COMS meeting on 7/25/2025
Minutes

Location: ZOOM
Time: 10AM - 12PM

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

Documentation of Quorum

Total Voting Members on Committee Roster: 29
Total Needed for Quorum: 10
Total Present at Call to Order: 32
Members Arriving After Call to Order: 3
Total Guests and Members of Public: 3

ATTENDEES PRESENT		
Committee Chair	**Committee Vice Chair**	
• M. Nibert	• S. Helaine	
Members		
• A. Baptista (IBC Member) • D. Barbeau (IBC Member) • S. Bhalchandra (IBC Member) • M. Dorf (IBC Member) • L. Gamer (IBC Member) • T. Kwan (Local Non-Affiliated Member) • S. Mohr (IBC Member)	• R. Lee (IBC Member) • M. Melisi (IBC Member) • B. Neugeboren (IBC Member) • M. Nilsen (IBC Member) • J. Park (IBC Member) • R. Polak (IBC Member) • R. Colgrove (IBC Member)	• R. Rasmussen (IBC Member) • A. Reid (IBC Member) • S. Santra (IBC Member) • J. Sixsmith (IBC Member) • M. Super (IBC Member) • T. Winters (IBC Member) • T. Brennan-Krohn (IBC Member)
Ex Officio Members		
• E. Mcloud	• M. Corrigan	

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
NONE		

Scheduled Business

Type	COMS #	Title	PI	Institution	Motion
Clinical Protocols	25-076	POLARIS: A PHASE 1, SINGLE DOSE, OPEN-LABEL STUDY OF GNTI-122 IN ADULTS WITH RECENTLY DIAGNOSED TYPE 1 DIABETES (T1D)	Jason Gaglia	Joslin Diabetes Center	The objective of this Phase I, open-label, multicenter study is to assess the safety and tolerability of GNTI-122; an autologous engineered Treg cell therapy, given as a single infusion with and without rapamycin in adult participants with recently diagnosed type 1 diabetes. GNTI-122 is engineered from a patient's primary CD4 T cells using CRISPR/Cas9 gene editing. It is manufactured off-site and shipped to Joslin Diabetes Center for administration only to study participants via intravenous infusion. This falls under section III-C of the NIH Guidelines, and will be conducted under BL2 per COMS policies and institutional biosafety manuals. The committee discussed the following: The clinical trial was reviewed by the Joslin IRB. The committee had no other comments or questions about this. A motion was made to approve the protocol. The committee voted. Approved:16

					Against: 0 Abstentions: 1
Appointed Review Protocols Involving Recombinant DNA	25-062	MCB121 Lab	Carolyn Elya	Harvard Faculty of Arts and Sciences (FAS)	This protocol covers work in the undergraduate, intermediate-level course MCB121-The Microbes. All students will have experience with microbial work from either LS1a/b or LS50a/b. The main objective of the course is to teach the students how to work safely with microbes performing standard techniques in greater depth than they received in their first-year courses. No minor students are expected in the class as there are a full year of pre-requisite courses to be able to enroll; however, the course head will follow all Youth Protection policies including keeping minors away from BL2 organisms, if the need arises. This protocol includes organisms with and without precedent that should be handled under BL1 and BL2 containment. The only NIH Guideline that applies is III-F for standard cloning in E. coli. The committee discussed the following: The course instructors have been educated on the requirements of the NIH Guidelines. The students will collect samples from a variety of surfaces in the environment. The committee discussed the safety and controls of personal environment sampling at BL2 containment and the risk to the students for these organisms. The committee discussed the partnership with the instructors on the protocol and future guidance to new instructors. There was general consensus to approve Streptococcus mutans at BL2 containment. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:16 Against: 0 Abstentions: 1
Appointed Review Protocols Involving Recombinant DNA	25-072	Transgenic Studies in Aquilegia, Tropaleolum , Aosa, and Arabidopsis	Elena Kramer	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year rewrite. The lab studies the evolution of floral developmental pathways in plants. The project uses non-pathogenic E. coli and Agrobacterium tumefaciens for production of plasmids used for transient and stable transformation of the plant models Arabidopsis thaliana, Aquilegia, Tropaleolum majus (nasturtium), and Aosa rupestris. T. majus and A. rupestris are new species added to the protocol. A disarmed strain of Tobacco Rattle Virus (plant virus) is used for stable transformation in these plant models. All plants will be grown in secured growth chambers. The risks of the research remain the same. The plants can be safely handled at BL-1 at the currently approved facilities. Plants will not be released into the environment; all transgenic plant materials must be autoclaved at the end of the experiments prior to disposal. This work falls under section III-E and III-F of the NIH Guidelines. The committee had no other comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:16 Against: 0 Abstentions: 1
Appointed Review Protocols Involving Recombinant DNA	25-074	Molecular Analysis of the Pathogenesis of Plasmodium and Babesia Parasites	Manoj Duraising h	Harvard T.H. Chan School of Public Health (HSPH)	This is a 5-year rewrite with no changes to scientific work. The lab investigates intracellular apicomplexan parasites including Plasmodium and Babesia species using genetic tools to identify genes critical for host cell entry and egress. Parasites are cultured in mammalian red blood cells under BL2, and in vivo studies use immunocompromised mice engrafted with these cells, requiring BL2-N when using human or primate blood. Genetic modifications include tagging, knockout, and overexpression, with phenotypic assays conducted in human cell lines and rodents. Toxoplasma gondii (occupational health stipulations apply), Cryptosporidium parvum, and Sarcocystis neurona are cultured short-term for transcriptomic studies. All work has COMS precedent and follows approved SOPs under BL2/BL2-N. NIH Guidelines (III-D, III-E, III-F) apply. USDA and/or CDC permits are required for transport of select organisms and human pathogens.

					The committee discussed the removal of the SOP from the laboratory's ERCC documentation. The committee also discussed that the potential for dangerous gain of function does not apply to this current work. The committee had no further discussion. A motion was made to approve the protocol with the changes to the SOP. The committee voted. Approved:16 Against: 0 Abstentions: 1
Standard Review Protocols Involving Recombinant DNA	21-059-A06	Investigation of Chromatin-Mediated Mechanisms in Cancer	Brian Liau	Harvard Faculty of Arts and Sciences (FAS)	The lab studies chromatin-mediated processes in cancer cells in an effort to find new therapeutic targets. This amendment adds new cancer cell lines to continue this work but does not change the nature of the work. The cancer cells will have various genes knocked out using CRISPR/Cas9. The new human cells lines will be used under BL2 containment practices when low-risk genes are used and BL2 with additional stipulations when high-risk genes are used. This work falls under the section III-E of the NIH Guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	22-003-A26	Infection in B7-Deficient Mice	Arlene Sharpe	Harvard Medical School (HMS)	The Sharpe Lab focuses on determining pathways involved in immune response, predominantly using mouse models. This amendment adds the use of a new genetically modified murine cell line to previously approved work. BL1/BL1-N containment is sufficient for the handling and administration of the cells to mice, and the work falls under sections III-D and III-F of the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	22-038-A02	Experimental Evolution and Antibody Binding Assays Using Budding Yeast and E. coli	Michael Desai	Harvard Faculty of Arts and Sciences (FAS)	The lab is adding new rooms to the protocol. The rooms added will be used for DNA and RNA quantification, flow cytometry, liquid handling robot for yeast cultures. The spaces have been inspected and are adequate for previously approved biological agents listed in the protocol. The amendment also adds a new expression plasmid encoding for glycoprotein Gp120 from HIV to generate protein for binding assays. Previously approved non-pathogenic E. coli and HEK293 cells will be used for these experiments. BL2 must be used for work involving the established human cell line. Experiments with non-pathogenic E. coli can be conducted under BL-1 practices. The work falls under Section III-E and III-F of the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	22-057-A15	Lipidomic and metabolic factors that contribute to cancer growth and metastasis	Jessalyn Ubellacker	Harvard T.H. Chan School of Public Health (HSPH)	Dr. Ubellacker's lab investigates the role of specific genes in tumor growth and metastasis, with a focus on lipid metabolism and ferroptosis, using in vivo models. They employ both human and mouse-derived cancer cell lines. This amendment adds new human cancer cell lines for lentiviral transduction in ongoing experiments. All human cell lines and lentivirus must be handled at BL2. This work falls under sections III-D, III-E and III-F of the NIH Guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.

					Approved: 17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	23-132-A04	Mouse Behavior Core "Umbrella" Protocol 2024	Barbara Caldarone	Harvard Medical School (HMS)	The amendment is to add new AAV serotypes encoding Cre-dependent channelrhodopsin for optogenetics experiments in mice, and to add cecal content from mice to perform microbiotic swap procedures. The work covered in this amendment can be safely performed in BL-1/BL1-N conditions. The AAV does not encode for any high hazard genes and is produced in the absence of helper viruses. Suitable disinfectant (e.g. freshly prepared 10% bleach) must be used for disinfection of AAV. Whenever possible, manipulation of AAV should be performed in a biosafety cabinet. Special precautions should be taken to avoid exposure from accidental needle sticks. The work covered in this amendment falls under Sections III-F and III-D of the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	24-005-A03	Cells, Tissues and Organoids Cultured with Soft Electronics	Jia Liu	Harvard School of Engineering and Applied Sciences (SEAS)	The laboratory integrates soft electronics with developing model organisms to study electrophysiology. This amendment broadens the research to investigate regeneration mechanisms in invertebrate models. The lab will obtain established transgenic Hydra vulgaris strains (expressing fluorescent reporter genes) from a collaborator and will use tissue fragments to monitor regenerative processes. Handling and use of transgenic H. vulgaris and its tissue can be done under BL1/BL1-N containment. This work falls under section III-D of the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	24-020-A04	Genetic Analysis of Sleep Regulation in Drosophila and mice	Dragana Rogulja	Harvard Medical School (HMS)	The Rogulja lab continues to study sleep patterns and the mechanisms of how sleep deprivation affects the body. They are updating their list of transgenic mice and expanding the AAV vectors used in mice. These vectors contain biosensor genes, recombinases, modulators of gene functions using chemical activators, and antioxidants. None of these genes are high-risk in this context. BL1/BL1-N and BL2/BL2-N standard stipulations apply. This work falls under NIH Guidelines categories III-D, III-E, and III-F. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	24-029-A28	Pathogen induced mechanisms of neuronal activation	Isaac Chiu	Harvard Medical School (HMS)	The lab focuses on investigating the role of the nervous system in mediating antimicrobial host defense and inflammation. This amendment is to cover the additions of new personnel and adeno-associated virus to its project studying innate immune-related pathways of neurodegeneration in ALS models. The lab also removed language referencing work with chimeric Sindbis virus that is no longer occurring (work with non-recombinant Sindbis virus remains). AAV.PHP.eB will carry proteins derived from human genes and be administered to mice to establish models of frontotemporal dementia. Work will be done under BL1 and BL2-N containment for the administration and handling of mice and downgraded to BL1-N housing post 72 hours. NIH guidelines III-D and III-E apply. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.

					Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	24-034-A03	Lentiviral-based Manipulation of Erythropoietic Gene Expression	Manoj Duraisingh	Harvard T.H. Chan School of Public Health (HSPH)	The Duraisingh lab uses mouse infection models and genetic techniques to investigate how apicomplexan parasites invade and develop within red blood cells. Methods previously established for Plasmodium species are being extended to include both wild-type and genetically modified Babesia species. Parasites will be cultured in human RBCs (Babesia divergens, Babesia duncani) or rodents (Babesia microti). Recombinant parasites will be generated by transfecting plasmids that express fluorescent reporters under parasite-specific promoters for downstream analysis. BL2/BL2-N is assigned to experiments with parasites and human plasma and serum. NIH Guidelines III-D, III-E and III-F apply. The committee discussed the following: This protocol involves mutagenesis of human pathogens and is an example of enhanced scrutiny for dangerous gain-of-function. There was not a concern for dGOF for this protocol. The committee discussed occupational health concerns written in the PI's 2024 standard operating procedure for Plasmodium. This study was approved with the following conditions: • PI will remove the SOP for Plasmodium from the COMS Protocol and refer to the standard procedure for seeking post-exposure care • Approval letter will not need updating The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	24-108-A09	Intestinal immune system analysis	Kazuki Nagashima	Harvard Faculty of Arts and Sciences (FAS)	This amendment adds a new viral vector, SAD19 rabies delta G, and two new mammalian cell lines. The lab will produce rabies viral vector in the new cell line B7GG to then infect a murine T cell line. These T cells will be co-cultured with a murine dendritic cell line. The viral particles produced should have the ability to first infect the T cell and then go through a cycle of reproduction to then infect the dendritic cell. Once the vector makes it to the dendritic cell it will be replication incompetent. All additions have COMS precedent, will be used at BL2 when in the presence of SAD19 Delta G rabies viral vector, and fall under NIH Guidelines III-D & III-E. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-013-A01	Decoding viral genomes	Shira Weingarten-Gabbay	Harvard Medical School (HMS)	The lab uses high-throughput methods to investigate viral open reading frames (ORFs) and translational dynamics during viral infection. This amendment introduces new plasmid backbones, vector inserts, and mosquito and human cell lines to study ribosome-organelle interactions using a biotin-based protein labeling method. Researchers will perform in vitro studies by transfecting cells with plasmids expressing short, non-infectious viral fragments. No animal work is involved. All procedures will be conducted under BL1 or BL2 conditions, following standard precautions. NIH Guidelines Sections III-D, III-E, and III-F apply. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols	25-059	Analysis of immunometabolic	Gökhan Hotamisligil	Harvard T.H. Chan School of	This is a 5-year rewrite. The lab studies metabolic diseases, with an emphasis on obesity and insulin resistance. New biomaterials include use of mRNA-lipid nanoparticles encapsulating reporters or therapeutic antibodies

Involving Recombinant DNA		responses, lipids and organelle biology in metabolic diseases		Public Health (HSPH)	in mice, human airway organoids, and commercial yeast two-hybrid systems to identify protein-protein interactions. Ongoing mouse studies involve metabolic challenges and infections (e.g., Influenza A PR8, Chlamydia pneumoniae) to assess adipose tissue function. The lab uses genetic tools including plasmids, shRNA, siRNA, mRNA, and viral vectors (AAV, 2nd and 3rd generation lentivirus, adenovirus, ecotropic murine retrovirus) for modulating genes or pathways not associated with high-risk phenotypes. Researchers study host-virus interactions using tagged SARS-CoV-2 proteins, pseudotyped lentiviruses, and comparative assays with HCoV-OC43 and HCoV-229E in human and NHP cell lines. NIH Guidelines III-D, III-E, and III-F apply, and no high-risk or replication-competent viral constructs are used. Previously assigned biosafety levels are maintained. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-061	Biological studies of novel molecules with anticancer and antibacterial properties 2025	Andrew Myers	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year renewal for #20-089. There are no new biological agents. The Myers lab tests small molecules for anti-cancer activity, measures antibiotic activity of potential new synthetic drug molecules against a variety of bacterial strains with natural antibiotic resistance or without, and tests novel antibiotics against S. aureus strains with various single and combo antibiotic resistances. They will use CRISPR/Cas9 to do genome-wide deletion screens of cancer cells for testing with synthetic antibiotics. These screens all only make transient deletions in the cells, and only a small number of cells on any deletion type. This work falls under section III-D, E, & F of the NIH *G*uidelines. The committee has determined that even when the screens delete cancer suppressing genes, the work does not rise to the level of high-risk. The committee discussed the following: • BL2+ was not required for this protocol. • Haemophilus influenzae vaccinne does not need to be offered to personnel. The BSO will make the following changes before final approval issued: • Re-write the risk assessment to align with BL2 with additional stipulations. • Update the approval letter to remove Occupational Health stipulations for Haemophilus influenzae. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:16 Against: 0 Abstentions: 1
Standard Review Protocols Involving Recombinant DNA	25-065	Studies of S. cerevisiae, S. pombe, and other yeasts	Fred Winston	Harvard Medical School (HMS)	This is a 5-year rewrite, no changes have been made to the protocol. Research focuses on understanding eukaryotic gene expression at the level of transcription and chromatin structure, which is studied in yeasts. The lab uses recombinant or synthetic nucleic acids that encode genes or fragments of genes from Saccharomyces cerevisiae, Schizosaccharomyces pombe, and possibly other organisms, including humans and non-infectious genes from RG2 viruses (e.g., surface proteins). Genes studied are considered low-risk genes. Saccharomyces bayanus is used for evolutionary studies only as it is related to S. cerevisiae. Non-pathogenic E. coli K12 strains are used for plasmid amplification and protein expression (some yeast and some human proteins). BL1 practices and procedures described under the COMS BL1 Policy must be followed for this work. This work falls under sections III-D, III-E and III-F of the NIIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17

					Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-066	Exploring How Neuronal Activity Influences Central Nervous System Developmen t	Michael Greenberg	Harvard Medical School (HMS)	The goal of this protocol is to understand how sensory experiences influence neural activity to shape the development of brain circuits in mammals, and how these processes are disrupted in neurological conditions affecting learning, memory, and cognitive function (such as autism). The protocol covers work with various human and non-human primate cells and tissues, replication incompetent viral vectors (3rd generation lentivirus, adeno-viral vectors, rabies SAD B19 delta-G vaccine strain, herpes simplex 1 viral vector, adeno-associated virus) used in cell culture and animals, and exempt quantities of tetrodotoxin. Gene targets are pathways involved in speech and language, learning, synpatic plasticity and development, and intercellular signaling. This work falls under NIH Guidelines categories III-D, III-E, and III-F and will be conducted under BL1, BL1N, BL2, BL2N (72 hours), and BL2N 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 protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-068	Portable Molecular Manufacturi ng (renew)	James Collins	Wyss Institute	This is a 5-year renewal that has an overall goal to create portable, low-cost, on-site and on-demand systems for the synthesis of pharmaceuticals, vaccines and other therapeutic proteins using freeze-dried, cell-free methodologies. The cell-free system includes lysates of non-pathogenic E. coli as a source of enzymes for transcription and translation to which are added plasmids encoding the protein of interest – after incubation, synthesized proteins are affinity purified and freeze-dried until use. BL1 and BL2 containment apply. The work falls under categories III-D and III-E of the NIH Guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-069	Planar Patch Array for Investigating In-vitro Neural Network Dynamics	Hongkun Park	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year renewal of this protocol. The lab uses planar patch clamp arrays to record from in vitro neural networks using rat cells as well as human cell lines infected with 3rd generation lentiviral vectors and AAV vectors. The vectors express optogenetically controlled fluorescent proteins. Viral vector production will take place in the lab, newer 3rd generation vectors will be purchased. Tetrodotoxin in quantities below regulated limits and one other neuronal toxin tetraethylammonium (TEA) will be used in the patch clamp assays. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-070	Transformati on of Drosophila	Welcome Bender	Harvard Medical School (HMS)	This is a 5-year rewrite. No changes have been made to the protocol and the risks of the study remain the same. The lab will continue to use Drosophila melanogaster and Tribolium castaneum transformed using various plasmids, which encode fluorescent reporter genes and/or regulatory proteins from fungi. E. coli K12 strains are used for standard plasmid cloning. The work falls under sections III-F and III-D of the NIH guidelines. ACL-1 is adequate for the maintenance and handling of these arthropods. BL-1 as per COMS policies must be followed. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted.

					Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-071	Cell Biological Studies of Signalling in Vertebrates	Adrian Salic	Harvard Medical School (HMS)	This 5-year renewal continues existing research on cell signaling and division, with no new materials or procedures. The lab uses recombinant DNA technology in E. coli, baculovirus-infected insect cells, and human cell lines to express proteins for biochemical assays. Replication incompetent lentiviral vectors are used in mammalian cells to create stable lines, express fluorescent proteins, and knock down genes using RNAi and CRISPR targeting the hedgehog/smoothened signaling pathway. A recombinant vector containing human coronavirus 229E and GFP, imported under a CDC permit, is also used to study viral infection dynamics in 293T cells. Work is conducted under BL1 or BL2 as appropriate. NIH Guidelines III-D, III-E and III-F apply. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-075	The Roles of Wnt and Hedgehog Signaling Molecules in Mammalian Embryonic Development and Oncogenesis	Yingzi Yang	Harvard School of Dental Medicine (HSDM)	This project studies how cells communicate during differentiation during embryonic development and during adulthood. The protocol covers replication incompetent viral vectors (lentiviral vectors, adenoviral vectors, adeno-associated viral vectors), human cells, and transgenic mice and cells/blood/tissues. This work falls under NIH Guidelines categories III-D, III-E, and III-F and will be conducted under BL1, BL1N, BL2, BL2N, and BL2 with additional stipulations containment per COMS policies and institutional biosafety manuals. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-077	HBS Life Lab Projects - Tissue and Cell work 2025 - 2030	Adam Cohen	Harvard Business School (HBS)	This is the 5-year rewrite for the HBS Life Labs tissue culture and cell projects. This protocol covers human and mammalian cells and tissues, both BL1 and BL2 microorganisms, lentiviral vectors to disrupt cancer cells, and plasmids to express non-toxin proteins for phage display. This work falls under sections III-D, III-E, and 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 protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-081	Glycans in Aging and Disease	Sophia Shi	Harvard Faculty of Arts and Sciences (FAS)	This is a new protocol. The research aims to uncover novel molecular mechanisms that drive brain aging and neurodegenerative diseases. The lab will study glycans, complex carbohydrates that permeate the brain's extracellular environment, in aging and disease. Human cells (primary and immortalized), murine cells and mice will be transfected or transduced with DNA plasmids, silencing RNA, or viral vectors, adeno-associated virus (AAV) in the absence of helper systems, or lentivirus for knockdown, overexpression, or interference of the target genes. Target genes include fluorescent reporters, proximity labeling reagents, gene editing (CRISPR-Cas9), glycan biosynthetic and degradation genes, glycoconjugate-associated genes and their protein partners and regulators. The viral vectors do not encode any high hazard genes. Non-pathogenic E. coli will be used for standard cloning. BL1, BL1-N, BL2, BL2-N(72) stipulations apply in accordance with COMS and institutional policies. 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 protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-084	A Novel Gene Therapy Approach for Alzheimer's Disease	Bruce Yankner	Harvard Medical School (HMS)	This is a 5-year rewrite protocol. No changes have been made. The group studies neuro-regulation and Alzheimer's disease progression. AAV in the absence of helper virus are used to deliver genes of interest fused with GFP into the brains of mice (wild type and transgenic). The vectors are packaged off-site. E. coli strains are used in the laboratory for standard cloning. BL1/BL1-N is recommended for this work. The main risk occurs during administration; sharps safety precautions will be prioritized. 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 protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-085	Engineering Fluorescent Proteins 2025	Adam Cohen	Harvard Faculty of Arts and Sciences (FAS)	This is a 5-year rewrite of this protocol. No new agents have been added.. In this project the PI is engineering fluorescent protein and optogenetic reporters to study physiological activity in cells to observe changes in membrane voltage in electrically excitable cells. The project includes the generation of transgenic Danio rerio and lab mice expressing fluorescent voltage indicators for in vivo experiments. Lentiviral and AAV vectors will be used for transfection of human cardiomyocyte cells and rat neurons expressing fluorescent and optogenetic reporters. The project also includes the use of nonregulated quantities of tetrodotoxin for treating neuronal cultures to block action potentials during in vitro imaging of rat or mouse neurons. No high-risk genes are used in this protocol. The work falls under BL1 and BL2 containment per COMS policies and under NIH sections III-D, III-E and III-F of the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Involving Recombinant DNA	25-087	LS50 Laboratory	Michael Desai	Harvard Faculty of Arts and Sciences (FAS)	This 5-year rewrite of this protocol is for the 1st year undergraduate class LS50. This class aims to teach standard molecular biology with non-hazardous microbes. Students will learn cloning in non-pathogenic E. coli and S. cerevisiae as well as basic microscopy. All rDNA work will be to first generate an antibody library in E. coli and then transform that library into S. cerevisiae. This is all work that can be done safely with BL1 lab practices. The work falls under NIH Guidelines III-E & F. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	21-106-A05	Biophysics of Chromosome Segregation and Metabolic Flux	Daniel Needleman	Harvard Faculty of Arts and Sciences (FAS)	The lab is amending the current protocol to add Tetrodotoxin (TTX) neurotoxin for in vitro experiments with murine cell lines in tissue culture. TTX is subject to The Harvard Biosafety Exempt Select Agent Toxin requirements for inventory, storage, transfer, and destruction. The maximum amount of TTX maintained in the lab must not exceed 500mg. Lab-specific SOPs must be followed. BL2 practices and procedures are required for handling TTX in the laboratory. The amendment also covers the addition of non-pathogenic E. coli and Bacillus subtilis for calorimetry and oxygen consumption experiments in vitro. These strains are well established, non-

					pathogenic lab strains and can be safely handled at BL1 in the laboratory. This work does not fall under the NIH guidelines. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	22-071-A13	Modulating Immune Responses	Jun Huh	Harvard Medical School (HMS)	The lab studies genes and molecules that play important roles in the innate and adaptive immune system in the context of inflammatory diseases and neurodevelopmental disorders. This amendment covers the addition of new study staff, a new bacterial community and the addition of a room. The hCom2 bacterial consortia is a synthetic gut microbiome community which offers a standardized model for studying the human gut microbiome and is used in mouse models of disease. The lab will be using the community in work already approved in this protocol, which includes its administration to mice. Although most bacteria in the community can be safely handled at BL1/BL1-N, the presence of some established pathogenic bacteria requires the mixture to be handled under BL2/BL2-N containment. No NIH guidelines apply. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	23-058-A03	Molecular Genetic and Biochemical Studies of Bacterial Pathogenesis and Resistance	John Mekalanos	Harvard Medical School (HMS)	The lab studies virulence of Vibrio cholerae. This amendment adds in vivo studies to examine interactions between V. cholerae and related phages using an established infant mouse model. Phages will be propagated on various V. cholerae strains purified and co-administered with V. cholerae to mice in accordance with approved infection protocols. Harvested animal tissues will be analyzed to quantify bacterial and phage levels, and to perform phage characterization. This work does not fall under the NIH Guidelines. Co-infection studies of V. cholerae and related phages require BL2/BL2-N containment with stringent measures for surface decontamination and aerosol control. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0
Standard Review Protocols Not Involving Recombinant DNA	25-024-A02	Environmental Sampling and Laboratory Processing	Hannah Healy	Harvard T.H. Chan School of Public Health (HSPH)	The Healy Lab studies pathogens and their broader microbial communities in the human-built environment, with a focus on engineered water systems. This amendment adds the use of Epstein Barr virus and the Daudi human cell line to the experiments involving wastewater surveillance. Work with these materials can be conducted under BL2 containment. Standard precautions must be taken while handling the human cell lines. No recombinant work is proposed, and NIH guidelines do not apply. The committee had no comments or questions about this protocol. A motion was made to approve the protocol. The committee voted. Approved:17 Against: 0 Abstentions: 0

Personnel Training
The PIs and their 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

BL2 Appendix – An updated version of the BL2 Appendix was shared with the committee members. The committee had no comments or questions about this updated policy. A motion was made to approve the new policy. The committee voted.
Approved:17
Against: 0
Abstain: 0

Reported Incidents
Members were presented with and informed of one incident from 7/8/2025, its risk assessment, and the corrective actions taken to prevent further occurrence.

Title: Spill/ Loss of containment:

Summary: Drosophila melanogaster were reported outside of their primary containment on 7/9/2025. Bottles of the flies were awaiting inactivation before final disposal, when the stoppers came loose from the bottles. The flies appear to have been fully contained within the laboratory, which is a room nested in a larger, main lab that is also approved for fly work. During the event, access to the room was restricted, room ventilation was turned to neutral pressure to attempt to retain flies in the space, and additional traps were added in the space and directly outside of the room. Efforts were also made to restrict fly access to fly food/other intact bottles of flies. No flies were observed in the traps added outside of the space, and the population of Drosophila within the lab declined rapidly as they gravitated to the traps in the room.

Corrective actions:
- An entomologist was consulted on the response and prevention measures.
- The lab will obtain tighter fitting caps for the bottles, tape caps that appear ill-fitting, and seal all bags awaiting inactivation before final disposal.
- Addition of a doorsweep to the fly room for added containment.

Notification: This incident was reported to COMS.

Old Business

There was no old business discussed at this meeting.

New Business

Training Articles of Interest:
One publication was shared with the committee for training purposes as follows:
- NIH suspends dozens of pathogen studies over 'gain-of-function' concerns

Public Comments
There were no public comments.

Adjournment

The meeting was adjourned at 11:24 am.