

## COMS meeting on 6/20/2025 Minutes

**Location:** ZOOM

**Time:** 10AM - 12PM

Harvard University Committee on Microbiological Safety (COMS)

[COMS@hms.harvard.edu](mailto:COMS@hms.harvard.edu)

### Documentation of Quorum

**Total Voting Members on Committee Roster:** 26

**Total Needed for Quorum:** 10

**Total Present at Call to Order:** 32

**Members Arriving After Call to Order:** 3

Total Guests and Members of Public: 2

ATTENDEES PRESENT		
Committee Chair	Committee Vice Chair	
<ul style="list-style-type: none"> <li>• M. Nibert</li> </ul>	<ul style="list-style-type: none"> <li>• S. Helaine</li> </ul>	
Members		
<ul style="list-style-type: none"> <li>• A. Baptista (IBC member)</li> <li>• D. Barbeau (IBC Member)</li> <li>• S. Bhalchandra (IBC member)</li> <li>• T. Brennan-Krohn (IBC Member)</li> <li>• R. Colgrove (IBC Member)</li> <li>• M. Dorf (IBC Member)</li> <li>• L. Gamer (IBC Member)</li> <li>• J. Kirby (IBC Member)</li> <li>• T. Kwan (Local Non-Affiliated Member)</li> </ul>	<ul style="list-style-type: none"> <li>• R. Lee (IBC member)</li> <li>• Y. Lu (IBC member)</li> <li>• M. Melisi (Biosafety Officer)</li> <li>• S. Mohr (IBC member)</li> <li>• B. Neugeboren (IBC member)</li> <li>• M. Nilsen (IBC member)</li> <li>• J. Park (IBC member)</li> <li>• R. Polak (IBC member)</li> <li>• K. Pritchett-Corning (IBC member)</li> </ul>	<ul style="list-style-type: none"> <li>• R. Rasmussen (IBC member)</li> <li>• A. Reid (Biosafety Officer)</li> <li>• S. Santra (IBC member)</li> <li>• J. Sixsmith (IBC member)</li> <li>• M. Super (IBC member)</li> <li>• D. Tipper (Local Non-Affiliated Member)</li> <li>• T. Winters (IBC Member)</li> </ul>
Ex-Officios		
<ul style="list-style-type: none"> <li>• B. Corning</li> <li>• E. Kuzmar</li> </ul>	<ul style="list-style-type: none"> <li>• S. Estime</li> <li>• M. Schatz</li> </ul>	<ul style="list-style-type: none"> <li>• E. Macleod</li> </ul>

### Call to Order

The meeting was called to order at 10am.

The meeting is now open for discussion.

### Meeting Minutes for Approval

Meeting	Minutes Approved	Link to Minutes
COMS meeting on 5/2/2025 (April Meeting) For 17 Against 0 Abstain 3	Yes	<a href="#">Link</a>

### Scheduled Business

Type	COMS #	Title	PI	Institution	Motion
Appointed Review Protocols Involving Recombinant DNA	21-139-A17	Evaluation of Immune Responses to coronavirus vaccines other emerging and re-	Kizzmekia Corbett-Helaire	Harvard T.H. Chan School of Public Health (HSPH)	This amendment adds new biomaterials to ongoing studies related to vaccine-induced immunity. Additions include seasonal, non-genetically modified influenza virus A and B strains for antigenicity assessment by flow virometry; generation of non-replicative, lentivirus-based pseudoviruses for neutralization assays; and receipt of heat-inactivated nonhuman primate samples from collaborators for simartevirus antibody screening and in vitro assays. For this, simian immunodeficiency virus will be cultured under BL2+ conditions. The lab will also obtain

		emerging viruses			<p>established and genetically modified human cell lines.-This work falls under NIH Guidelines sections III-D, III-E, and III-F, and will be conducted under BL1, BL2, and BL2+ per COMS policies and institutional biosafety manuals.</p> <p>The scientific reviewer presented their review.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 19 Against 0 Abstentions 1</p>
Appointed Review Protocols Not Involving Recombinant DNA	24-003-A01	Characterization of vaccine protection and viral pathogens - BSL-3	Kizzmekia Corbett-Helaire	Harvard T.H. Chan School of Public Health (HSPH)	<p>The lab proposes to use flow virometry to analyze SARS-CoV-2 virions from clinical swabs, cultured cells, and unmodified variant stocks to track changes in surface protein expression over time. All samples are fixed with 4% PFA before flow virometry. The work does not involve animal models, and research is exempt from the NIH Guidelines. Occupational health considerations apply for some organisms. In the absence of validation data, SARS-CoV-2 stocks or infected samples received from BL3 facilities must be managed under BL3 containment until inactivation. Virus isolates will not be cultured concurrently at any time. Work will be conducted under BL1, BL2, BL2 with additional stipulations, or BL2+ containment per COMS policies and institutional biosafety manuals.</p> <p>The Chair presented an external review to the committee.</p> <p>The committee discussed the project. The work is only for SARS-CoV-2 strains and does not involve DURC. The PI has updated the protocol to answer all questions related to DURC and to reflect all agents involved, not only those pertinent to this amendment. The committee discussed occupational health vaccination recommendations where vaccinations are available. The approval letter includes the stipulation “Research staff must be informed of the opportunity to meet with an occupational health physician or professional.” The committee discussed that the possibility of vaccine availability may change. Members discussed the validation of removing RG3 materials from the BL3 containment level. A motion was made to approve the project. The committee voted. Approved 19 Against 0 Abstentions 1</p>
Appointed Review Protocols Not Involving Recombinant DNA	24-013-A05	Friend or Foe & MUPPETS 2024	Johan Paulsson	Harvard Medical School (HMS)	<p>This amendment adds new biological material to design devices to screen and detect microorganisms from environmental and clinical samples. The amendment adds new sources of previously approved pathogens (feline immunodeficiency virus, rhinovirus), adds new organisms (Clostridiodes difficile, Candida auris, Mycobacterium fijiensis), and changes the biosafety containment level for one organism (equine arteritis virus) per USDA permit requirements (the organism was already being handled at appropriate containment level). This work does not fall under the NIH Guidelines and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. Some organisms have occupational health consultation considerations or more stringent disinfection requirements.</p> <p>The scientific reviewer presented their review to the committee. The Chair presented an external plant review to the committee.</p>

					<p>The committee discussed the project. Members discussed specific stipulations for <i>C. difficile</i> and <i>C. auris</i>. CDC recommends <i>C. auris</i> at BL2 containment and additional stipulations are provided to laboratory personnel. A motion was made to approve the project. The committee voted.</p> <p>Approved 18 Against 0 Abstentions 2</p>
Appointed Review Protocols Not Involving Recombinant DNA	25-054	SARS-CoV-2 Propagation and Studies	Phyllis Kanki	Harvard T.H. Chan School of Public Health (HSPH)	<p>This new protocol aligns the lab's SARS-CoV-2 research with the updated CDC and NIH guidance, following the virus's reclassification from RG3 to RG2. There are no changes to the scientific objectives or methods. The lab will continue to investigate coronavirus biology to improve public health interventions, using standard techniques such as qPCR, protein analysis, imaging, and flow virometry. Biosafety levels are assigned according to the EHS Biosafety Research Matrix. Material transport will adhere to an EHS-approved SOP. The project does not employ recombinant DNA tools or animal models; therefore, NIH Guidelines do not apply. Different virus isolates will not be cultured contemporaneously at any point. Occupational health considerations apply for some organisms. Work will be conducted under BL1, BL2, or BL2+ containment per COMS policies and institutional biosafety manuals.</p> <p>The scientific reviewer presented their review.</p> <p>The committee discussed the project. Members discussed the definition of BL2+ and that propagation of SARS-CoV-2 is completed under BL2+ containment. Members reviewed the approval letter for stipulations on occupational health and restriction of co-culturing. A motion was made to approve the project. The committee voted.</p> <p>Approved 19 Against 0 Abstentions 1</p>
Standard Review Protocols Involving Recombinant DNA	20-050-A06	HBS Life Lab Projects - Tissue and Cell work	Adam Cohen	Harvard Business School (HBS)	<p>This amendment adds a new company to develop T-cells targeting cancer. The group will use human cell lines, human blood, and lentiviral vectors targeting knockdown of oncogenes or introduction of tumor suppressors. This work falls under NIH Guidelines categories III-D and III-F, and will be conducted under BL2 containment per COMS policies and institutional biosafety manuals.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted.</p> <p>Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving Recombinant DNA	21-066-A52	2021 Renewal: Engineering cellular and viral vectors for in vivo delivery	George Church	Wyss Institute	<p>The lab studies new approaches to therapeutic gene, RNA, and protein delivery by engineering viral packaging proteins to incorporate traditionally non-viral cargoes, including mRNAs, non-coding RNAs, and proteins. This amendment is to add human cell lines to the already approved list of human cell lines for in vitro and in vivo work. No new procedures are being added and the work can be safely done following BL2 and BL2-N procedures and practices. This work falls under III-D and III-E of the NIH Guidelines.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted..</p> <p>Approved 20 Against 0</p>

					Abstentions 0
Standard Review Protocols Involving Recombinant DNA	23-039-A50	Church Lab NRB COMS: Transformative Molecular Technologies	George Church	Harvard Medical School (HMS)	<p>The amendment adds two human cell lines for previously approved research described in the protocol. The epithelial cancer cell line will be utilized in ongoing gene editing studies involving nickase-based techniques. The research will explore the silencing, inhibition, knockout, or overexpression of endogenous genes related to DNA damage and the innate immune response using siRNA, CRISPR-based methods, gene delivery via plasmids, second-generation lentiviruses, PiggyBac transposons, or mRNA. A neuroblastoma-derived cell line will be used to investigate the overexpression of genes involved in transcription regulation and cellular stress responses using similar delivery methods. None of the targeted genes are classified as high-risk. Experiments with human cell lines must be conducted at BL2. This work falls under III-D, III-E, and III-F of the NIH Guidelines.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving Recombinant DNA	23-053-A03	Sample preparation for in situ characterization.	Richard Walsh	Harvard Medical School (HMS)	<p>The amendment adds the analyses of a frozen, genetically modified human cell line infected with herpes simplex virus 1 (HSV1) at the core facility. The core will take all necessary precautions and handling of the material will follow BL2 practices. The work falls under III-F of the NIH Guidelines.</p> <p>The committee had no comments or questions about this project.. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving Recombinant DNA	23-136-A09	Center for Nanoscale Systems (CNS) Biological Sample Prep Facilities	David Bell	Harvard Faculty of Arts and Sciences (FAS)	<p>The amendment adds human vascular cells to the protocol. This work falls under NIH Guidelines category III-F, and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving Recombinant DNA	24-001-A05	Antimicrobial Resistance: Imaging-based diagnostics and mechanism 2024	Johan Paulsson	Harvard Medical School (HMS)	<p>This amendment adds new microorganisms to study antibiotic resistance with the goal to develop new treatments. The amendment adds new organisms (<i>Borrelia burgdorferi</i>, <i>Clostridioides difficile</i>, <i>Candida albicans</i>, <i>Candida auris</i>, <i>Mycobacterium smegmatis</i>) and rDNA work to label and knock-down endogenous genes. This work falls under NIH Guidelines categories III-D and III-E, and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. Some organisms have occupational health considerations or more stringent disinfection requirements.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving	25-051	Dynamic Proteomics in Living Cells	Galit Lahav	Harvard Medical School (HMS)	<p>This is a 5-year renewal to study DNA damage and repair pathways in mammalian cells. The lab works with non-pathogenic bacteria and yeast, murine and mammalian cells, human and non-human primate cells, and lentiviral vectors to express and disrupt</p>

Recombinant DNA					<p>a variety of genes involved in the p53 pathway, DNA repair, cell cycle regulation, apoptosis, cell death reporters, and others (such as reporters and fluorescent tags). This work falls under NIH Guidelines categories III-D, III-E, and III-F, and will be conducted under BL1, BL2, and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Involving Recombinant DNA	25-060	Olfactory processing in mice 2025	Venkatesh Murthy	Harvard Faculty of Arts and Sciences (FAS)	<p>This is a 5-year renewal. They have added no new agents but have made corrections to list everything in the proper place. Agents have been checked against newer protocols to confirm that no biosafety levels or safety stipulations have changed or been added. The lab uses volatile odorants to understand how mice behavior is influenced. They also use viral vectors for labeling and tracing neuronal cells. No high-risk genes are involved in this work. This work falls under NIH Guidelines categories III-D, III-E, and III-F, and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals.</p> <p>The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 20 Against 0 Abstentions 0</p>
Standard Review Protocols Not Involving Recombinant DNA	24-121-A02	Infection and Inflammation 2024-2029	Ruaidhri Jackson	Harvard Medical School (HMS)	<p>The lab focuses on identifying novel regulators of the immune system's response to infection inflammation and mucosal immunity. This amendment covers the addition of a new virus and two hormones for the mice pregnancy process. The hormones hCG and PMSG (not COMS-regulated material) will be used for hyperovulation and timed pregnancy in female mice. Influenza virus A strain PR8 will be used in both in vivo and in vitro studies already approved in the protocol. The virus may be safely handled under BL2/BL2-N containment with the risk of aerosolization minimized by using a biosafety cabinet and aerosol proof rotors. No recombinant work is planned, and NIH Guidelines do not apply.</p> <p>A voting member left the meeting before the discussion. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 19 Against 0 Abstentions 0</p>

### 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**

There were no new policies or procedures to discuss at this meeting.

## **Reported Incidents**

Members were informed of one incident from 6/6/2025, its risk assessment, and the corrective actions taken to prevent further occurrence.

Title: Sharps Injury

Summary: A researcher sustained an injury from a glass needle used to place commercially available heparin coated agarose beads near human cells. The researcher went to grab some Kimwipes during clean up and did not notice the needle placed nearby. Upon removal of the glove and inspecting the injury, the researcher detected a small drop of blood. The researcher washed with soap and water, put on an antibiotic, and then went to the urgent care center. An Occupational Health physician was consulted on the course of treatment.

Corrective Actions:

- Re-training staff on the importance of glove integrity checks and sharps safety
- Reviewing the laboratory emergency response guidance document periodically
- Completing an injury claim report as soon as possible following an injury

Notification: This incident was reported to COMS. This incident does not require reporting to NIH.

## **Old Business**

There was no old business to discuss at this meeting.

## **New Business**

### **2026 COMS Meeting Schedule**

The new 2026 COMS Meeting schedule was provided to committee members.

### **Training Articles of Interest:**

Three publications were shared with the committee for training purposes as follows:

1. Introduction to Biosafety and Biosecurity for Potential Pandemic Pathogens and Dual-Use Research of Concern
2. Chinese Nationals Charged with Conspiracy and Smuggling a Dangerous Biological Pathogen into the U.S. for their Work at a University of Michigan Laboratory
3. Alien from Wuhan, China, Charged with Making False Statements and Smuggling Biological Materials into the U.S. for Her Work at a University of Michigan Laboratory

## **Public Comments**

There were no public comments.

## **Adjournment**

The meeting was adjourned at 11:10am.