**COMS meeting on 11/7/2025**
**Minutes**

**Location:** ZOOM
**Time:** 10:30AM - 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:** 28
**Members Arriving After Call to Order:** 10
**Total Guests and Members of Public:** 4

| ATTENDEES PRESENT | | |
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| **Committee Chair** | **Committee Vice Chair** | |
| • S. Helaine | • M. Nibert | |
| **Members** | | |
| • A. Baptista (IBC member)<br>• D. Barbeau (IBC member)<br>• S. Bhalchandra (IBC member)<br>• T. Brennan-Krohn (IBC member)<br>• R. Colgrove (IBC Member)<br>• M. Dorf (IBC member)<br>• L. Gamer (IBC member)<br>• T. Kwan (Local Non-Affiliated Member) | • R. Lee (IBC member)<br>• M. Melisi (Biosafety Officer)<br>• S. Mohr (IBC member)<br>• B. Neugeboren (IBC member)<br>• M. Nilsen (IBC member)<br>• J. Park (IBC member)<br>• R. Polak (IBC member)<br>• R. Rasmussen (IBC member) | • A. Reid (Biosafety Officer)<br>• S. Santra (IBC member)<br>• J. Sixsmith (IBC member)<br>• M. Super (IBC member)<br>• D. Tipper (Local Non-Affiliated Member)<br>• T. Winters (IBC member) |
| **Ex-Officios** | | |
| • B. Corning<br>• S. Elwell | • M. Corrigan<br>• E. Macleod | • S. Estime<br>• E. Kuszmar |

**Call to Order**
The meeting was called to order at 10:25 AM.
The meeting is now open for discussion.

**Meeting Minutes for Approval**

| Meeting | Minutes Approved | Link to Minutes |
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| None | | |

**Scheduled Business**

| Type | COMS # | Title | PI | Institution | Motion |
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| Appointed Review Protocols Involving Recombinant DNA | 24-011-A04 | Comparison of Signal Processing Between Microbial Species 2024 | Michael Springer | Harvard Medical School (HMS) | This is a new project to study enrichment of rare earth metals. The amendment adds new bacteria, some of which will be genetically modified to enhance genes involved in rare earth metal accumulation. This work falls under section III-E of the NIH Guidelines and will be conducted under BL1 and BL2 containment per COMS protocols and institutional biosafety manuals.<br><br>The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:18<br>Against: 0<br>Abstentions: 1 |
| Appointed Review Protocols Involving | 25-122 | Chemical and Biological Diversity of Marine Mollusks | Mande Holford | Harvard Faculty of Arts and Sciences (FAS) | This is a new protocol. The main goal of the research is to study novel venom peptides from marine snails and cephalopods for ion channel and receptor activity and the development of new therapeutics. Protocol involves in vitro recombinant protein work in E. coli, Pichia pastoris, and AAV work with human established cell lines, gene knock out in cephalopods, and immune |

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| Recombinant DNA | | | | | response studies with dengue and influenza viruses in vitro. The work falls under sections III-D and III-E of the NIH Guidelines. Work will be conducted under BL1, BL1-N, BL2 and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals.<br><br>• The committee discussed the risks associated with omega conotoxin.<br>• The drug Prialt is a synthetic peptide version of omega conotoxin, which has an LD50 far outside the thresholds of Guideline Section III-B and Appendix F. Exposure risks are minimalized due to small quantities generated in a laboratory.Previous discussions with Dengue virus were mentioned and risks of exposure. A vaccine is always recommended, when available, for infection prevention. There is no vaccine for dengue in the United States. The occupational health recommendations do not include dengue titers for this protocol.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Appointed Review Protocols Not Involving Recombinant DNA | 24-099-A06 | Systems Serology Profiling of Humoral Immune Responses in Infectious Disease and Cancer | Ryan McNamara | Harvard T.H. Chan School of Public Health (HSPH) | A member associated with this study was placed in a Zoom waiting room. This amendment adds plasma, serum, and bronchoalveolar lavage samples from a variety of sources, including healthy, vaccinated, and challenged human, Non human primates (NHP), and mouse studies. Samples will be used for serological analyses, including the Systems-predicted Neutralizing Antibody (SNAb) assay, for a high-throughput prediction of neutralization capacity against multiple viral antigens. The work does not involve the culture of viruses or pathogens. No recombinant DNA will be used in these procedures. The work will be conducted under BL1, BL2 and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals. No NIH Guidelines apply.<br><br>The committee discussed the following:<br>• A stipulation has been added to the approval letter that addresses NHP material risk.<br>• The lab will use vaccine studies and the NHP materials originated from pathogen-free colonies screened for Herpes B virus.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:17<br>Against: 0<br>Abstentions: 1<br><br>A member associated with this protocol was brought back into the meeting after the voting. |
| Standard Review Protocols Involving Recombinant DNA | 20-232-A40 | Studies of the Intestinal Microbiota in Colitis, Colitis-Associated Colorectal, and Sporadic Colorectal Cancer | Wendy Garrett | Harvard T.H. Chan School of Public Health (HSPH) | This amendment adds obligate anaerobes: Eubacterium rectale, Enterocloster clostridioformis (formerly Clostridium clostridioforme), and Bacteroides fragilis for in vivo and in vitro studies. These bacteria will not be genetically modified as part of the research. In addition, new plasmid vectors will be added for cloning and expression in non-pathogenic E. coli strains. The work falls under sections III-E and III-F of the NIH Guidelines and will be conducted under BL1/BL1-N and BL2/BL2-N containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving | 21-113-A02 | Electrophysiology activity manipulation in non-human primates | Carlos Ponce | Harvard Medical School (HMS) | This amendment adds non-human primate bodily fluids, additional adeno-associated viral vectors, and lentiviral vectors to study vision. This work falls under section III-D of the NIH Guidelines and will be conducted at BL2 and BL2-N containment per COMS policies and institutional biosafety manuals. |

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| Recombinant DNA | | | | | The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 23-127-A03 | Regeneration in Axolotls 2023 | Jessica Whited | Harvard Faculty of Arts and Sciences (FAS) | This amendment adds the use of animal tissue, axolotl protein production, and viral vector use to study limb regeneration in a mammalian model. This work falls under sections of III-D, III-E, and III-F of the NIH Guidelines. The work will be conducted under BL1 containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 25-097-A01 | Mechanisms of Intracellular Bacterial Pathogen Infection | Darren Higgins | Harvard Medical School (HMS) | This amendment is for adding a yeast (Pichia pastoris) and recombinant protein expression system to determine which properties of serum albumin enable Listeria monocytogenes to sense and respond to albumins. Researchers will use yeast to clone, express and purify recombinant human and bovine serum albumins and generate amino acid substitution and truncation mutants of these proteins. Mutant proteins will then be tested with approved wild-type and gene-deletion strains of L. monocytogenes to identify the specific amino acids or domains required for bacterial sensing and response. This work falls under section of III-E of the NIH Guidelines. The work will be conducted under BL1 containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 25-116 | Bacterial Envelope Assembly | Tom Bernhardt | Harvard Medical School (HMS) | This is a 5-year rewrite. The project aims to identify genes critical for proper bacterial envelope assembly by employing standard molecular techniques to modify envelope-related genes in previously approved RG1 and RG2 bacterial species. The lab also investigates the molecular mechanisms underlying vancomycin resistance in a lab-adapted Staphylococcus aureus strain that lacks key virulence genes. The work falls under sections III-D, III-E, and III-F of the NIH Guidelines. The work will be conducted under BL1, BL2, and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 25-124 | Construction of Genetically Engineered Mice.V3 | Jonathan Seidman | Harvard Medical School (HMS) | This is a 5-year rewrite. The lab generates transgenic mice (knockouts and knock ins) to mimic mutations found in human cardiac disease. DNA fragments or CRISPR/CAS9 are introduced into the oocytes via microinjection or electroporation, or alternatively, genetically modified mouse embryonic stem cells are implanted into the blastocysts for the generation of transgenic mutants. Non-pathogenic E. coli is used to propagate plasmids introduced into mouse oocytes. This work falls under section III-E of the NIH Guidelines. This work falls under BL1/BL1-N containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |

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| Standard Review Protocols Involving Recombinant DNA | 25-126 | Genetic mechanisms of mammalian CNS Development | Susan Dymecki | Harvard Medical School (HMS) | This is a 5-year rewrite. The group focuses on elucidating mechanisms of cellular differentiation and function in the mammalian brain through in vivo and in vitro techniques. The lab uses non-pathogenic E. coli for plasmid cloning, murine and human established cell transfections with plasmids to manipulate neuron activity in vitro, harvested mouse tissue and human tissue for laboratory analyses, and breeding/housing of transgenic mice. The work falls under sections III-D, III- E, and III- F of the NIH Guidelines. The work will be conducted under BL1, BL1-N, and BL2 containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 25-127 | Safety Submission: Multicolor and time-resolved electron microscopy - 2026 | Maxim Prigozhin | Harvard Faculty of Arts and Sciences (FAS) | This is a 5-year rewrite. The lab proposes to create new biophysical tools and develop instrumentation for color imaging of nanoscale cellular structures, cells, and tissue. The lab will develop these new tools specifically to study cellular signaling and processes involved in infection. They will use human cells, bacteria (pathogenic & non), and viral vectors. The work falls under sections of III-D, III-E, and III-F of the NIH Guidelines. The work will be conducted at BL1 and BL2 containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Not Involving Recombinant DNA | 21-107-A54 | Discovery of New Biosynthetic Pathways and Enzymes 2021 | Emily Balskus | Harvard Faculty of Arts and Sciences (FAS) | This amendment adds five new bacterial species for DNA-damaging studies and natural product identification. No rDNA work will take place with these species and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. No NIH Guidelines apply.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Not Involving Recombinant DNA | 22-121-A06 | Investigation of fatty acid metabolism in cellular homeostasis and neurodegeneration | Jeeyun Chung | Harvard Faculty of Arts and Sciences (FAS) | This amendment adds tetrodotoxin to the protocol. The toxin will be used in neuronal tissue culture in the lab's study of neurodegeneration, and stocks will be kept below the exempted quantities limitations. The work does not fall under the NIH Guidelines, and will be conducted under BL2 containment per COMS policies and institutional biosafety manuals.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Not Involving Recombinant DNA | 23-039-A62 | Church Lab NRB COMS: Transformative Molecular Technologies | George Church | Harvard Medical School (HMS) | The lab is adding Candida albicans, Candida auris, and Candida tropicalis to the protocol. No genetic modifications will be made. They will be used for in vitro testing and analyses against proteins. The work will be conducted under BL2 containment as per COMS Policies. No NIH Guidelines apply.<br><br>The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.<br><br>Approved:19<br>Against: 0<br>Abstentions: 0 |

**Personnel Training**
The PI and lab 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 lab and agent-specific training for their staff.

**Laboratory Inspection**
The Institutional Biosafety Officer confirmed compliance with the COMS inspection policy 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**

Incident #1: Near-Miss Incident
Summary: On 10/2/2025, a researcher in a BL3 lab noticed a potential PPE malfunction. They immediately exited the facility and doffed their PPE. Materials were appropriately secured and stored, and no work was being done at the time.

Corrective Action: All PPE worn was appropriate and visually inspected to ensure function before wearing. The researcher followed all lab SOPs in exiting the facility. There is no history of intermittent failures of this equipment, but other facility PPE was further inspected.

Notification: A notification was prepared and submitted to COMS and Boston Public Health Commission (BPHC).

Incident #2: Personnel Exposure
Summary: On 10/3/2025, while handling a needle used previously with wildtype, non-pathogenic *E. coli*, a researcher accidentally pricked their fingertip. Nitrile gloves were removed, but a glove check was not performed. It is unknown if personal protective equipment (PPE) was compromised. There was no visible blood upon doffing the glove, but a faint red spot was observed at the site. The researcher immediately washed with soap and water for approximately 5 minutes and followed with medical wipes in the lab's emergency kit. The researcher reported the incident to EHS and their Principal Investigator. Medical consultation was offered to the researcher, but they declined at the time.

Corrective Action: Reminders were given on proper handwashing time, best work practices to minimize distractions, having a sharps container within easy reach, and how to seek medical care.

Notification: This incident was reported to COMS.

Incident #3: Failure to obtain IBC Approval
Summary: When a laboratory reached out to Environmental Health and Safety (EHS) to determine if there was a registration process or storage requirement for a biological toxin, EHS Biosafety determined that the toxin was not listed on their COMS protocol.

Corrective action: The laboratory secured the toxin and submitted an amendment to their COMS protocol on the same day as the incident. An editable, toxin-specific standard operating procedure template to document work practices will also be provided to the lab.

Notifications: This incident was reported to COMS.

Incident #4 Personnel Exposure
Summary: A possible exposure to an adeno-associated viral vector (AAV, BL1) occurred when a researcher accidentally stuck themselves with a contaminated needle following a procedure. At the time of the accident, the researcher was wearing appropriate personal protective equipment and following other facility requirements. A glove integrity check was not performed, and exposure was presumed. The researcher washed the injury with soap and water and reported it to their supervisor.

Corrective Actions: Retraining of the researcher in exposure response procedures. Ensuring all supplies are located at the workstation prior to beginning work (e.g., sharps containers).

Notifications: This incident was initially reported to COMS, Cambridge Public Health, and NIH OSP for the personnel exposure in accordance with required timelines. A formalized report will be sent to each entity after the November 7, 2025 COMS Meeting.

**Old Business**

There was no old business to discuss at this meeting.

**New Business**

Training Articles of Interest:
Nine publications were shared with the committee for training purpose as follows:

1. The NIH Ordered Me to Stop My ‘Dangerous’ Gain-of-Function Research. It Isn’t Dangerous at All.
2. What is Mirror Life? Scientists are Sounding the Alarm
3. Mirror Biology: Governing the Next Frontier of Life Sciences
4. A New Social Compact to Grapple with ‘Mirror Life’
5. Why Implementation Gaps Could Undermine Synthetic Nucleic Acid Oversight
6. How to Mitigate and Respond to Threats in the Laboratory Live
7. Better Biosecurity for the Bioeconomy
8. The AI Model OpenFold3 Takes a Crucial Step in Making Protein Predictions
9. A Divergent Betacoronavirus with A Functional Furin Cleavage Site in South American Bats

**Public Comments**
There were no public comments.

**Adjournment**
The meeting was adjourned at 11:30 AM.