COMS meeting on 9/19/2025
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: 26
Total Needed for Quorum: 10
Total Present at Call to Order: 29
Members Arriving After Call to Order: 0
Total Guests and Members of Public: 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) • R. Colgrove (IBC Member) • M. Dorf (IBC member) • L. Gamer (IBC member) • J. Kirby (IBC member) • T. Kwan (Local Non-Affiliated Member)	• R. Lee (IBC member) • M. Melisi (Biosafety Officer) • S. Mohr (IBC member) • B. Neugeboren (IBC member) • M. Nilsen (IBC member) • J. Park (IBC member) • R. Polak (IBC member) • K. Pritchett-Corning (IBC member)	• A. Reid (Biosafety Officer) • J. Sixsmith (IBC member) • D. Tipper (Local Non-Affiliated Member) • Thomas Winters (IBC member)
Ex-Officios		
• B. Corning	• M. Corrigan	• S. Estime
• M. Schatz		

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 5/30/2025	Yes	Link
COMS meeting on 6/20/2025	Yes	Link
For 14 Against 0 Abstain 1		

Scheduled Business

Type	COMS #	Title	PI	Institution	Motion
Appointed Review Protocols Involving	21-086-A15	Presynaptic Mechanisms	Pascal Kaeser	Harvard Medical School (HMS)	This amendment adds details on behavioral studies for mice injected with AAV vectors containing the alpha-synuclein gene or alpha-synuclein preformed fibrils. No new COMS regulated material is being added. The work falls under category III-D of the NIH Guidelines and will be conducted

Recombinant DNA					under BL2N-72 hours containment per COMS policies and institutional biosafety manuals. The committee discussed the project. The following will be communicated to the Principal Investigator: • Please examine a fully disposable cage for the experiment that can be disposed as biohazard waste. The availability of disposable cage liners may be more challenging to procure. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 15 Against 0 Abstentions 1
Appointed Review Protocols Involving Recombinant DNA	22-040-A06	Structural Biology of RNA Mediated Processes	Victoria D'Souza	Harvard Faculty of Arts and Sciences (FAS)	The laboratory studies RNA structure and how the structure influences mechanisms of action. This amendment adds a lab strain of HIV to be used at very low titers and low volumes in human cell lines to elucidate effects of mutations in Pol gene on transcription, and an Ebola mini-genome for the study of genome transcription and potentially clinically relevant drugs that could interfere with transcription. The minigenome has the entire coding region of the virus deleted, in the place of the viral proteins there is a reporter gene. The minigenome along with the genes provided in trans on 4 separate plasmids account for less than 2/3 of the full genome. The VP40, GP, and VP24 genes have been completely removed making the minigenome incapable of producing infectious virus. This work falls under catergory III-D and III-E of the NIH Guidelines. Work will be done at BL2 (Ebola minigenome) or BL2+ (HIV lab strain) per COMS policies and institutional biosafety manuals. The Ebola minigenome work is new. Only the Ebola genes necessary for the mini-genome work will be present in the lab. The committee discussed the following: • There is no potential for DURC with the minigenome work since the laboratory will not use the full virus, and the full genome will not be present in the lab. Although certain viral genomes are subject to the select agent regulation, this protocol is not subject to the regulations. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 16 Against 0 Abstentions 1
Appointed Review Protocols Involving Recombinant DNA	22-139-A05	Viral entry, replication, and anti-viral immunity	Jonathan Abraham	Harvard Medical School (HMS)	The laboratory conducts structural and functional studies of alphavirus receptors. This amendment adds replication-competent Una virus (UNAV) and O'nyong-nyong virus (ONNV) UgMP30 strain to study host factors using in vitro replication-based assays. These mosquito-borne alphaviruses are classified as RG2 in literature. The PI proposes to use viral envelope glycoproteins from UNAV and ONNV to generate Sindbis-based replication-competent chimeric viruses for in vitro tissue culture work with mammalian/mosquito cells. The work falls under category III-D of the NIH Guidelines and will be conducted under BL1, and BL2 containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 16 Against 0 Abstentions 1
Appointed Review Protocols Involving Recombinant DNA	23-066-A02	E muscae behavioral modification in flies 2023	Carolyn Elya	Harvard Faculty of Arts and Sciences (FAS)	The lab studies how the fungus Entomorphthora muscae affects the behaviors of Drosophila melanogaster and which host genes and cells are involved. In this amendment the lab wishes to add two new bacterial species and two new fungal species that can infect D. melanogaster. Lab will compare the behaviors of flies infected with the new generalist fly pathogens in contrast to how the flies infected with the original specialist pathogen behave. One of the new fungi expresses the fluorescent protein, GFP. The other new species are unmodified. The lab has no plans for future genetic modifications to the new species. The work can be done with BL1 precautions, III-D and III-E of NIH Guidelines apply. The committee discussed the following:

					• The work with fungus in Drosophila falls under NIH Guidelines Section III-D and will be added to the BSO Risk Assessment and approval letter. • The approval letter and BSO Risk Assessment will be revised to include NIH Guidelines Section III-D. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 1
Appointed Review Protocols Involving Recombinant DNA	24-072-A01	Physiology and evolution of brewer's yeast, Saccharomyces cerevisiae	Andrew Murray	Harvard Faculty of Arts and Sciences (FAS)	The laboratory studies experimental evolution using yeast species. The amendment adds two new yeast species that have been genetically modified previously and will be further genetically modified. One new species, Lachancea kluyveri (formerly Saccharomyces kluyveri), the BSO only found evidence for it as a human opportunistic pathogen in patients with HIV/AIDS, and is otherwise not recognized as a human pathogen. The other new species is Candida glabrata. The recombinant portion of the work falls under category III-E of the NIH Guidelines and will be conducted at BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee discussed the following: C. glabrata containment level was discussed. Occupational health representatives shared that C. glabrata can be challenging for those patients that have not just immunosuppressed conditions but other hospital conditions. C. glabrata will remain at BL2 and the new name Nakaseomyces glabrata will be added to the protocol.. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 16 Against 0 Abstentions 1
Appointed Review Protocols Involving Recombinant DNA	25-083	Population genomics of Neisseria gonorrhoeae 2025	Yonatan Grad	Harvard T.H. Chan School of Public Health (HSPH)	This is a 5-year rewrite. The group investigates the transmission, evolution, and pathogenesis of Neisseria species using molecular microbiology, genomics, and epidemiological approaches. In addition to targeted mutagenesis to study antimicrobial resistance, the PI will also employ standard chemical mutagenesis (EMS) on Neisseria gonorrhoeae, using only strains susceptible to multiple antibiotics to minimize risk of generating untreatable strains. No new reagents will be introduced; all listed strains have prior COMS approval. Genetic studies in nonpathogenic strains are for evolutionary context, and not expected to increase pathogenicity. This work falls under categories III-D, III-E, and III-F of the NIH Guidelines and will be conducted at BL1 and BL2 per COMS policies and institutional biosafety manuals. All necessary permits and documentation for acquiring Neisseria will be obtained. Some agents require consultation with occupational health to be offered. The committee discussed the following: • The occupational health knowledge on resistance profiles to N. gonorrhea agents in the laboratory and how to access information off-hours. A post-exposure plan was discussed that may include meeting with the laboratory and reviewing the antibiotic resistance profile of the agents in use in the laboratory. • The approval letter does include requirement for maintaining a list of those resistant strains. The laboratory will not develop pan resistance strains. All strains will be susceptible to at least two antibiotics. The personnel must be trained to carry the approval letter and list of strains help educate the covering physician in an exposure response. • The clinical isolates must be clearly identified to not be Neisseria meningitidis. N. meningitidis will be screened out. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 1
Appointed Review Protocols	25-094	BSL3 - Growth, virulence,	Sarah Fortune	Harvard T.H. Chan School of	A member associated with this study was placed in a Zoom waiting room during the discussion and vote.

Involving Recombinant DNA		antibiotic susceptibility and host responses in Mycobacterium tuberculosis		Public Health (HSPH)	This 5y rewrite introduces no new materials. It covers BL3 work with Mycobacterium tuberculosis (Mtb) strains, including clinical isolates, established laboratory strains, and other members of the Mtb complex. No multidrug-resistant strains are used; all strains remain drug-susceptible. Bacteria are genetically modified and analyzed both in vitro and in vivo in mice. Human specimens infected with Mtb or human immunodeficiency virus (HIV) and Non-Human Primate (NHP) materials infected with Mtb or Simian Immunodeficiency Virus (SIV) are used, and Mtb+ HIV co-infection studies are performed. The work falls under categories III-D, III-E, III-F of NIH Guidelines and will be conducted under BL1, BL2, BL2+ and BL3 containment per COMS policies and institutional biosafety manuals. Stipulations are outlined in the approval letter. The committee discussed the following: • Biosafety manual and BL3 training were discussed. • Some Category 2 concerns of gain of function was noted. However, this was reviewed by both the laboratory and has been externally evaluated to fall outside of scope of gain of function regulations. • Following the meeting, ~~t~~the protocol summary, approval letter and BSO RA will be sent externally for review. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 1 A member associated with this study was brought back into the meeting after the discussion and vote.
Appointed Review Protocols Involving Recombinant DNA	25-096	Dissection of essential, stress response and virulence genes in Mycobacteria	Sarah Fortune	Harvard T.H. Chan School of Public Health (HSPH)	A member associated with this study was placed in a Zoom waiting room during the discussion and vote. This is a 5y rewrite. The lab continues to investigate host genes and pathways affected by Mycobacterium tuberculosis (Mtb) and the mechanisms by which the pathogen survives and replicates under immune and antibiotic pressures. Research under this protocol will be limited to BL1 and BL2 strains of Mycobacterium, E. coli, human cell lines, transgenic mice and materials derived from TB-negative human and non-human primates (NHPs). No Mtb-positive samples are involved. Genetic modifications are limited to well-characterized strains and genes involved in basic immunological or metabolic functions, not known to confer increased risk to laboratory personnel or the environment. This work falls under NIH Guidelines sections III-D, III-E, III-F and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. Occupational health requirements and other applicable stipulations have been outlined in the approval letter. The committee discussed the following: • The laboratory provided data on clinical samples that included testing and filtration for safe use at BL2 containment. • The committee discussed the appendix for BL2 with additional stipulations. • No concerns of gain of function were noted. This was reviewed by both the laboratory and has been externally evaluated to fall outside of scope of gain of function regulations. • Following the meeting, the protocol summary, approval letter and BSO RA will be sent externally for review. The following questions will be communicated to the PI. • Please include documentation of the work deemed not gain of function to be conducted at BL2. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 1

					A member associated with this study was brought back after the discussion and vote of this protocol.
Standard Review Protocols Involving Recombinant DNA	21-059-A07	Investigation of Chromatin-Mediated Mechanisms in Cancer	Brian Liau	Harvard Faculty of Arts and Sciences (FAS)	The lab is trying to understand how chromatin-mediated mechanisms in cancer cells can be used as therapeutic targets. This amendment adds new high-risk (oncogenic) gene targets to their current list of targets to be used in 3rd generation lentiviral vectors in cell culture. These new targets may be knocked out, mutated or over-expressed. They will produce viral vectors and then use them to infect cells. The lab already uses similar genes. The work falls under categories III-D and III-E of NIH Guidelines and will be conducted under BL2 with additional stipulations per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	21-065-A08	Regulation of protein synthesis and quality control	Susan Shao	Harvard Medical School (HMS)	This amendment adds human and mammalian cell lines to study protein synthesis and degradation pathways. For functional studies, CRISPR guide RNAs will be delivered using a 2nd generation lentiviral vector system for stable expression or ribonucleoprotein (RNP) complexes for transient, non-viral genome editing. The targeted genes are not considered high-risk for tumorigenicity. This work falls under categories 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. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	21-099-A31	HBS Life Lab Projects 2021-2026	Adam Cohen	Harvard Business School (HBS)	This amendment adds new companies and projects to the protocol. The new work will involve commercially available human saliva to test disease detection markers, lentiviral vector work in human and mouse or pig cells to develop a reporter system for genes involved in drug addiction, and non-pathogenic Escherichia coli and Saccharomyces cerevisiae to grow plasmids. This work falls under categories III-D and III-F of the NIH Guidelines, and will be conducted under BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	21-119-A05	Characterization of substrates of human granzymes	Judy Lieberman	Harvard Medical School (HMS)	This amendment will add new viruses and cell lines to study innate immunity to virus infection. The amendment adds human cytomegalovirus (HCMV) containing fluorescent proteins, influenza H1N1 and H3N2, a cell line containing latent Epstein-Barr virus, and human and mammalian cell lines to propagate the viruses and to test the innate immunity of infection. This work falls under category III-D of the NIH Guidelines and will be conducted under BL1 and BL2 per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	21-143-A03	AAV transfection protocol for brain studies	Jeff Lichtman	Harvard Faculty of Arts and Sciences (FAS)	The lab works to map the connections in the brain and nervous system. This amendment adds intramuscular AAV vector injections along with their already approved AAV vector brain injections. They will only use reporter and Cre constructs, no high-risk gene work. The work will be done at BL1/BL1-N per COMS policies and institutional biosafety manuals, and falls under category III-D of NIH Guidelines. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18

					Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	22-078-A04	Parasitic specialized protein synthesis pathway	Melissa Leger-Abraham	Harvard Medical School (HMS)	The lab employs genetic manipulation of Babesia divergens (Rouen 1987) to study genes encoding a putative apicoplast transporter. This amendment is to add N-terminal tags (eg., HA tag), serine-glycine linkers, and protease cleavage sites (3C or TEV) to the transporter using the approved pFEGFP plasmid vector. Additionally, cryo-EM/cryo-ET will be used on lysed Babesia and Plasmodium parasites to visualize their organelles at high resolution. Locations for rapid freezing (cryo-plunging) and imaging have been included. The work falls under categories III-D, III-E and III-F of NIH Guidelines and will be conducted under BL2 containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	22-079-A04	Epigenetic regulation of gene expression in development, ageing, cancer and neural function	Yi Zhang	Harvard Medical School (HMS)	This amendment adds spermatogonial stem cells from transgenic mice to study mechanisms controlling sperm cell production. The cells will contain fluorescent markers. This work falls under category III-D of NIH Guidelines and will be conducted under BL1/BL1N containment according to COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	23-039-A58	Church Lab NRB COMS: Transformative Molecular Technologies	George Church	Harvard Medical School (HMS)	The lab is amending to add bacteriophages (T4 and Mu) and bacterial contractile injection systems (CISs), protein complexes resembling bacteriophage tails, as novel vehicles for therapeutic delivery. Non-pathogenic E. coli will be used for producing these protein complexes, genetically reprogramming them to load new therapeutic cargos and target defined cell types such as HEK293T cells. Bacteriophages T4 and Mu will be used to deliver therapeutic cargos. This work falls under the categories III-E and III-F of NIH Guidelines and will be conducted under BL1 and BL2 containment according to COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	23-063-A01	Optical examinations of the processes coordinating bacterial growth, shape, and division, and how the rates of these processes are coordinated.	Ethan Garner	Harvard Faculty of Arts and Sciences (FAS)	The lab studies the bacterial cell wall to understand how it assembles and functions. This amendment adds various strains of Staphylococcus aureus wild type and with various antibiotic resistance genes. The work falls under category III-D of NIH Guidelines and will be conducted under BL2 and BL2 with additional stipulations containment according to COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	23-136-A10	Center for Nanoscale Systems (CNS) Biological Sample Prep Facilities	David Bell	Harvard Faculty of Arts and Sciences (FAS)	This protocol covers all biological work conducted in the Center for Nanoscale Studies (CNS). The CNS facilities are used for preparation of and all types of imaging of biological samples. It is a shared use facility by both Harvard and Non-Harvard users. The amendment adds one new human cell line for atomic force microscopy (AFM) measurements, and green fluorescent protein mRNA that will be manufactured via in vitro transcription and encapsulated in lipid nanoparticles (LNP) in an external lab, which will then be suspended in buffer and brought to this lab (CNS), where they will be undergo dynamic light scattering analysis. The work falls under category III-F of NIH Guidelines and will be conducted under BL1

					and BL2 containment according to COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	24-016-A03	Tissue Stem Cells and Regeneration: 2024	Amy Wagers	Harvard Faculty of Arts and Sciences (FAS)	The lab studies stem cells that mediate the generation and regeneration of blood and muscle cells. In this amendment they seek to add several new human cell lines and the yeast Saccharomyces cerevisiae. They also updated the protocol to add E coli to the rDNA Section. Stipulations for lentiviral vector work are updated. The work falls under categories III-D, III-E and III- F of NIH Guidelines and will be conducted under BL1 and BL2 containment according to COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	24-121-A04	Infection and Inflammation 2024-2029	Ruaidhri Jackson	Harvard Medical School (HMS)	The overall goal for the Jackson Lab is to identify novel regulators of the immune response to infection, inflammation and mucosal immunity. This amendment includes the addition of new study personnel, several transgenic mouse strains, and a new bacterial agent. Listeria monocytogenes will be used in animal studies in which mice are exposed to inflammatory mediators. The work will be conducted under BL1-N and BL2/BL2-N containment per COMS policies and institutional biosafety manuals. NIH guidelines III-F apply. Occupational health stipulations apply for handling of some organisms. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-034-A01	Mechanisms of Aging and Associated Dysfunction	David Sinclair	Harvard Medical School (HMS)	The lab is amending to add two established human cells and one primary human cell line to the protocol for already approved experiments. Established colon cells will be transduced with lentiviral vectors previously approved in the protocol. These cells will be used in mouse xenografts to study cancer/tumor growth. Because lentiviral work (2nd and 3rd generation) includes overexpression of high-risk genes, additional stipulations apply, as previously described in the protocol. The work falls under the NIH guidelines sections III-E and III-D and BL2/BL2-N containment applies. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-047	HMS Single Cell Core	Mandovi Chatterjee	Harvard Medical School (HMS)	This is a new COMS protocol for a departmental core facility that studies single cell and spatial transcriptomics. The protocol covers a variety of human, non-human primate, mouse, and insect tissues, cell lines, and primary cells. This falls under section III-F of the NIH Guidelines, and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. The lab has confirmed that they will not work with samples requiring higher containment. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-059-A01	Analysis of immunometabolic responses, lipids and organelle	Gökhan Hotamisligil	Harvard T.H. Chan School of Public Health (HSPH)	The lab studies fatty acid binding proteins in metabolic diseases, in the context of obesity and insulin resistance. This amendment expands LNP-mediated delivery to include tagged mRNAs for endogenous metabolic regulators such as fatty acid-binding proteins FABP4 and FABP5, in addition to the previously approved therapeutic antibodies. mRNAs are synthesized off-site through cell-free in vitro transcription and will be

		biology in metabolic diseases			introduced in mammalian cells (in vitro) and mice strains (in vivo) to investigate metabolic pathways and protein localization. Proteins may be tagged for visualization or mutated to enhance or reduce function. Proposed work falls under categories III-D and III-E of NIH Guidelines and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-073	Molecular genetic and biochemical characterization of interactions between SARS-CoV-2 proteins 2025	John Mekalanos	Harvard Medical School (HMS)	This is a 5-year rewrite with no changes to scientific research. The objective is to study SARS-CoV-2 S and 3a gene variants by expressing synthetic constructs in nonpathogenic E. coli, Sf9 insect cells (via baculovirus), or mammalian cells (via non-viral vectors) to purify tagged proteins and assess their effects on innate immunity, cytokine production, and cell death. Blood from COVID-19 convalescent patients is utilized for antibody studies. Antibody genes from sorted B cells will be cloned and expressed in E. coli. The described work falls under NIH Guidelines sections III-D, III-E and III-F and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-089	Signal Transduction Mechanisms in S. cerevisiae	Elaine Elion	Harvard Medical School (HMS)	This is a 5-year rewrite. No changes have been made to the protocol. Activities include only storage of bacteria (non-pathogenic E. coli) and yeast (S. cerevisiae, Candida glabrata, Kluyveromyces lactis) and sharing/shipping strains. Storage and packaging for shipment will be under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. Sections III-F and III-E of the NIH Guidelines apply. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-090	Immune Responses in Infection and Disease	Ruth Franklin	Harvard Medical School (HMS)	The laboratory's research focuses on how the immune system responds to infection and inflammation, and its role in promoting tissue repair and survival following injury or inflammation. The lab employs both in vitro and in vivo methods in their protocol which include the use of human cell lines, genetically modified murine cells lines, and murine tissues, blood, cells, and fluids. Mice are exposed to Influenza A (WSN/33/PR8 strain), Streptococcus pneumoniae and other agents to evaluate immune responses. Viral vectors (3rd generation, replication incompetent lentivirus, adeno-associated viral vectors (AAV)) encoding murine specific CRISPR library guides will be used in mice to knock down genes involved in differentiation of different cell types of the respiratory tract. 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 containment per COMS policies and institutional biosafety manuals. Some agents require a consultation with occupational health be offered. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-092	Using lentivirus to study pancreatic beta cell biology	Peng Yi	Joslin Diabetes Center	The lab will conduct research to understand the mechanism of pancreatic beta cells regeneration and replication, autoimmunity against beta cells and try to find a way to protect beta cells from autoimmune attack. This work falls under sections III-D and III-E of the NIH Guidelines and work will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals.

					The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-095	Analysis of Biofluid Metabolites in the Analytical Chemistry Core	Michael James	Harvard Medical School (HMS)	This is a new registration for the Analytical Chemistry Core (ACC) at HMS to receive biological samples from non-Harvard entities. All biological materials such as supernatants from bacterial and mammalian cell cultures; will be handled exclusively by Core staff, following biosafety protocols for Liquid Chromatography-Mass Spectrometry (LC-MS) analysis. Incoming materials will be evaluated and accepted only after a consultation with the Core Director. The work falls under section III-F of the NIH Guidelines and will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-097	Mechanisms of Intracellular Bacterial Pathogen Infection	Darren Higgins	Harvard Medical School (HMS)	This 5-year rewrite continues research on Listeria monocytogenes virulence and immune responses using mouse models and in vitro systems. A new objective seeks to identify L. monocytogenes genes that respond to serum albumin and define their role in pathogenesis. The lab works with wild type and attenuated Listeria monocytogenes strains. Targeted deletions designed to reduce bacterial virulence are generated via allelic exchange using E. coli vectors to introduce in-frame deletions of virulence genes. Other biomaterials include human cell lines, Non-human primate cell lines, murine cell lines, and murine tissues extracted from infected mice. The work falls under NIH Guidelines sections III-D, III-E and III-F and will be conducted under BL1/BL1-N and BL2/BL2-N containment per COMS policies and institutional biosafety manuals. Occupational health stipulations apply for some organisms. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-098	Applying human stem cell technologies to the study of diabetes through the use of recombinant DNA, genome editing, and lentiviral vector systems	Douglas Melton	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year renewal with no changes. The lab works to develop new treatments for diabetes using stem cell technologies. The protocol includes the use of BL1/BL1-N and BL2/BL2-N materials, and the work falls under NIH Guidelines sections III-D, III-E and III-F. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-101	2025 Molecular assessment of the papillomaviruses, their cellular targets, and HPV-mediated immortalization	Peter Howley	Harvard Medical School (HMS)	This protocol is a 5-year rewrite with no changes made. The Lab continues to investigate the molecular biology of papillomaviruses aiming to understand their role in human cancers and how the virus evades the immune system. Standard molecular techniques are utilized to overexpress or knock out subgenomic elements and proteins encoded by the papillomavirus, including high risk oncogenes. The protocol covers work with replication incompetent viral vectors (3rd generation lentiviral vectors, amphotropic murine retroviral vectors), plasmids cloned and propagated in E. coli, siRNA and the use of Sendai virus in cell culture studies. Work will be conducted under BL1, BL2 and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals. The work falls under sections III-D, III-E, and III-F of the NIH Guidelines. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted.

					Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-105	Patterning and morphogenesis of the vertebrate embryo	Clifford Tabin	Harvard Medical School (HMS)	This is a 5-year rewrite for the lab with no changes.The group will continue to study development through recombinant techniques. Plasmids and electroporation or avian leukosis virus (ALV) are used to introduce genes of interest (e.g. genes involved in embryonic and limb development) into experimental organisms and cell lines (mouse, fish and bird). Work includes plasmid propagation in non-pathogenic E. coli, plasmid transformation in cells and animals, and transduction of cell lines and animals with ALV vectors carrying genes of interest. Aquatics water waste must be treated with bleach prior to drain disposal (10% final dilution for 20 minutes). The work falls under NIH Guidelines III-D, III-E, III-F and will be conducted at BL1/BL1-N practices per COMS policies and institutional bioasfety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Involving Recombinant DNA	25-109	Regeneration and embryonic development in aquatic invertebrates	Mansi Srivastava	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year rewrite protocol. The lab will continue to study animal regeneration mechanisms. Hofstenia miamia and Nematostella vectensis are aquatic invertebrates used in the study. Non-pathogenic E. coli is used for plasmid amplification. Genes from Hofstenia and Nematostella cloned into plasmid vectors are used for creating transgenic worms. BL-1 practices per COMS policies and institutional biosafety manuals are adequate for this work. The work falls under sections III-F and III-D of the NIH Guidelines. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	20-235-A27	Use of novel biomaterials for developing cellular and molecular therapies against infectious and oncogenic diseases	David Mooney	Wyss Institute	The lab studies various biomaterials (e.g. hydrogels) to physically and temporally control the interaction of cells and tissues with bioactive molecules such as cytokines, immunogens, and cell surface proteins; studies are applicable for tissue engineering and regeneration, cancer immunotherapy and vaccination development. This amendment adds Pancreatic Ductal Adenocarcinoma (PDAC) human cell line, patient-derived pancreatic tissue, E. coli nissle and KPC mouse pancreatic ductal carcinoma mouse cell line. The work will be conducted under BL1 and BL2 containment per COMS policies and institutional biosafety manuals. No NIH Guidelines apply. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	21-107-A51	Discovery of New Biosynthetic Pathways and Enzymes 2021	Emily Balskus	Harvard Faculty of Arts and Sciences (FAS)	The lab studies bacteria to find new clinically useful metabolites, pathways to synthesize the metabolites, and new chemical transformations. This amendment adds 9 new strains to be used in Phage Induction Tests. The work will be conducted at BL1 and BL2 per COMS policies and institutional biosafety manuals. No NIH Guidelines apply. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	24-029-A29	Pathogen induced mechanisms of neuronal activation	Isaac Chiu	Harvard Medical School (HMS)	The lab investigates the role of the nervous system in antimicrobial host defense and inflammation. This amendment includes the addition of two new bacterial strains, an additional source for an already approved bacteria (Lactobacillus rhamnosus), and the use of an additional room for animal work. Lactobacillus casei and Streptococcus sanguinis will be used in animal experiments designed to manipulate the oral microbiome to study the contribution of different bacteria to dental pain and inflammation. All work

					will be conducted under BL1/BL1-N or BL2/BL2-N per COMS policies and institutional biosafety manuals. NIH Guidelines do not apply. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	24-090-A01	working with NHP tissue & AAV injections	Marge Livingstone	Harvard Medical School (HMS)	This amendment adds the use of exempt quantities of tetrodotoxin. The toxin will be used in non-human primates to study the function of the visual system. No NIH Guidelines apply and work will be conducted at BL2 and BL2N per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 18 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	25-085-A01	Engineering Fluorescent Proteins 2025	Adam Cohen	Harvard Faculty of Arts and Sciences (FAS)	The lab studies the physiology of cells and creates fluorescent reporters for different cellular activity. To test some cellular activities, they use toxins to elicit or suppress a fluorescent response. This amendment adds exempt quantities of botulinum toxin to their protocol for use in mice. They will store the toxin in a locked location. No NIH Guidelines apply. All work with the toxin will take place in designated BL2/BL2-N lab space following COMS policies and institutional biosafety manuals. They will follow all documentation requirements. The lab will keep their stocks below the exempted quantity. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 Abstentions 0
Standard Review Protocols Not Involving Recombinant DNA	25-103	FRSEMR 24Q Biology of Symbiosis	Colleen Cavanaugh	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year rewrite. No changes have been made to the protocol. This undergraduate teaching lab will continue to explore microbial symbiosis by microscopy observations of several materials in the lab. Materials include cultured non-pathogenic E. coli, lichens collected around campus, and Rhizobium leguminosarum cultured with pea seeds. These materials can be safely handled following BL1 practices described on COMS policies. For microbes collected from the surface of student's tongues, BL2 practices will be followed. Eye protection and gloves should suffice for all steps during the collection and handling of the tongue microbial samples. Students should avoid the use of sharps whenever possible. No NIH Guidelines apply. The committee had no comments or questions about this project. A motion was made to approve the project. The committee voted. Approved 17 Against 0 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
Retiring of the Risk Assessment Policy
The committee approved to retire this policy as the information is now contained in the Protocol Review policy. The committee had no comments or questions. A motion was made to approve the retiring of the policy. The committee voted.
Approved: 18
Against: 0
Abstentions: 0

Reported Incidents

Committee members were presented with and informed of two incidents from August 2025, the risk assessment, and the corrective action taken to prevent further occurrence.

Incident #1
Title: Near Miss
Summary: On 8/15/2025, there was an instantaneous power fault from the Eversource tie line that affected Harvard's BL3 facilities. Medical Area Total Energy Plant (MATEP) power supply picked up the full Eversource load to compensate for the lost supply. No one was present in the BL3 laboratories at the time of the incident and materials were appropriately secured and stored.

Corrective Action: Systems worked as expected to compensate for a loss of power by one of the campus electrical providers. The school will continue to verify appropriate triaging of events and ensure systems function during such outages to maintain containment and safety through performance verification testing and preventative maintenance schedules.

Notification: The incident report was prepared and submitted to COMS and Boston Public Health Commission (BPHC).

Incident #2
Title: Non-Compliance and Exposure
Summary: On 8/27/2025, two researchers sustained splashes to the face with Cupriavidus gilardii while working on the open bench in a BL2 laboratory. During the accident investigation, it was confirmed that the splashes contained both wildtype and genetically modified bacteria (to express PETases and MHETases). The splash occurred when researchers were filtering supernatant that had already been filtered through a 0.45 µm filter and was being further filtered through a 0.22 µm filter. Personnel decontaminated the lab bench, removed personal protective equipment (PPE), and washed their faces with soap and water and rinsed for 15 minutes. They later reported the incident to the lab manager, who provided the contact information for the occupational health vendor. No open cuts, wounds, or broken skin, and no contact to the eyes, nose, or mouth were noted by either researcher as proper PPE was worn. The work on the open bench was a deviation from the operational plan and IBC requirements for use of a biosafety cabinet during work with splash potential at BL2. The genetic modification of Cupriavidus gilardii had not been submitted to the IBC for evaluation and approval, indicating noncompliance with the NIH Guidelines.

Corrective Actions: Termination of the project involving the noncompliance. Review and revision of training and COMS registration procedures in collaboration with Life Lab, EHS, and COMS.

Notification: This incident was initially reported to COMS, BPHC, and NIH OSP for the exposure and noncompliance in accordance with required timelines. A formalized report was sent to each entity after the Sept 19, 2025 COMS meeting.

Old Business
There was no old business to discuss at this meeting.

New Business.

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

1. Personnel Exposure Studies to Multi-Source Diffusion of Bioaerosols Under Biosafety Laboratory - Level 2 Plus Operating Conditions
2. Reintroduction of the BIOSECURE Act: Potential Impact on the Biotechnology Industry
3. NH Publishes Plan to Drive Gold Standard Science
4. Exclusive: NIH Schemes To Keep Risky Viral Research Alive Despite Trump Crackdown
5. Herpes B Virus Occupational Exposures and Diagnostics
6. An Ancient Influenza Genome from Switzerland Allows Deeper Insights into Host Adaptation During the 1918 Flu Pandemic in Europe
7. NIH Kicks Off Yearlong Effort to Modernize Biosafety Policies

NIH Regional Meetings:
Committee members were informed that NIH will be hosting regional meetings to gather feedback and comments on the NIH Guidelines in preparation for modernizing their policies. The first meeting will be held on September 30th, 2025 from 2pm-4pm for Region 1. Committee members were informed that anyone is welcome to register to attend or provide comments to the COMS Office.

Public Comments
There were no public comments.

Adjournment
The meeting was adjourned at 12:00 PM.