaire	Harvard T.H. Chan School of Public Health (HSPH)	Approved This amendment is for the addition of CRISPR-engineered HEK293T knockout cells targeting candidate coronavirus receptors. The recombinant cell lines will be produced and received from a collaborator. Pseudoviruses will be generated in-house using VSV or lentiviral backbones engineered to express reporter genes, along with coronavirus spike proteins, to assess receptor-dependent viral entry. Researchers will culture the CRISPR-engineered cells and assess them with spike-pseudotyped pseudoviruses in viral entry and protein binding assays. This work falls under sections III-D, III-E and III-F of the NIH Guidelines and will be conducted under BL2 containment per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-051-A01	Dynamic Proteomics in Living Cells	Galit Lahav	Harvard Medical School (HMS)	Approved This amendment adds the use of adeno-associated viruses for the over-expression of the p53 tumor suppressor gene. The vectors will be used to modify various human cells. This work falls under Category III-E of the NIH Guidelines and will be conducted under BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombi	25-064	Zoonotic surveillance subgroup 2b Coronavir	Phyllis Kanki	Harvard T.H. Chan School of Public	Approved This is a 5 year rewrite with no scientific changes. The goal is to develop a coronavirus surveillance immunoassay to detect pan-group 2b, SARS-CoV, and SARS-CoV-2 antibodies targeting the N, S, and S-RBD proteins. Recombinant proteins are either purchased commercially or expressed in mammalian tissue

nant DNA		us (CoVs) and SARS pseudotype studies of cell receptors and tropism determinants		Health (HSPH)	culture. Standard retroviral and lentiviral vector systems with MLV and HIV-based backbones are also used to express pseudotyped viruses to study viral entry mechanisms. Non-pathogenic E. coli is used to amplify plasmids encoding SARS-CoV-2 and VSV-G proteins for expression in mammalian cells. Work will be conducted under BL1 and BL2 containment following COMS policies and institutional biosafety manuals. NIH Guidelines III-D and III-F apply. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-106	Assembly of Anellovirus VLPs around nucleic acid	Vinothan Manoharan	Harvard School of Engineering and Applied Sciences (SEAS)	Approved This is a new protocol. The lab aims to study the kinetics of Virus-like Particle (VLP) assembly using interferometric scattering microscopy. The project consists of two parts: (1) images will only be taken of the coat protein, anellovirus ORF1 protein or fully packaged VLPs consisting of coat protein around recombinant nucleic acids containing a non-coding region of the wild-type Anellovirus genome, (2) imaging the direct assembly of VLPs by conjugating the nucleic acids to a glass substrate and flowing coat protein in a sample chamber. This work falls under sections III-E and III-F of the NIH Guidelines and will be conducted under BL1 per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-108	ICCB-Longwood Screening Facility	Jennifer Smith	Harvard Medical School (HMS)	Approved This is a 5 year rewrite for a core facility studying small molecules, functional genomics, assay development, and high throughput small molecule screening. The core handles a variety of human tissues, bodily fluids, rodent cells, human cells (established and primary), BL1 and BL2 organisms. Some of the samples may be genetically modified. The only rDNA work done in the core is growing non-pathogenic Escherichia coli containing plasmids for protein purification. One project will be part of a teaching lab where students will be instructed on how to use instruments in the core facility with the material covered on this protocol. This work falls under Categories III-D, III-E, and III-F and will be done at BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-110	Biomarker Analysis Service Center: Analysis of Fat Soluble Vitamins, Fatty Acids, and Lipoprotein in Human Samples (Plasma and Tissues) and Foods	Qi Sun	Harvard T.H. Chan School of Public Health (HSPH)	Approved This is a 5 year rewrite for the Biomarker Analysis Service Center within the Department of Nutrition. The core offers HPLC, GC-FID, lipid analysis, and ELISA services to researchers and external (academic and commercial) users. They receive anonymized human samples including blood, tissue and body fluids. Materials are stored in designated freezers and processed onsite for aliquoting and for extraction and analysis of nutritional biomarkers. All samples are collected from healthy individuals and are not expected to contain pathogens. The work does not involve use of recombinant DNA technology and will be conducted under BL1 and BL2 containment following COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0

Standard Review Protocols Involving Recombinant DNA	25-113	Maitenance of genomic integrity in the C. elegans germline	Monica Colaiacovo	Harvard Medical School (HMS)	Approved This is a 5 year rewrite with no scientific changes. The lab will continue to use Caenorhabditis elegans as a model system for studies of DNA repair in the germline. The lab also uses E. coli (K12 and derivatives), and Saccharomyces cerevisiae for transformation and analysis of protein-protein interactions in yeast two-hybrid assays. Recombinant work to investigate deletions, insertions and tags of genes associated with DNA damage and repair pathways is performed. The work can be safely done under BL-1 following related COMS policy. The work falls under Sections III-D and III-F of the NIH guidelines. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-114	Safety Submission: Mechanisms of Protein Targeting, Turnover, and Homeostasis in Yeast and Humans - 2025	Vladimir Denic	Harvard Faculty of Arts and Sciences (FAS)	Approved This is a 5 year rewrite with no scientific changes. The lab works to understand how cells handle misfolded proteins in both human and yeast cells. They are also working to understand more globally how the cells perform and regulate autophagy (self-eating: recycling of internal cellular components). They will use human cells, 2nd generation lentiviral vectors, non-pathogenic Escherichia coli, and Saccharomyces cerevisiae. The only high-risk genes work will take place in genome-wide screens, which the Committee has deemed to be low-risk work. BL1 & BL2 precautions will be used as appropriate, Bloodborne Pathogen Standard applies, NIH Guidelines III-D, E, & F cover the work. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-115	Molecular Basis of Behavior	Stephen Liberles	Harvard Medical School (HMS)	Approved This is a 5 year rewrite with no scientific changes. The lab investigates chemosensory receptors and the role of the vagus nerve in regulating vital physiological functions. Their work uses genetic and recombinant approaches in vitro and in vivo (mouse models), including genetically modified mammalian cell lines, tissues, blood, and fluids. Recombinant proteins are expressed in nonpathogenic E. coli and mammalian cells to study receptor function. Mice are challenged with a variety of bacteria, viruses, and parasites to examine behavioral and physiological responses. All biomaterials have COMS precedents. Research falls under sections III-D, III-E and III-F of the NIH Guidelines, and will be conducted under BL1/BL1-N, BL2/BL2-N containment per COMS policies and institutional biosafety manuals. Some agents require a consultation with occupational health be offered. These stipulations and animal facility-related stipulations are included in the approval letter. The committee discussed vaccine offerings with occupational health. The lab uses delta g-deleted rabies and the C-strain (wild-type) and would not be offered vaccine. The information should be shared with the new Harvard Cccupational Health Group. Clarifying the number of personnel whom might be exposed would be best. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombi	25-117	C. elegans Olfactory Learning on Pathogenic Bacteria	Yun Zhang	Harvard Faculty of Arts and Sciences (FAS)	Approved This is a 5 year rewrite with no scientific changes. The lab will continue to study molecules and pathways that regulate learning. The project uses the Caenorhabditis elegans model to investigate learning behavior in avoiding pathogenic bacteria. The lab will generate transgenic C. elegans and conduct behavioral analysis on locomotion, and on feeding behavior using various

nant DNA					pathogenic bacteria listed below. This work falls under NIH guidelines Section III-D and III-F. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Appointed Review Protocols Not Involving Recombinant DNA	25-063	SARS-CoV-2 Diagnostics and Infection	Phyllis Kanki	Harvard T.H. Chan School of Public Health (HSPH)	Approved This is a 5y rewrite for this project, with no changes to biomaterials or procedures. The lab studies the biology, pathogenesis, and immune responses of SARS-CoV-2 (including variants), SARS-related coronaviruses, and other human coronaviruses to support the development of effective diagnostic tools. Researchers work with human and nonhuman primate specimens, some of which may contain SARS-CoV-2 variants. This project does not involve use of recombinant DNA and therefore falls outside the scope of NIH Guidelines. OSHA BBP Standard is applicable for human source material, some materials require occupational health consultation. It was noted that although SARS-CoV-2 culture can now be performed at a minimum of BL2 following CDC and NIH updates and its reclassification from RG3 to RG2, the PI has chosen to continue using the designated BL3 facility for their previously approved work with SARS-CoV-2. The new biosafety levels in the approval letter are assigned based on the research matrix developed by Harvard EHS Biosafety, and work will be conducted under the appropriate containment per COMS policies and institutional biosafety manuals. The lab is responsible for securing any CDC/USDA VS-16 permits needed for the acquisition and transport of agents and for complying with all associated permit conditions. The committee discussed the following: The lab has opted to conduct BL2 experiments in the BL3 lab. The work does not require BL3 containment. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 16 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	24-013-A08	Friend or Foe & MUPPETS 2024	Johan Paulsson	Harvard Medical School (HMS)	Approved This amendment adds additional organisms (Salmonella enterica serovar Newport, Bacteroides vicugnae) and the use of wastewater samples to develop assays to detect microbes in a variety of environmental samples. This work does not fall under the NIH Guidelines and will be conducted at BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	25-123	Great Experiments course	Philip Sadler	Harvard Faculty of Arts and Sciences (FAS)	Approved The Great Experiments class recreates experiments from the history of science. This protocol covers Alexander Fleming's experiments with penicillin. The students will culture Penicillium chrysogenum and non-pathogenic, K12-derived Escherichia coli singly and in co-culture to watch the growth inhibition on E coli by P chrysogenum. they will also culture environmental samples and culture them with E coli to show growth inhibition. The work will be done with BL1 or BL2 precautions to follow COMS policies, does not fall under any NIH Guidelines. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved: 17 Against: 0 Abstentions: 0

Personnel Training
The PI and laboratory staff are required to be trained in accordance with the COMS Training Policy. Current PI training was verified by the Institutional Biosafety Officer for all protocols discussed at today's meeting and PIs are responsible for ensuring laboratory and agent-specific training for their staff.

Lab Inspections
The Institutional Biosafety Officer provided inspection dates for all protocols discussed at today's meeting. Facilities are considered appropriate for the proposed work and proposed containment levels. No significant findings/noncompliance were noted to the committee. The laboratories are working on any necessary corrective actions.

New Policies and Procedures

None

Reported Incidents

Members were presented with and informed of one incident from 9/8/2025, its risk assessment, and the corrective actions taken to prevent further occurrence.

Title: Failure to obtain IBC Approval:

Summary:
During the investigation of a near-miss incident, the BSO determined that the lab was using a cell line not approved on their protocol. It was communicated to the lab that the cell line would need to be registered before work with it could continue.

Corrective actions:
- The PI submitted a scientific amendment to the existing protocol to register the cell line.
- The lab will adopt the use of a spreadsheet to keep track of individual cell lines and to be maintained in the Supporting Documents.

Notification: This incident was reported to COMS.

Old Business

There was no old business discussed at this meeting.

New Business

1. Dangerous Gain of Function Reviews
   Dangerous Gain of Function reviews have been conducted at the request of NIH by a collaboration of Harvard EHS, COMS Office, Office of Academic and Researcg Integrity and the pre-award office. No dangerous gain of function work has been identified. Please contact COMS if you have any questions.

Training Articles of Interest:

2. The committee was provided with several articles for the purposes of COMS member training.
   - World's first AI-designed viruses a step towards AI-generated life
   - NIH Policy on Enhancing Security Measures for Human Biospecimens
   - Public trust in science has declined since COVID — virologists need to unite around safety standards

Public Comments
There were no public comments.

Adjournment

The meeting was adjourned at 10:30am.