Fred Hutch Cancer Center

MINUTES OF THE FRED HUTCHINSON CANCER CENTER
INSTITUTIONAL BIOSAFETY COMMITTEE

May 21, 2026 IBC Meeting, 10:00 am, M3-A805 & 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 Kom-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*
☒	☐	Allison Zelikoff MN, RN, COHN-S, Occupational Health Manager, *Member*

NON-MEMBERS

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 10:00 am.

I. ANNOUNCEMENTS AND UPDATES

- New section on the Agenda and Minutes for reviewing and documenting outstanding action items from the previous meeting along with their resolutions.

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 March 19, 2026 and April 20, 2026 IBC Meetings were approved unanimously.

IV. REVIEW OF ACTION ITEMS

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*Action Item*	*Resolution*
Simon, S	New	E126.8: Simon lab at FHCC	Verify the spinfection procedure mentions aerosol caps	In Vitro Procedures text states “All centrifugation steps will use aerosol caps on centrifuge buckets to prevent aerosolization of any infectious particles.”
Buck	Renewal	E126.9: Buck lab at FHCC	Stereotaxic injections can’t be done in a BSC- these injections will be done at ABSL-2 and use barrier precautions/PPE rather than a BSC. Comp Med to develop SOPs for performing procedures in ABSL-2 that are done outside the BSC. Clarification on what “intrabulbar” injections are and to update the in vivo administration table. Suggestion that if active work resumes, to notify the biosafety team for a review. Update- removed “intrabulbar” and replaced with “stereotaxic injection to the brain.”	They changed “intrabulbar” to “stereotaxic injections” and switched HSV to influenza. They are not injecting HSV into the brain, but are injecting influenza. If the lab plans to start this work, we will work with CM on a method to conduct the injections outside the BSC in ABSL-2 using barrier methods and run it by the IBC.
Houghton	Renewal	E126.11: Houghton lab at FHCC	The IBC discussed risks associated with use of adenoviral vectors in vivo. These vectors cannot replicate but may be shed from mice for a short time post-administration. Administration via intratracheal or intranasal routes must take place inside a BSC, after which animals may be housed at ABSL-1. As a precaution, cages will be handled inside a BSC for 72 hours post-administration, after which standard practices apply.	EH&S, on behalf of the IBC, partnered with Comparative Medicine to create a new policy around administration of adenoviral vectors to rodents, which includes the safety practices recommended by the IBC.

Orozco	Renewal	E126.13: Orozco lab at FHCC	Clarification is requested that the cell lines with positive HIV results are truly HIV positive. And if this is true, they should be handled at BSL-2+.	Cell lines in question are confirmed HIV negative and the protocol has been updated.
Barry	Amendment	E125.2 Add plasmid DNA administrations in-vivo	The amendment mentions the collection of mouse samples for flow cytometry; confirm that this is described in the parent protocol.	This is confirmed and described in the parent protocol.

V. NEW BUSINESS

Human Gene Transfer Applications

Principal Investigator:	***RG Number:***	***Biosafety Level:***	***NIH Sections:***
Deng	RG1126396	BSL-2 (preparation)	III-C

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

The Investigational Drug Product (IDP) for this trial is a nanoparticle, specifically a lipid nanoparticle with mRNA cargo (mRNA-LNP) for treatment of people with non-small cell lung cancer.

- The mRNA-LNP formulation is made offsite.
- The mRNA-LNP formulation is received by the Fred Hutch Investigational Drug Services pharmacy and transported onsite by Fred Hutch clinical couriers. The mRNA-LNP 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 pharmacist.
- The preparation is administered in the Clinical Trials Unit clinic or the Thoracic Head and Neck Care Neighborhood by nursing staff using clinic standard precautions.

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 are appropriate. Study PI training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***RG Number:***	***Biosafety Level:***	***NIH Sections:***
Mazziotta	RG1126017	BSL-1	III-C

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

The Investigational Drug Product (IDP) for this trial is a modified cell product, specifically autologous T cells, for treatment of acute myeloid leukemia.

- Modifications are made to the T cells onsite by transduction with replication-incompetent lentiviral vectors.
- Modified cells are received and stored by the Fred Hutch Cellular Therapy lab (CTL), transported onsite by CTL, and thawed at bedside by CTL using clinic standard precautions.
- Modified cell product is administered by Immunotherapy Clinic nurses using clinic standard precautions.

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. Study PI training is up-to-date and complete.	Approved unanimously

Principal Investigator:	***RG Number:***	***Biosafety Level:***	***NIH Sections:***
Shapiro	RG1126515	BSL-2 (preparation)	III-C

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

The Investigational Drug Product (IDP) for this trial is a nanoparticle, specifically a lipid nanoparticle with mRNA cargo (mRNA-LNP), for vaccination against HIV-1 in people living with HIV. The prime and boost products have distinct mRNAs as cargo which encode for different HIV envelope proteins.

- The mRNA-LNP formulation is made offsite.
- The mRNA-LNP formulation is received by the Fred Hutch Vaccine Trials Unit and transported onsite by VTU pharmacists and clinicians. The mRNA-LNP formulation is mixed with diluent and prepared for injection under BSL-2 containment in an aseptic isolator glove box at VTU by the VTU pharmacist.
- The preparation is administered in the VTU clinic by VTU clinicians using clinic standard precautions.

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. Study PI training is up-to-date and complete.	Approved unanimously

CATEGORY “A” IBC REVIEWS

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Dey	Renewal	E226.1: Dey lab at FHCC	III-D-1, III-D-4

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

The overall goal of the lab is to investigate how gut microbial metabolism influences pathophysiology and physiology in gastrointestinal cancers and motility. The lab looks for environmental regulators of bacterial metabolism to prevent carcinogenesis in the GI tract and modulate gut motility.

- RG1 and RG2 bacteria, some with corresponding bacteriophages, will be handled at BSL-1 and BSL-2, respectively.
- Human tissue samples will be handled at BSL-2 for processing.
- Administration of modified and unmodified bacteria to mice will be done within a BSC followed by housing at ABSL-2.
- FACS will be performed on unmodified mouse cells at BSL-1.
- CRISPR systems will be delivered by electroporation to bacteria to edit colibactin toxin and hydrolase genes at BSL-2.

Comments & Discussion:

- 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.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously, conditional upon clarification of Comments above

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Galloway	Renewal	E226.2: Galloway lab at FHCC	III-D-3, III-D-4, III-E-1, III-F-1, III-F-2, III-F-3, III-F-5, III-F-8

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

The overall goal of this lab is 1) to study the long-term protection afforded by human papillomavirus (HPV) vaccines with the goal of improving the dosing regimens and 2) study how Merkel cell polyomavirus (MCPyV) causes Merkel cell carcinoma (MCC).

- Gene targets include human transcription factors including some oncogenes, viral capsid proteins and fluorescent/luminescent reporters. Modifications will be made using transfection, lentiviral vectors and CRISPR/Cas editing.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Administering modified mouse cell lines that have tested negative for vivarium-excluded pathogens to mice will be done at ABSL-1.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression and will be handled at BSL-2.
- Routine culturing of human and mouse cell lines will be done at BSL-2.
- Production and use of lentiviral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- Other types of viral vectors based on gammaretroviruses, poxviruses and baculoviruses are currently in storage only and all work will be approved by the IBC in the future if active use resumes.
- Human primary cells and blood products will be handled at BSL-2 for neutralization assays.
- Merkel cell polyomavirus particles will be produced and used to infect human dermal fibroblast cell lines at BSL-2. Human papillomavirus pseudovirus particles will be produced and used for neutralization assays at BSL-2.
- Flow cytometry analysis will be performed on unmodified and modified human and mouse cells at BSL-1 or BSL-2, depending on fixation status and source of samples. No cell sorting will be performed.
- CRISPR system will be delivered by lentiviral vector to human cell lines to knock out integrated viral sequences at BSL-2.
- Confocal microscopy will be performed on fixed mouse tissues 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:***
MacPherson	Renewal	E226.3: MacPherson lab at FHCC	III-D-3, III-D-4, III-E, 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 understand molecular mechanisms underlying human cancers and to identify novel therapies. The lab focuses on small cell lung cancer and tries to model subsets of this tumor type that harbor specific gene mutations, followed by subsequent genetic screens and therapeutic studies to test effects of novel strategies for treating lung cancer.

- Gene targets include human and mouse signaling molecules and transcription factors, including oncogenes and genome-wide libraries along with fluorescent/luminescent reporters; modifications will be made using transfection, viral transduction and CRISPR/Cas editing.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Breeding/handling transgenic mice will be done at ABSL-1.
- Routine culturing of human and mouse cell lines will be done at BSL-2.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression at BSL-2.
- Human primary tissues and blood will be handled at BSL-2 for isolation of tumor cells and establishment of patient derived xenograft models.
- Administering adenoviral vectors to mice will be done within a BSC followed by housing at ABSL-1.
- Administering modified cell lines and PDX models that have tested negative for vivarium-excluded pathogens to mice will be done at ABSL-1.
- Administering PDX models that are untested to mice will be done within a BSC followed by housing at ABSL-2.
- Production and use of lentiviral vectors and adenoviral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- CRISPR system will be delivered by lentiviral vector to human and mouse cells to knockout or activate gene targets at BSL-2.
- FACS will be performed on unfixed modified human cells 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:***
McGuire	Renewal	E226.4: McGuire lab at FHCC	III-D-2, III-D-3, III-D-4, III-E, III-E-1, III-E-3, 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 antibody response to viral proteins that are relevant to vaccine design. The lab produces recombinant viral proteins which are used to isolate antibodies from natural infection and characterize their binding and neutralizing potentials to inform vaccine design with a focus on HIV-1 and EBV, as well as other viruses.

- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Routine culturing of human, mouse, hamster and non-human primate cell lines will be done at BSL-2.
- Human and non-human primate primary blood cells will be handled at BSL-2 for processing.
- Breeding/handling transgenic mice will be done at ABSL-1.
- Gene targets include human, mouse and non-human primate antibody receptors and viral protein sequences. Modifications will be made using transfection, viral transduction, electroporation and CRISPR/Cas editing.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression at BSL-2.
- Production and use of lentiviral vectors, gammaretroviral vectors and adeno-associated viral vectors for transduction of mammalian cells will be done at BSL-2.
- CRISPR system will be delivered by viral vector or electroporation to mammalian cells to knockout or introduced rearrangements to antibody genes at BSL-2.
- Nanoparticles composed of inorganic molecules and alphavirus replicons or lipids and mRNA will be administered to mice within a BSC followed by housing at ABSL-1.

- Risk Group 2 viruses will be generated from producer cell lines and used for in vitro assays or administered to mice at BSL-2/ABSL-2.
- Non-replicating pseudoviruses based on Risk Group 3 viruses will be proceduced from plasmid transfection and used for in vitro assays at BSL-2+.
- Administering modified and unmodified cell lines that have tested negative for vivarium-excluded pathogens to mice will be done within a BSC followed by housing at ABSL-1.
- FACS will be performed on unfixed lentivirally modified human and mouse cell lines at BSL-2; human primary cells from HIV-1+ patients and non-human primate samples at BSL-2+.

Comments & Discussion:

- 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 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.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously, conditional upon clarification of Comments above

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Stephan	Renewal	E226.5: Stephan lab at FHCC	III-D-3, III-D-4, III-E-1, III-E-3, III-F-1, III-F-8

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

The overall goal of this lab to address limited patient access to CAR-T therapies by developing a bedside production approach that enables rapid generation of patient-specific CAR-T cells without the need for specialized manufacturing facilities. This strategy uses a gene therapy-based microfoam to genetically modify freshly isolated T cells for same-day subcutaneous reinfusion, potentially expanding CAR-T treatment availability to standard clinical settings.

- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression and will be handled at BSL-2
- Administering lentivirally 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.
- Recombinant synthetic nucleic acids or molecules lipid nanoparticles expressing mRNA will be administered to animals within a BSC at ABSL-1
- Human cell lines, primary cells will be handled at BSL-2 for culturing, transductions with lentiviral particles, and lipid mRNA nanoparticles.
- Nanoparticles composed of lipids and mRNA nucleic acids will be used to transfect human cells, in a BSC at BSL-2.
- FACS analysis will be performed on modified human cells at BSL-1.

Comments & Discussion:

- Confocal microscopy was selected in the application but there was no description of how it would be used.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously, conditional upon clarification of Comments above, 1 recusal

Principal Investigator:	EMUA Type:	EMUA Number & Title:	NIH Sections:
Warren	Renewal	E226.6: Warren Lab at FHCC	III-D-3, III-E, III-E-1, III-F-1, III-F-2, III-F-3

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

The overall goal of this lab is to study the cellular and molecular mechanisms underlying T cell–mediated cancer regression, with a focus on CD8+ and CD4+ T cell responses observed in settings such as allogeneic transplants and immune checkpoint inhibition. Their work characterizes antigenic targets of tumor-infiltrating lymphocytes (TILs) in cancers including renal cell carcinoma and Kaposi sarcoma, identifying both host-derived and viral antigens (e.g., KSHV and HIV-1) recognized by tumor-reactive T cells.

- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression and will be handled at BSL-2.
- Gene targets include human immune genes and viral proteins; modifications will be made using lentiviral transduction.
- Routine culturing of human and non-human primate cell lines will be done at BSL-2.
- KSHV virus will be produced by inducing cells that carry a recombinant rKSHV.219 strain of KSHV or in cells that have non-integrated KSHV genomes 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.	Approve unanimously

Principal Investigator:	EMUA Type:	EMUA Number & Title:	NIH Sections:
Black	Amendment	E323.1: Sorting mouse cells infected with LCMV Armstrong	N/A

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

This amendment is to add the sorting of mouse cells from animals experimentally infected with Lymphocytic choriomeningitis virus (LCMV) Armstrong strain by an external user.

- FACS will be performed on these cells at BSL-2+ within the Flow Core facility.
- A Medical Management Plan is available.

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:
Mayers	Amendment	E424.2: Human primary tissues and FACS on bacteria in semi-permeable capsules	N/A

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):
This amendment is to add use of flow cytometry and FACS to analyze and sort bacteria from homogenized lung tissue encapsulated inside semi-permeable capsules as a method to enrich for bacterial signal in downstream metagenomics/transcriptomic applications to better understand bacterial activity within the lung environment. • New locations of the Srivatsan lab (Fred Hutch) BSL-2 tissue culture room for encapsulating cells and bacteria into semi-permeable capsules and the Flow Cytometry Core for cytometry of these capsules. • Human primary lung tissue samples and a human lung cell line will be handled and processed at BSL-2, and mouse primary lung samples from Fred Hutch colony mice will be handled at BSL-1. • Cytometry analysis at BSL-1 and sorting activities at BSL-2 on these cells and tissues as well as approved non-MDRO bacteria.
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 are confirmed appropriate.	Approved unanimously

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
McElrath	Amendment	E125.14: Plasmodium falciparum sporozoites and Pf-infected RBCs for immunogenicity assay	N/A

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):
This amendment is to add a project with the goal of assessing the T cell immunogenicity of a sporozoite malaria vaccine. • Human primary cells will be handled at BSL-2 for processing and antigen stimulation. • Flow cytometry analysis will be performed on human primary cells at BSL-2. • 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:***
New personnel training is up-to-date and complete. Facilities are confirmed appropriate.	Approved unanimously

Principal Investigator:	**EMUA Type:**	**EMUA Number & Title:**	**NIH Sections:**
Orozco	Amendment	E126.13: Addition of lentivirus for transducing cell lines	III-D-3, III-E, III-E-1

Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):
The overall goal of this amendment is to add lentiviral vectors to be used for expression of approved genes in approved cell lines. • Lentiviral vectors will be produced by the Fred Hutch Vector Core and will be used by the lab to transduce mammalian cell lines at BSL-2. • Fixed or unfixed transduced cell lines will be analyzed on cytometers at BSL-1. No sorting will be performed.

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

CATEGORY "B" IBC REVIEWS

Principal Investigator:	***EMUA Number:***	***NIH Sections:***	***Summary (including training and facilities):***
Berger	E126.4	III-D-3, III-D-4, III-E, III-E-1, III-F-2, III-F-3, III-F-8	• Addition of new lab strain E.coli for cloning will be handled at BSL-1. • Addition of new human cell line for approved procedures that will be handled at BSL-2. • Addition of new transfer plasmids for approved lentiviral vector systems that will be handled at BSL-2. • Updates to adenoviral viral vector in vivo handling procedures to align with policy. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Bloom	E325.3	III-D-3	• Deep mutational scanning of CHIKV and VEEV (TC-83) non-structural proteins within the RVP system • All procedures are previously approved, and gene targets and RVP systems are within previously defined and evaluated groups. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Collisson	E124.5	III-D-3, III-D-4, III-E, III-E-1	• Addition of new personnel. • New personnel training is up-to-date and complete. • Addition of new human cell lines for approved procedures that will be handled at BSL-2. • Addition of new human and mouse non-oncogenic gene targets. • Addition of new transfer plasmid for approved lentiviral vector system that will be handled at BSL-2. • Addition of new method of delivery for CRISPR/Cas9 matchinery for gene editing in approved cells that will be used at BSL-2. • Addition of cell sorting for approved modified cell lines to be done at BSL-1 or BSL-2, depending on the species and modification method. • Updates to adenoviral viral vector in vivo handling procedures to align with policy. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Kiem	E224.2	III-D-3, III-D-4, III-E	• Adding new gene targets and new source for nanoparticles • All procedures are previously approved, and gene targets are within previously defined groups.

			• There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Lee	E125.6	III-D-3, III-E, III-E-1	• Addition of new human and mouse non-oncogenic and oncogenic gene targets that are within previously defined groups. • Addition of new transfer plasmids for approved lentiviral and gammaretroviral vector systems that will be handled at BSL-2. • Addition of new method of delivery for CRISPR/Cas9 matchinery for gene editing in approved cells that will be used at BSL-2. • Addition of cell sorting for approved modified cell lines to be done at BSL-2 or BSL-2+, depending on the modification. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Silberstein	E223.7	III-D-4	• Addition of synthetic dsDNA-based adjuvant for in vivo administration. • All procedures are previously approved. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Stamatatos	E125.8	III-D-4	• Addition of synthetic dsDNA and ssDNA-based adjuvants for in vivo administration. • All procedures are previously approved. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
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):*
McElrath	E125.14	3.16.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Parkhurst	E325.5	3.16.26	N/A	Add funding source
Li	E324.8	3.18.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Overbaugh	E423.3	3.25.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Hahn	E124.10	4.13.26	N/A	Add funding source
Bloom	E325.3	4.13.26	N/A	Add personnel.

				New personnel training is up-to-date and complete.
Henikoff	E324.9	4.13.26	N/A	Add funding source
Dhodapkar	E225.1	4.13.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Gujral	E425.4	4.13.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Lund	E124.11	4.13.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Mayers	E424.2	4.13.26	N/A	Encapsulation of lab strains E.coli and B.subtilis into semi-permeable capsules followed by FACS. Facilities are confirmed appropriate.
Hirayama	E424.1	4.15.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Nelson	E424.6	4.22.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Thomas	E425.1	4.24.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Overbaugh	E423.3	4.28.26	N/A	Add funding sources. Add personnel. New personnel training is up-to-date and complete.
Hockenbery	E223.6	5.4.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Arimura	E124.4	5.6.26	N/A	Add funding sources. Add personnel. New personnel training is up-to-date and complete.
Cheung	E125.3	5.7.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Thomas	E425.1	5.8.26	N/A	Add personnel. New personnel training is up-to-date and complete.

EMUA CLOSEOUTS

- Bedford E124.1

UPDATES/PROGRAM REVIEW

- Polio Virus Containment Survey

INCIDENTS, ACCIDENTS, AND PROBLEMS

- Eye exposure to modified human cells, 3/24/26

VI. OTHER BUSINESS

- Fred Hutch Locations for Human Gene Transfer (HGT) Activities (PowerPoint)
- FHCC Comparative Medicine Shared Resource Requirement: ABSL-1 Handling of Adenoviral Vectors via Intranasal and Intratracheal Routes [effective 4/24/2026]
    - Administrations must take place within a BSC and cages handled within a BSC for 72 hours post-administration

Meeting adjourned at 12:04 pm.

Signed by:
Keith Jerome
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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, Chief Administrative Officer