Fred Hutch Cancer Center

MINUTES OF THE FRED HUTCHINSON CANCER CENTER
INSTITUTIONAL BIOSAFETY COMMITTEE

March 19, 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*
☒	☐	Alexandre 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

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 10:00 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 January 22, 2026 IBC Meeting were approved unanimously.

IV. REVIEW OF ACTION ITEMS

None

V. NEW BUSINESS

Human Gene Transfer Applications

Principal Investigator:	***RG Number:***	***Biosafety Level:***	***NIH Sections:***
Fong	RG1126217	BSL-1	III-C

Summary (including type of IDP, target disease, IDP life cycle and known/anticipated safety concerns):

The Investigational Drug Product (IDP) for this trial is a modified cell product, specifically T cells, for treatment of metastatic castration-resistant prostate cancer.

- Modifications are made to the T cells offsite by electroporation.
- Modified cells are received by the FH Cellular Therapy lab (CTL), transported onsite by CTL and thawed at bedside by CTL using clinic standard precautions.
- Modified cells are administered by Immunotherapy Clinic nurses using clinic standard precautions.

Comments & Discussion:

The Committee reviewed this work and confirmed that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are 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:***
King	RG1126068	BSL-1	III-C

Summary (including type of IDP, target disease, IDP life cycle and known/anticipated safety concerns):

The Investigational Drug Product (IDP) for this trial is a modified cell product, specifically T cells, for the treatment of GPC3-positive solid tumors.

- Modifications are made to the T cells offsite by transduction with replication-incompetent gammaretroviral vector.
- Modified cells are transported to FH by Sponsor staff and thawed at bedside by Sponsor staff using clinic standard precautions.
- Modified cells are administered by Immunotherapy Clinic nurses using clinic standard precautions.

Comments & Discussion:

The Committee reviewed this work and confirmed that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are 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

CATEGORY "A" IBC REVIEWS

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Simon, S	New	E126.8: Simon lab at FHCC	III-D-3, III-D-4, III-E, III-F-1, III-F-2, III-F-3

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

The overall goal of the lab is to develop immunotherapies for cancer using genetically engineered immune cells that recognize and eliminate cancerous cells. The research uses preclinical mouse models of cancer, human tumor, and tissue samples and methods in molecular biology, gene transfer, gene editing, and synthetic biology to accomplish these goals.

- 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.
- Human blood and primary cells will be handled at BSL-2 for processing.
- Gene targets include human tumor target genes, chimaric antigen receptors, and cytokine receptors; modifications will be made using lentiviral vectors, gammaretroviral vectors, CRISPR/Cas, and lipid nanoparticles.
- Production and use of lentiviral and gammaretroviral vectors for transduction of human and mouse cells will be done at BSL-2.
- Administering unmodified and modified cell lines that have tested negative for vivarium-excluded pathogens will be done within a BSC followed by housing at ABSL-1.
- FACS will be performed on unmodified and modified human and mouse cells at BSL-2.

Comments & Discussion:

Verify spinfection procedure specifically mentions aerosol caps.

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:***
Buck	Renewal	E126.9: Buck lab at FHCC	III-D-3, III-D-4, III-E, III-F-8

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

This research aims to understand how the nervous system detects and interprets odors and social cues to drive hormonal and instinctive behaviors, and how the olfactory system develops. It also investigates how neural circuits regulate functions like appetite, fear, reward, and reproduction, and how these processes are influenced by sensory signals or disease. Additionally, the work explores the potential for microbes to enter the brain through the olfactory pathway, linking sensory biology with mechanisms of infection.

- Gene targets include olfactory receptors, fluorescent markers, G protein-coupled proteins and other non-oncogenic genes; modifications will be made using adenoviral and lentiviral transduction, and CRISPR/Cas editing.

- 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
- Human cell lines will be handled at BSL-2 for culturing
- Production and use of lentiviral vectors, AAV, pseudorabies virus, and glycoprotein-deficient rabies virus for transduction of human cell lines will be done at BSL-2
- Administering mouse-adapted influenza, lentivirus, VSV, and HSV-1 to mice will be done within a BSC, followed by housing at ABSL-2.
- Administering glycoprotein-deficient rabies virus, Pseudo-Rabies virus, and AAV to mice will be done within a BSC, followed by housing at ABSL-1.
- FACS will be performed on fixed infected mouse cells at BSL-2

Comments & Discussion:

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."

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

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Houghton	Renewal	E126.11: Houghton 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 the lab is to determine the mechanistic basis of immune escape in cancer. The lab interrogates human lung cancer samples for immune suppression mechanisms and uses in vivo models to optimize and validate potentially beneficial genetic alterations and treatment regimens.

- 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 genes involved in cell cycle, transcription, genes involved in neutrophil biology, and fluorecent reporters.
- Production and use of lentiviral and gammaretroviral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- CRISPR systems will be delivered by transfection to mouse cells in vitro at BSL-2.
- Administration of unmodified and modified cell lines that have tested negative for vivarium-excluded pathogens and Adenoviral vectors to mice will be done within a BSC followed by housing at ABSL-1.
- FACS will be performed on unmodified and modified human and mouse cells at BSL-1 and BSL-2.

Comments & Discussion:

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.

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

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Orozco	Renewal	E126.13: Orozco lab at FHCC	III-D-4, 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 assess the therapeutic effect of novel antibodies or antibody derivatives developed for the treatment of leukemia in a targeted or pre-targeted system of radioimmunotherapy (RIT).

- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Routine culturing of human cell lines will be done at BSL-2. Some cell lines have been modified by other labs.
- Mammalian expression vectors are transfected into mammalian cells to drive transgene expression and will be handled at BSL-2.
- Transgenes are non-oncogenic/tumor suppressive
- CRISPR system will be delivered by plasmid transfection to human cancer cells to knock out a gene or target edit 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 will be performed on modified human cells at BSL-2.

Comments & Discussion:

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+.

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

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Termini	Renewal	E126.15: Termini 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 the lab is to study how blood is made, how blood recovers from stress, and how blood becomes cancerous. The aim is to understand the molecules that control these processes to help better utilize blood cells to help patients suffering from a variety of diseases.

- Gene targets include human and mouse enzymes, transcription factors, oncogenes, tumor suppressors, and reporters; modifications will be made using viral transduction and CRISPR/Cas editing.
- Lab strains of E. coli for routine cloning will be handled at BSL-1.
- Mammalian expression vectors are transfected into mammalian cells to drive shRNA expression and will be handled at BSL-2.
- Breeding/handling transgenic mice will be done at ABSL-1.
- Administering unmodified and 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 (or ABSL-2 if untested).
- Routine culturing of human and mouse cells and cell lines will be done at BSL-2.
- Production and use of lentiviral vectors and gammaretroviral vectors for transduction of human and mouse cell lines will be done at BSL-2.
- FACS will be performed on virally-modified human and mouse cells at BSL-2 or BSL-2+, depending on gene target.

Comments & Discussion:

The Committee reviewed this work and confirmed that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are 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:***
Barry	Amendment	E125.2 Add plasmid DNA administrations in-vivo	III-D-4, III-F-1

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

- The overall goal of this amendment is to hydrodynamically administer plasmid DNA to the liver of a mouse to induce Fibrolamellar – like cancer and study the immune response of this rare form of liver cancer.
- Administering recombinant/synthetic nucleic acids to mice will be done within a BSC followed by housing at ABSL-1.

Comments & Discussion:

The amendment mentions the collection of mouse samples for flow cytometry; confirm that this is described in the parent protocol.

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

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Cao	Amendment	E225.5: EBV immortalization of cell lines	N/A

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

The purpose of this addition is to transform B cells by infection with Epstein-Barr Virus (EBV) to create a repository for distribution to researchers.

- Culture of marmoset blood leukocytes to produce EBV-conditioned viral supernatant will be done at BSL-2.
- Transduction of human B cells with EBV using the conditioned supernatant will be done at BSL-2.

Comments & Discussion:

The Committee reviewed this work and confirmed that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are 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:*
Esvelt	Amendment	Addition of modified murine cells and AAV for in vivo administration	III-D-3, III-D-4

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

The purpose of this amendment is to 1) add the administration of modified murine cells to evaluate tumor metastasis behavior, and 2) add the administration of adeno-associated virus (AAV) vectors for in vivo gene editing.

- Administration of modified cell lines that have tested negative for vivarium-excluded pathogens and AAV vectors will be done within a BSC 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:*
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.	Approved, 2 recusals

CATEGORY “B” IBC REVIEWS

Principal Investigator:	*EMUA Number:*	*NIH Sections:*	*Summary (including training and facilities):*
Chowning	E126.10	III-F-1, III-F-2, III-F-3, III-F-8	The overall goal of this lab is to provide equipment and supplies necessary to conduct basic molecular biology experiments to secondary schools in WA state and beyond, as well as work with students and teachers directly on-site at FH to provide engaging, hands-on experiences. • Renewal of full EMUA, with all work exempt from the NIH Guidelines and occurring at BSL-1. • Facilities have been inspected and all findings resolved. • Training is up-to-date and complete.
Lampe, J	E126.12	III-F-1	The overall goal of the lab is to characterize and quantify the microbiome in preserved human gut (stool) and preserved human tumor and normal tissue to understand the role of the microbiome in human health and disease. • Renewal of full EMUA, with all work exempt from the NIH Guidelines and occurring at BSL-1. • Facilities have been inspected and all findings resolved. • Training is up-to-date and complete.
Sandmaier	E126.14	NA	The lab analyzes clinical trial specimens treated with radiation to determine if radioimmunotherapy would be beneficial. • Renewal of full EMUA, with all work exempt from NIH Guidelines • Facilities have been inspected and all findings resolved. • Training is up-to-date and complete.

Fong	E324.6	III-D-3, III-E-1, III-F-8	• Adding new RG1 bacteria and yeast strains, new cell lines, and new lentivirus vectors to support CAR- T-cell design. • Training is up to date, and facilities are confirmed appropriate with no changes.
Kiem	E224.2	III-D-3, III-D-4, III-E, III-E-1	The project will use the PM1 T cell line under BSL-2+ conditions to produce HIV-1 viral stocks and evaluate gene editing strategies. It introduces a new Sauri CRISPR-Cas9 system and chimeric AAV vectors carrying the Sleeping Beauty transposon to deliver and integrate reporter or therapeutic genes—such as targeting RFXANK to correct immune deficiency—in cell lines and primary cells. • Gene targets include human and NHP non-oncogenic or tumor suppressive proteins; modifications will be made using AAV, CRISPR Cas 9 editing, and virus-like particles. • Production and use of AAV for transduction of human and NHP cells will be done at BSL-1. • Production and use of eVLPS for transduction of human cell lines and NHP cells will be done at BSL-2. • Administering AAV, 3rd generation eVLPS to mice will be done within a BSC, followed by housing at ABSL-1. • Administering 2nd-generation eVLPS to mice will be done within a BSC, followed by housing at ABSL-2. • Administering nanoparticles to mice will be done within a BSC, followed by housing at ABSL-1. • Nanoparticles composed of a cationic polymer and lipids and mRNA, CRISPR ribonucleoproteins, and other nucleases will be administered to mice within a BSC, followed by housing at ABSL-1. • no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Mian	E424.3	III-D-3, III-E-1	• Addition of new transfer plasmids for approved lentiviral vector system that will be handled at BSL-2. • Addition of cell sorting for approved modified cell lines to be done at BSL-2. • There are no changes to personnel, facilities, or maximum approved containment level due to this amendment.
Simeonov	E325.1	III-D-4	• Addition of new personnel. • New personnel training is up-to-date and complete. • Addition of new mouse cancer cell lines to be handled at BSL-1 or BSL-2, if transduced with lentiviral vectors. • Cell sorting of virally-transduced mouse cells 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.

			• There are no changes to facilities or maximum approved containment level due to this amendment.
Thomas	E425.1	III-D-3, III-D-4, III-E, III-E-1, III-F-1, III-F-8	• Adding 3 cell lines, one gammaretroviral construct, additional mouse strains, and a new toxin. • Training is up to date, and there are no changes to containment or the facility.
Batch Comments & Discussion:			
The Committee reviewed this work and confirmed that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are implemented in accordance with institutional and regulatory standards			
Batch Vote & Recusals/Abstentions:			
Approved unanimously, 1 recusal			

CATEGORY "C" BSO REVIEWS

Principal Investigator:	***EMUA Number:***	***Approval Date:***	***NIH Sections:***	***Summary (including training for amendments adding personnel):***
Beronja	E123.4	1.16.26	N/A	Add FACS procedure on approved modified cells. Facilities are confirmed appropriate. Add personnel. New personnel training is up-to-date and complete.
McGuire	E322.5	1.26.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Henikoff	E324.9	1.26.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Mayers	E424.2	1.29.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Sullivan	E323.12	1.30.26	N/A	Add FACS procedure on approved modified cells. Facilities are confirmed appropriate.
Talbot	E425.10	2.2.26	N/A	Add new helminth, T.muris for administration to mice. Facilities are confirmed appropriate.
Gujral	E425.4	2.26.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Ghajar	E125.4	2.27.26	N/A	Add personnel. New personnel training is up-to-date and complete.
Overbaugh	E423.3	3.9.26	N/A	Add SEB. Facilities are confirmed appropriate.
Lund	E124.11	3.10.26	N/A	Add FACS procedure on healthy human PBMCs. Facilities are confirmed appropriate.

EMUA CLOSEOUTS

- Riddell E323.4

UPDATES/PROGRAM REVIEW

Biosafety Officer gave presentation on how to review Human Gene Trials for the IBC

INCIDENTS, ACCIDENTS, AND PROBLEMS

None

VI. OTHER BUSINESS

None

Meeting adjourned at 11:40 AM

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

DocuSigned by:
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Susan Parazzoli MS, RBP
Biosafety Officer

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