Fred Hutch Cancer Center

MINUTES OF THE FRED HUTCHINSON CANCER CENTER
INSTITUTIONAL BIOSAFETY COMMITTEE

July 23, 2026 IBC Meeting, 10:00 am, M1-A303 & MS Teams

ATTENDANCE

MEMBERS

Present	*Absent*	
☒	☐	Kevin Barry PhD, Public Health Sciences, *Member*
☒	☐	Elizabeth Cromwell, PDX Program Lead, *Member*
☒	☐	Bernadeta Dadonaite PhD, Staff Scientist, Basic Sciences, *Member*
☐	☒	Neelendu Dey MD, PhD, Clinical Research Division, *Member*
☐	☒	Michael Emerman PhD, *Community Member*
☒	☐	Marian Esvelt DVM, Associate Director, Comparative Medicine, *Member*
☒	☐	Taran Gujral PhD, Human Biology, *Member*
☒	☐	Tony Han, BSL-3/ABSL-3 Facility Manager, *Member*
☐	☒	Alex Hirayama MD, Clinical Research Division, *Member*
☒	☐	Keith Jerome MD, PhD, Vaccine and Infectious Disease, *Chairperson*
☒	☐	Michelle Gochnour MN, RN, COHN-S, *Community Member*
☒	☐	John McNevin MSc, Program Manager, Vaccine and Infectious Disease, *Member*
☒	☐	Jacqui Murray-Wijelath PhD, *Community Member*
☒	☐	Susan Parazzoli MS, RBP, Biosafety Officer, *Member*
☒	☐	Stefan Radtke PhD, Staff Scientist, Translational Science & Therapeutics, *Member*
☐	☒	Joshua Schiffer MD, MSc, Clinical Researcher, *Member*
☒	☐	Shivani Srivastava PhD, Clinical Research Division, *Member*
☒	☐	Susan Strenk, Research Technician IV, Vaccine and Infectious Disease, *Member*
☒	☐	Andrea Towlerton MSc, *Community Member*
☒	☐	Allison Zelikoff MN, RN, COHN-S, Occupational Health Manager, *Member*

NON-MEMBERS

Dagmar Achtelik, Administrative Coordinator, EH&S, *Committee Secretary*
Liz Kindred, Director, Environmental Health & Safety
Jake White, Assistant Biosafety Officer, Environmental Health & Safety
Cindy Wladyka, EH&S Specialist for Biosafety, Environmental Health & Safety

VISITORS

None

Dr. Jerome, Chairperson, called the meeting to order at 10:01 am.

I. ANNOUNCEMENTS AND UPDATES

- None

II. REMINDER FOR CONFLICT OF INTEREST

The chair reminded the committee that the NIH Guidelines, Section IV-B-2-a-(4) states: "No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest."

III. MINUTES

Minutes from the May 21, 2026 IBC Meeting were approved unanimously.
Minutes from the June 29, 2026 Special IBC Meeting were approved unanimously.

IV. REVIEW OF ACTION ITEMS FROM PRIOR MEETINGS

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*Action Item*	*Resolution*
Dey	Renewal	E226.1: Dey lab at FHCC	• Add the missing location for storage of agents. • Improve the description of erythromycin resistance in *Bacteroides* spp. • Expand the description of phages and their experimental use. • Consider the use of plastic cryovials over glass vials for agent storage.	• Agents are stored in a secure, labeled freezer in an adjacent corridor. • Erythromycin resistance in *Bacteroides* description updated. In short, erythromocin is not a first-line antibiotic, is not recommended for anaerobic infections, and all work will take place at BSL-2. • Phage infection will be used as a variable in bacteria carcinogenesis experiments. • The lab is open to using plastic cryovials. Glass vials no longer needed will be disposed of into biohazard sharps.
McGuire	Renewal	E226.4: McGuire lab at FHCC	• Containment requirements for the different non-viral expression vectors should be separated to specify BSL-1 for introduction into E.coli and BSL-2 for introduction into mammalian cells. • For viral protein expression procedure, if lentiviral transduction is used, then resulting protein supernatant should not be used at BSL-1 until sufficiently inactivated. • Statement about lab members likely having pre-existing immunity to EBV should be removed. • Both systems for generating HIV	• Containment requirements have been updated in this manner. • Procedures have been added, including complete media change after 24 hours followed by at least 5 days of culture at 37C, to substantially reduce the risk of residual virus before using supernatant for downstream assays as BSL-1. • Statement has been removed. • Both systems for generating HIV pseudovirus will be used at BSL-2+ until detergent inactivation of lysates. • Centrifuge procedures have been clarified and all spins will be in aerosol

			pseudovirus should be used at BSL-2+ until detergent inactivation of lysates. • Locations, engineering controls and spill procedures should be confirmed for etiologic agent production.	tight rotors or buckets. A spill procedure has been added.
Stephan	Renewal	E226.5: Stephan lab at FHCC	• Confocal microscopy was selected in the application but there was no description of how it would be used.	• PI responded with a 1-3 sentence description of what they are imaging, which samples, and how it relates to the described work. This was shared with the IBC reviewer who had no further questions.

V. NEW BUSINESS

Human Gene Transfer Applications

Principal Investigator:	***RG Number:***	***BSL/Precautions:***	***NIH Sections:***
Tachiki	RG1126661	BSL-2 (preparation) Contact (administration)	III-C

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The Investigational Drug Product (IDP) for this trial is a viral agent, specifically an oncolytic vaccinia virus with functional inactivation of two viral genes to preferentially allow activity in cancer cells, along with expression of three transgenes to induce immune responses in cancer cells, for treatment of people with various solid tumors.

- The virus formulation is made offsite.
- The virus formulation is received by the Fred Hutch Investigational Drug Services pharmacy and transported onsite by Fred Hutch clinical couriers. The virus formulation is drawn into a syringe and prepared for injection under BSL-2 containment in a biosafety cabinet in the Sloan Clinic pharmacy by a Fred Hutch pharmacy technician (and confirmed by a pharmacist).
- The preparation is administered in the Clinical Trials Unit clinic by the principal investigator (for intratumoral administration) or clinic staff (for intravenous administration) using clinic contact precautions.
- Follow-up swabs and samples will be collected in CTU by clinic staff and sent to the sponsor for processing. Precautions during sample collection will be either standard or contact, depending on the absence or presence of pustules.

Comments & Discussion:

Preparation at BSL-2 is appropriate. Administration (both ITu and IV) should be contact precautions with PPE of gown, tight-fitting goggles or full face shield, surgical mask and double gloves. PPE should be the same for injection site and pustule swabs.
Administration must occur in a single patient room with a solid door (not a curtain partitioned bay).
In the event of spill outside of BSC containment, the room should be evacuated for 30 minutes to allow aerosols to disperse. Then disinfectants should be used, ensuring appropriate contact time (i.e. at least 10 minutes for quats or bleach and at least 5 minutes for PeridoxRTU).
Occupational Health can provide the JYNNEOS vaccine, which may offer protection against this IDP.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and are appropriate. Study PI training is up-to-date and complete.	Approved unanimously

CATEGORY “A” IBC REVIEWS

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***

Bedalov	Renewal	E326.1 Bedalov lab at FHCC	III-D-3, III-D-4, III-E-1, III-E-3

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The overall goal of this lab is to study how cells copy their DNA and control gene activity. The lab uses yeast and mouse models to understand how cells ensure that their genetic material is accurately duplicated before cell division. The lab seeks to understand why errors in these processes occur in cancer and developmental disorders with the ultimate goal of guiding new therapeutic strategies.

- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Yeast strains are transformed with non-viral plasmid DNA at BSL-1.
- Routine culturing of human and mouse cell lines will be done at BSL-2.
- Breeding and handling of transgenic mice will be done at ABSL-1.
- Gene targets include human, mouse, and yeast genes involved in DNA replication and cell cycle.
- Production and use of lentiviral and adeno-associated viral vectors for transduction of human and mouse cells will be done at BSL-2.
- CRISPR system will be delivered by viral vector to mouse cells to perform a genome screen at BSL-2.
- Administering replication incompetent viral vectors to mice will take place at ABSL-1.
- Flow cytometry will be performed on modified human, mouse, and yeast cells at BSL-1.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Bernstein	Renewal	E326.2 Bernstein lab at FHCC	III-D-3, III-D-4, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The overall goal of this lab is to study genetic regulation of hematopoietic cell differentiation and similar mechanisms in cancer stem cells, which drive tumor growth and resist treatment, with the ultimate goal of developing target therapies to eliminate cancer stem cells and prevent disease recurrence.

- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Routine culturing of human, mouse, and other mammalian cells will be done at BSL-2.
- Gene targets include human Notch ligands, cell surface reporters, and fluorescent reporters.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression at BSL-2.
- Production and use of lentiviral vectors for transduction of mammalian cell lines will be done at BSL-2.
- Administration of human primary cells and cell lines that have tested negative for vivarium-excluded pathogens will be performed inside a BSC followed by housing at ABSL-1.
- FACS will be performed on modified human and mouse cells at BSL-2.

Comments & Discussion:

Add IRB source for human peripheral blood and bone marrow samples, if applicable.
Specify where syringes are prepared prior to administration to mice.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***

Beronja	Renewal	E326.3: Beronja lab at FHCC	III-D-3, III-D-4, III-E-1, III-F-1, III-F-8

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The overall goal of this lab is to study the fundamental biological mechanisms associated with tumor growth, with an overarching goal to identify genes and gene pathways that can be used as novel targets in cancer therapy.

- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Routine culturing of human and mouse cell lines will be done at BSL-1 (mouse) or BSL-2 (human).
- Breeding of transgenic mice will be done at ABSL-1.
- Gene targets include human and mouse whole genome shRNA or cDNA libraries as well as invertebrate fluorescent/luminescent reporters. Modifications will be made using transfection, viral transduction and CRISPR/Cas editing.
- Production and use of lentiviral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- CRISPR/Cas system will be delivered by viral vector to mouse cells to knockout gene targets at BSL-2.
- Administering modified cell lines that have tested negative for vivarium-excluded pathogens to mice will be done within a BSC followed by housing at ABSL-1.
- Administering lentiviral vectors to mice will be done either within a BSC (if the procedure logistics allow) or in the closed ultrasound room for in utero administration of small (1 µL) volumes followed by housing at ABSL-1.
- FACS will be performed on modified human and mouse cells at BSL-2.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Clurman	Renewal	E326.4	III-D-3, III-D-4, III-E, III-E-1, III-E-3, III-F-1, III-F-2, III-F-3, III-F-8

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

- The overall goal of this lab is to is to understand the functions of key cell cycle regulators and their downstream targets, using tissue culture and mouse xenotransplant models, in order to develop novel therapeutic strategies that exploit their deregulation to kill cancer cells in all types of human cancers.
- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Gene targets include human, bacteria, viral proteins, oncogenes, tumor suppressors, and reporters; modifications will be made using viral transduction, expression plasmids, nucleofection and CRISPR/Cas editing.
- Human cell lines, will be handled at BSL-2 for culturing, processing and transductions
- Transient expression plasmids will be transduced into human and mouse cells exressing oncogenic and non-oncogenic inserts at BSL-2
- Production and use of lentiviral vectors, AAV and gammaretroviral vectors for transduction of human cell lines; mouse cell lines will be done at BSL-2.
- CRISPR system will be delivered by lentiviral vector, nucleofection and AAV to human and mouse cells to knock out a gene, or site-specific mutagenesis at BSL-2.
- Administering modified cell lines that have tested negative for vivarium-excluded pathogens to mice will be done within a BSC followed by housing at ABSL-1.
- Administering modified cell lines that have tested positive for pathogens to mice will be done within a BSC followed by housing at ABSL-2.
- FACS analysis will be performed on fixed modified human cells, fixed modified mouse cells at BSL-1.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Dudakov	Renewal	E326.5	III-D-4,III-E-3, III-F-1, III-F-2, III-F3, III-F-8

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

- The aim of the lab is to investigate acute and profound thymic damage, such as that caused by common cancer cytoreductive therapies or conditioning regimens as part of hematopoietic cell transplantation, which leads to prolonged T cell deficiency. We use in vivo and in vitro models to investigate the mechanisms that drive natural regeneration of the thymus so that they may be exploited into clinically relevant therapeutic strategies that can be used to boost thymic function and thus enhance T cell immunity.
- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Human cell lines, will be handled at BSL-2 for culturing, processing and transductions
- Gene targets include human T-cell receptors, cytokines and signaling molecules, some genes are oncogenic
- Recombinant strains of mouse commensal bacteria will be propagated at BSL-1 and administered to mice at ABSL-2
- Recombinant synthetic nucleic acids or molecules plasmid DNA will be administered to animals within a BSC at ABSL-1
- The EMUA included work that is not subject to, or is exempt from, the NIH Guidelines. This work has been reviewed and had a robust risk assessment performed by the IBC to ensure proposed containment is appropriate.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Otegbeye	Renewal	E326.7: Otegbeye lab at FHCC	III-D-3, III-E, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The Therapeutic Products Program, which includes the Cell Processing Facility, is a Fred Hutch Shared Resource that provides GMP production and quality control of cellular therapeutic products for Phase I-II clinical trials.

- Unmodified RG1 and RG2 bacteria and fungi will be handled at BSL-2 for quality control microbiological growth assays.
- Routine culturing of human cell lines will be done at BSL-2.
- Human primary cells will be handled at BSL-2 for transduction with lentiviral vectors and quality control.
- Gene targets include human cell receptors and modifications will be made using viral transduction, CRISPR/Cas editing and non-viral transposase systems.
- Use of commercially purchased lentiviral vectors for transduction of human cells will be done at BSL-2.

- CRISPR/Cas systems will be delivered by electroporation to human cells to knockout or insert a gene at BSL-2.

Comments & Discussion:

The IBC questioned whether plasmid maps could be provided for the components of the listed viral vector systems.

The IBC would like cleaning procedures for after use of bacterial and fungal etiologic agents to be clearly stated.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Veatch	Renewal	E326.8 Veatch lab at FHCC	III-D-3, III-D-4, III-E, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The overall goal of this lab is to develop T cell therapies to target solid human malignancies. The lab uses mouse models of melanoma, lung cancer, and colon cancer and helper CD4 T cells to test and develop these therapies.

- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Routine culturing of human and mouse cell lines will be done at BSL-2.
- Gene targets include human and mouse T cell receptors, chimeric antigen receptors, antigens, immune stimulators, and marker/reporter genes.
- Mammalian expression vectors are transfected into human and mouse cells to drive transgene expression at BSL-2.
- Production and use of lentiviral, gammaretroviral, and adeno-associated viral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- CRISPR systems will be delivered by electroporation, lipid nanoparticle, or viral vector to human and mouse cells to knockout target genes at BSL-2.
- Human tissue samples and primary cells will be handled at BSL-2 for processing and culturing.
- Administration of modified cell lines that have tested negative for vivarium-excluded pathogens to mice will be done within a BSC followed by housing at ABSL-1.
- Administration of modified cell lines that have tested positive for vivarium-excluded pathogens and diphtheria toxin to mice will be done within a BSC followed by housing at ABSL-2.
- FACS will be performed on modified and unmodified cells at BSL-1, BSL-2, or BSL-2+ dependent on the individual sample.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Dey/Peterson	Amendment	E226.1 & E323.8: Phage-mediated gene therapy	III-D-1, III-D-2

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

- The goal is to design phages that can deliver specific genes into bacteria and change how important bacteria behave within the microbiomes of human or other host organisms.
- Phages will be constructed and assembled in-vitro with reporter or therapeutic genes inserted at BSL-2
- Phages will be added to genetically modified bacteria at BSL-2
- CRISPR Cas 9 system will be used to turn off genes in E. coli at BSL-2
- Gene targets and inserts include flourescent reporters and E. coli genes
- The EMUA included work that is not subject to, or is exempt from, the NIH Guidelines. This work has been reviewed and had a robust risk assessment performed by the IBC to ensure proposed containment is appropriate.

Comments & Discussion:

The IBC would like more clarification and content on how the bacteriophages are handled and transported between the labs.

Training & Facilities:	***Vote & Recusals:***
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.	Approved unanimously, conditional upon clarification of Comments above

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Hirayama	Amendment	E424.1 Addition of In Vitro and In Vivo Studies for Lentiviral-Mediated CAR T Cell Engineering	III-D-3, III-D-4, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

- This amendment adds procedures to test the feasibility of generating engineered immune cells in vivo, such as CAR-engineered T cells targeting human malignancies
- Gene targets include human immune system proteins, fluorescent proteins and CAR-T, and modifications will be made using viral transduction
- Production and use of lentiviral vectors for transduction of human cell lines and in-vivo administration will be done at BSL-2
- FACS will be performed onmodified mouse cells at BSL-1.
- Addition of one personnel

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
No changes to facilities, or maximum approved containment level due to this amendment. Training has been completed by new personnel.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Hsieh	Amendment	E424.5: Add funding sources, personnel, intra-prostatic administration of lentivirus in mice and mesenteric vein administration of modified cells in mice	III-D-3, III-D-4, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The purpose of this amendment is to add a short hairpin (shRNA) library for knockdown of cancer-related gene targets in mouse urothelium. The amendment also adds new routes of administration for this library as well as for modified cells.

- Gene targets include mouse oncogenes and tumor suppressors as well as fluorescent reporters.
- Production of lentiviral vectors for transduction of mouse cells will be done at BSL-2.
- Administering modified cell lines that have tested negative for vivarium-excluded pathogens to mice will be done in a close procedure room followed by housing at ABSL-1.
- Administering lentiviral vectors to mice will be done either within a BSC (if possible for procedural logistics) or on the bench in a closed procedure room while wearing additional PPE (e.g. full face shield), followed by housing at ABSL-1.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
New personnel training is up-to-date and complete. No changes to facilities or maximum approved containment level due to this amendment.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Peterson	Amendment	E323.8: New Peterson plasmid #118, Plat-E cells, RAW 264.7 cells and production of gammaretroviral vectors	III-D-3, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The purpose of this amendment is to produce ecotropic retroviral vectors for transducing mouse lymphocytes.

- Routine culturing of human and mouse cell lines will be done at BSL-2.
- Production and use of ecotropic gammaretroviral vectors for transduction of mouse cell lines will be done at BSL-2.
- FACS will be performed on modified mouse cells at BSL-2.

Comments & Discussion:

The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.

Training & Facilities:	***Vote & Recusals:***
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Strong	Amendment	E325.6 Strong lab at FHCC	III-D-3, III-F-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):

The purpose of this amendment is to add mass-spec immunopeptidomics on latent KSHV lysogens to identify targets for immunotherapies.

- Routine culture and processing of human cell lines will be done at BSL-2.
- Production and use of lentiviral vectors for transduction of human cell lines will be done at BSL-2.

Comments & Discussion:	
The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.	
Training & Facilities:	***Vote & Recusals:***
New personnel training is up-to-date and complete. No changes to facilities or maximum approved containment level due to this amendment.	Approved unanimously

CATEGORY "B" IBC REVIEWS

Principal Investigator:	***EMUA Number:***	***NIH Sections:***	***Summary (including training and facilities):***
Bloom	E325.3	III-D-1, III-D-2, III-D-3	• This amendment adds Andes virus Gn/Gc lentivirus pseudotyping. • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Collisson	E124.5	III-D-3, III-D-4, III-D, III-E-1	• Add new human and mouse cell lines for approved procedures at BSL-2. • Add new non-oncogenic gene targets. • Add new non-viral vector for expressing recombinase in cells. • Add new transfer plasmids for lentiviral vectors that will be handled at BSL-2. • Add flow cytometry and sorting of cells modified with the new vectors to be done at BSL-1 or BSL-2, depending on the species and modification method. • Add administration to mice of new modified mouse cells followed by housing at ABSL-1. • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Kiem	E224.2	III-D-4, III-E, III-F-1	• In-vitro and In-vivo use of LNP-mRNA against HIV Env • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Kiem	E224.2	III-D-3, III-E	• This amendment adds a new transgene and additional cell lines to generate targeted virus/virus-like particles and decoration on nanoparticles for cell targeting. No changes to methods of production or handling from previously approved protocols. • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Mayers	E424.2	III-D-4	• Add new genetically modified strains of Pseudomonas aeruginosa (non-MDRO) for in vitro work to be done at BSL-2. • Add administration to mice of new P.aeruginosa strains and previous K.pneumonia, S. aureus, S. pneumoniae and E.coli strains (non-MDRO) followed by housing at ABSL-2. • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Peterson	E323.8	III-D-3, III-E-1	• Adding two new lentivirus constructs for production in FH Vector Core at BSL-2. • Vector constructs express CARs against HIV and CD20 envelope proteins.

			• Vectors will be used to transduce human and non-human primate cell lines at BSL-2 for approved downstream assays.
Simeonov	E325.1	III-D-3, III-E, III-E-1	• Add new human cell line for approved procedures at BSL-2. • Add new vectors for non-viral transfection. • Add new transfer plasmids for lentiviral vectors that will be handled at BSL-2. • Add flow cytometry and sorting of cells modified with new vectors to be done at BSL-1 or BSL-2, depending on the activity and modification method. • No changes to personnel, facilities, or maximum approved containment level due to this amendment.
Tsukiyama	E326.8	III-F-1, III-F-2, III-F-3, III-F-4, III-F-5, III-F-6	• This EMUA Renewal for the Tsukiyama lab at FHCC describes work exempt from the NIH Guidelines. • Facilities have been inspected and all findings resolved. Training is up-to-date and complete.
Batch Comments & Discussion:			
The Committee reviewed this work and confirmed the research is clearly described, the associated risks recognized, and appropriate biosafety practices implemented in accordance with institutional and regulatory standards.			
Batch Vote & Recusals/Abstentions:			
Approved unanimously, 2 recusals			

CATEGORY “C” BSO REVIEWS

Principal Investigator:	***EMUA Number:***	***Approval Date:***	***NIH Sections:***	***Summary (including training for amendments adding personnel):***
Dhodapkar	E225.1	5.13.2026	N/A	Add funding
Henikoff	E324.9	5.14.2026	N/A	Add funding
Dudakov	E123.5	5.18.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Simeonov	E325.1	5.19.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Thomas	E425.1	5.26.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Radich	E325.12	6.1.2026	N/A	Add personnel New personnel training is up-to-date and complete. and new lab spaces
Boonyaratanakornkit	E223.2	6.3.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Mayers	E424.2	6.5.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Radich	E325.12	6.8.2026	N/A	Add personnel New personnel training is up-to-date and complete. Add new lab spaces Facilities are confirmed appropriate.
Lee	E125.6	6.16.2026	N/A	Add personnel

				New personnel training is up-to-date and complete.
Malik	E325.4	6.22.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Hill	E323.10	6.23.2026	N/A	Add funding Add personnel New personnel training is up-to-date and complete.
Biggins	E225.3	6.25.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Termini	E126.15	6.29.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Warren	E226.6	7.2.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Parkhurst	E325.5	7.9.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Hill	E323.10	7.13.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Henikoff	E324.9	7.13.2026	N/A	Add personnel New personnel training is up-to-date and complete.
Hahn	E124.10	7.13.2026	N/A	Add personnel New personnel training is up-to-date and complete.

EMUA CLOSEOUTS

None

UPDATES/PROGRAM REVIEW

Presentation: Containment for Cytometry Activities

INCIDENTS, ACCIDENTS, AND PROBLEMS

None

VI. OTHER BUSINESS

None

Meeting adjourned at 11:59 am.

Signed by:
Keith Jerome
CB83B35EA7A9430...

Keith Jerome, MD PhD
Vaccine and Infectious Disease
Institutional Biosafety Committee Chairperson

DocuSigned by:
09CC928C5E494BB...

Susan Parazzoli MS, RBP
Biosafety Officer

cc: Dr. Thomas J. Lynch, President, and Director
Dr. Nicole (Niki) Robinson, EVP & Chief Operating Officer