# COMS meeting on 5/29/2026
# 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:** 16
**Total Voting Members Present:** 19

| ATTENDEES PRESENT | | |
|---|---|---|
| **Committee Chair** | **Committee Vice Chair** | |
| • S. Helaine | • R. Rasmussen | |
| **Members** | | |
| • A. Baptista (IBC Member)<br>• S. Bhalchandra (IBC Member)<br>• T. Brennan-Krohn (IBC Member)<br>• M. Dorf (IBC Member)<br>• L. Gamer (IBC Member)<br>• S. Mohr (IBC Member)<br>• T. Kwan (Local Non-Affiliated Member)<br>• R. Colgrove (IBC Member) | • Y. Lu (IBC Member)<br>• M. Melisi (Biosafety Officer)<br>• B. Neugeboren (IBC Member)<br>• M. Nilsen (IBC Member)<br>• J. Park (IBC Member)<br>• R. Polak (IBC Member)<br>• K. Pritchett-Corning (IBC Member)<br>• A. Reid (Biosafety Officer) | • S. Santra (IBC Member)<br>• L. Silva (IBC Member)<br>• J. Sixsmith (IBC Member)<br>• D. Tipper (Local Non-Affiliated Member)<br>• T. Winters (IBC Member)<br>• C. Walsh (IBC Member) |
| **Ex-Officios (Non-Voting)** | | |
| • B. Corning | • M. Corrigan | • S. Estime |
| • E. Macleod | • E. Kuszmar | |
| **Guests and Members of Public (Non-Voting)**: 5 | | |

## Call to Order

The meeting was called to order at 10:00 A.M.
The meeting is now open for discussion.

## Introduction of Guests

Two guests were introduced.

## Meeting Minutes for Approval

| Meeting | Minutes Approved | Link to Minutes |
|---|---|---|
| COMS meeting on 3/27/2026 | yes | Link |

## Scheduled Business

| Type | COMS # | Title | PI | Institution | Motion |
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| Appointed Review Protocols Involving Recombinant DNA | 21-066-A61 | 2021 Renewal: Engineering cellular and viral vectors for in vivo delivery | George Church | Wyss Institute | The work under this protocol includes identifying novel methods, and improving conventional methods, for delivering gene-encoding nucleic acids to various cell types. This amendment includes: (1) research to harness and test a cell injection system composed of bacterial phage tail elements to deliver proteins, (2) testing a similar system of contractile tail phages for potential nucleic acid delivery, and 3) testing a replication-and packaging-defective human cytomegalovirus as a viral vector. This falls under Sections III-D, III-E, and III-F of the NIH Guidelines and will be conducted under BL1 and BL2 per COMS policies and institutional biosafety manuals. |

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| | | | | | The committee discussed the following:<br><br>The reviewer raised one issue for the committee: Candida tropicalis originates from ATCC and is listed as BL1 containment. The reviewer therefore recommended that BL1 containment be used by the lab. No incidents were identified in which this strain has caused disease in humans, although the wild-type strain does cause disease. The committee noted that this strain appears to lack virulence factors and that it would be difficult to identify origination of disease. While some virulence factors may be present, it is generally considered a commensal bacterium. The committee further discussed the appropriate containment level and whether the absence of infection can be considered non-pathogenic. The committee noted that if the lab obtains a different strain in the future, all strains will require BL2 containment. The committee agreed on BL2 containment for C. tropicalis.<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 Recombinant DNA | 21-107-A76 | Discovery of New Biosynthetic Pathways and Enzymes 2021 | Emily Balskus | Harvard Faculty of Arts and Sciences (FAS) | The lab studies bacteria to find new chemical transformations, novel natural products, and other metabolites. They also use some strains to determine the effects on metabolism from gene deletions. In this amendment they add multiple knockout strains of non-pathogenic Escherichia coli to study the effects of the knockouts on metabolism, as well as several new bacterial strains for biochemical discovery, and two strains for cloning and protein expression. This falls under Sections III-D, III-E and III-F of the NIH Guidelines and will be conducted under BL1 and BL2 per COMS policies and institutional biosafety manuals.<br><br>The BSO noted that no occupational health stipulations were included in the letter. The occupational health representative confirmed that no stipulations are needed for the agents in use.<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: 19<br>Against: 0<br>Abstentions: 0 |
| Appointed Review Protocols Involving Recombinant DNA | 22-139-A07 | Viral entry, replication, and anti-viral immunity | Jonathan Abraham | Harvard Medical School (HMS) | A member associated with this study was placed in a Zoom waiting room before the discussion of this protocol.<br><br>The lab studies flavivirus receptors and mechanisms of virus entry. This amendment adds an insect-specific Binjari virus (BinJV) to generate chimeric viruses with a BinJV non-structural protein backbone and structural proteins from two flaviviruses: yellow fever virus (strain 17D and Asibi) and tick-borne encephalitis virus (Neudoerfl, European subtype). BinJV-flavivirus chimeras will be used for cryo-EM and cell-based functional assays, similar to their approved work on alphavirus receptors. This falls under Sections III-D and III-E of the NIH Guidelines and will be conducted under BL2 per COMS policies and institutional biosafety manuals.<br><br>The BSO confirmed that all in vitro construct work is being conducted exclusively by the lab.<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: 17<br>Against: 0<br>Abstentions: 1 |

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| | | | | | A member associated with this study was brought back into the meeting after the vote. |
| Appointed Review Protocols Involving Recombinant DNA | 26-030 | Rapid, low-cost detection of microbes using freeze-dried, programmable biomolecular components | James Collins | Wyss Institute | This is a 5-year rewrite for the lab to develop a rapid and mobile assay system to rapidly screen for the presence of RNA pathogens. The work involves testing the system on a range of different pathogens. Similar approaches will be used to detect intracellular virus infection using replication-incompetent lentiviral vectors to deliver RNA sensors and reporter genes. In addition, the lab is undertaking a new sustainability project to engineer bacteria, originally isolated from harsh environments that include high temperatures, to survive and secrete PET plastic-degrading enzymes in stressful environments. The work falls under Sections III-D, III-E, and III-F of the NIH Guidelines and will be conducted under BL1, BL1-N, and BL2 per COMS policies and institutional biosafety manuals.<br><br>An occupational health representative asked whether the PI is using Influenza A and, if so, noted that it needs to be reflected in the approval letter. The BSO confirmed that Influenza A is listed in the protocol, but the lab is not actively working with this virus at this time. The committee agreed that the vaccine offering needs to be added to the approval letter.<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 |
| Standard Review Protocols Involving Recombinant DNA | 23-132-A07 | Mouse Behavior Core "Umbrella" Protocol 2024 | Barbara Caldarone | Harvard Medical School (HMS) | This amendment adds the use of Adeno-associated virusto overexpress the Tau gene in the mouse brain. Antisense oligonucleotides (ASOs) will be used for Tau knockdown/gene silencing, and tissues will be harvested at the end of the experiments. Tau is a prion-like protein but is not a classic prion agent. Recombinant rAAV-Tau preparation and administration will be conducted at BL2. BL2N-72hrs practices are recommended as a precaution during the AAV shedding period; after this period, animals can be housed at BL1-N. Harvesting brain tissue samples will be done following BL2 practices. Injection and housing of ASO-treated animals can be safely performed at BL1/BL1-N. The work falls under Section III-D of the NIH guidelines and can be conducted under BL1, BL1-N, BL2 and BL2-N-72hrs per COMS policies and institutional biosafety manuals.<br><br>The committee discussed the containment level for the proposed experiments and agreed to downgrade all work to BL1/BL1-N, as previously approved. The containment level for animal work will be BL1-N, and the recommended containment level for infected tissues will be BL1-N throughout, with no requirement for an initial BL2-N period. All AAV expression of Tau protein administration procedures will also be conducted at BL1-N.<br><br>The proposed disinfection for all work surfaces and materials exposed to tissues inoculated with AAV expressing Tau is 1% SDS with a 1-hour contact time in addition to standard disinfection protocols for AAV, such as 10% bleach. All wipes must be disposed of as solid biowaste. Current literature supports protein aggregation and indicates no substantial evidence of occupational exposure risk when handling post-exposure tissues. No laboratory-acquired infections (LAIs) in humans have been reported, as confirmed by the occupational health representative and the BSO. Safety considerations, including lab animal housing and potential animal exposure, were reviewed as part of the committee's assessment.<br><br>The committee agreed with the literature and proposed BL1/BL1-N containment. |

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| | | | | | Action: The protocol was approved at BL1/BL1-N, with cage disinfection as written using 1% SDS and 10% bleach. The BSO risk assessment will be revised following the meeting.<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 |
| Standard Review Protocols Involving Recombinant DNA | 24-108-A14 | Intestinal immune system analysis | Kazuki Nagashima | Harvard Faculty of Arts and Sciences (FAS) | The lab studies the gut microbiome and its interaction with the immune system. This amendment adds the isolation of environmental bacterial communities swabbed from fruit, several new strains of bacteria, replication incompetent lentiviral and retroviral vectors, and human colorectal cell lines. This falls under Sections III-D and III-E of the NIH Guidelines and will be conducted under BL1, BL1-N, BL2, and BL2-N per COMS policies 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: 19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 24-121-A08 | Infection and Inflammation 2024-2029 | Ruaidhri Jackson | Harvard Medical School (HMS) | The overall goal for the lab is to identify novel regulators of the immune response to infection, inflammation, and mucosal immunity. This amendment includes the addition of a recombinant strain of HSV-2, which will be used for in vivo studies. Agents require a consultation with occupational health be offered. This falls under Section III-D of the NIH Guidelines, and will be conducted under BL2 and BL2-N per COMS policies 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: 19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 26-006-A01 | Viral-mediated overexpression, knockdown or knockout of signaling pathways involved in tumor initiation and progression | Joan Brugge | Harvard Medical School (HMS) | The lab studies chemotherapy resistance in ovarian cancer using viral vector-based methods in cell culture, animal, and patient-derived (PDX) models. This amendment is to generate stable ovarian cancer cell lines and PDX models using a vendor-packaged lentiviral vector expressing the diphtheria toxin receptor (DTR) and a fluorescent reporter for visualization. Researchers will administer diphtheria toxin to selectively eliminate transduced cells in vitro and in vivo to assess their role in treatment response. This work falls under Sections III-D and III-E of the NIH Guidelines and will be conducted under BL2 and BL2-N per COMS policies and institutional biosafety manuals.<br><br>The committee discussed the addition of Diphtheria toxin. The occupational health representative noted that Tdap is offered to all researchers.<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: 19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving Recombinant DNA | 26-016-A01 | Studies of the Ubiquitin-Proteasome System | Daniel Finley | Harvard Medical School (HMS) | The lab studies the role of ubiquitin-proteasome system using recombinant techniques. This amendment expands their goal with the use of vendor-packaged AAV vectors expressing the human A53T αSynuclein (SNCA) in cell culture and animal models. The work falls under Sections III-D and III-E of the NIH Guidelines and will be |

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| | | | | | conducted under BL2 and BL2-N-72hrs per COMS policies and institutional biosafety manuals.<br><br>Biosafety levels had been assigned per COMS precedent. The committee had an in-depth discussion on the safety of the vector system and agreed to downgrade the containment level for animal work from BL2-N-72hrs to BL1-N. Similarly, the invitro work with AAV-hA53T-SNCA and handling the tissues from mice infected with AAV-hA53T-SNCA, previously assigned BL2, were revised to BL1.<br><br>The proposed disinfection for animal work with AAV-human Synuclein (SNCA) was maintained at 1% SDS with a minimum 1-hour contact time in addition to standard disinfection protocols such as 10% bleach. All wipes must be disposed of as solid biowaste. The committee discussed that while current literature supports protein aggregation, there is no substantial evidence of occupational exposure risk associated with handling post-exposures tissues. No laboratory-acquired infections (LAIs) in humans have been reported, as confirmed by occupational health representative and BSO members. Another member noted that there is no literature supporting transmission of αSynuclein from mice to humans, or from mouse to mouse, except when it is directly injected into the mouse. It is therefore not considered an infectious form. While the use of disinfectant when handling tissues is prudent, requiring BL-2 conditions is challenging for some laboratories. A veterinary member raised the potential risk of low-dose αSynuclein shedding in urine. Safety considerations, including lab animal housing and potential animal exposure, were reviewed as part of the committee's assessment.<br><br>A member noted that the lab does not currently have an assigned BL2 room for animal procedures. The committee noted that any stipulations must be practical and safely implementable within the existing facility.<br><br>The committee agreed with the literature and proposed BL1/BL1-N containment level.<br><br>Action: The protocol was approved at BL1/BL1-N, with cage disinfection as written using 1% SDS and 10% bleach, the BSO risk assessment will be revised following the meeting.<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 |
| Standard Review Protocols Involving Recombinant DNA | 26-038 | Genetic Manipulations of Neural Precursors of the Nervous System [2026] | Jeffrey Macklis | Harvard Faculty of Arts and Sciences (FAS) | This is a 5-year rewrite. In this study, genes of interest are transferred into specific regions of the central nervous system of rodents to investigate the genes' role in the differentiation of neural stem cells. The work involves human, non-human primate, and rodent cells, as well as transgenic mice and viral vectors, and includes both low- and high-risk genes. This 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, BL2 with additional stipulations, and BL2-N-72hrs per COMS policies 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: 19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Involving | 26-040 | Genetic Modification of iPSCs with Cas9/Crispr (2026) | Christine Seidman | Harvard Medical School (HMS) | This is a 5-year rewrite. The investigators are adding a new human induced pluripotent stem cell (iPSC) line and mouse primary cells, but the overall scope of the research remains unchanged. Non-pathogenic E. coli will be used for plasmid propagation. Cell lines will be cultured and transfected or transduced with lentiviral and adeno-associated viral |

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| Recombinant DNA | | | | | (AAV) vectors to modulate expression of cardiac-specific genes. These target genes are related to cardiac function and do not fall into the high-risk gene categories as defined by COMS. Mouse cells, AAV, and non-pathogenic E. coli can be safely handled at BL1. All experiments involving human iPSCs and lentiviral vectors must be conducted at BL2. This work falls under Sections III-D, III-E and III-F of the NIH Guidelines and will be conducted under BL1 and BL2 per COMS policies 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: 19<br>Against: 0<br>Abstentions: 0 |
| Standard Review Protocols Not Involving Recombinant DNA | 23-086-A03 | Optogenetic Spasticity Management | Shriya Srinivasan | Harvard School of Engineering and Applied Sciences (SEAS) | This protocol focused on reducing the effects of plasticity through optogenetic modulation of peripheral tissues. This amendment adds the use of exempt amounts of Tetrodotoxin for neurophysiological studies in animals. This does not fall under NIH Guidelines and will be conducted at BL2 and BL2-N per COMS policies 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: 19<br>Against: 0<br>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**

The following two policies had proposed revisions reviewed and voted on by the committee.

1. COMS Inspection Policy
2. COMS Introduction Policy

The committee had no other comments or questions about these two revised policies. A motion was made to approve the protocol. The committee voted.

Approved: 19
Against: 0
Abstentions: 0

**Reported Incidents**

No incidents were presented at this meeting.

**Old Business**

No old business was presented at this meeting.

**New Business**

Articles of Interest:
The committee was provided with nine articles for the purposes of COMS member training.

1. External Review of Environmental, Biosafety, and Biosecurity Considerations for Synthetic Cell Research and Development
2. UW Lab Researcher Admits to Adding Poisonous Chemicals to Coworker's Water Bottle and Shoes
3. Viruses Allegedly Stolen from High-Security Lab Cause Stir in Brazil
4. Bioterrorism and Biocrimes: the Illicit Use of Biological Arms in the 20th Century
5. The Quiet Crisis
6. White Paper on Repositioning Biosafety From a Compliance Burden to National Strategic Infrastructure
7. Man Found Guilty on 12 Counts for Running Illegal Biolab in Reedley
8. COVID Cover-Up: Hiding Star Researcher Ralph Baric's Ties to Global Pandemic

**Public Comments**

There were no public comments.

**Adjournment**

The meeting was adjourned at 11:00 A.M.