Fred Hutch Cancer Center

MINUTES OF THE FRED HUTCHINSON CANCER CENTER
INSTITUTIONAL BIOSAFETY COMMITTEE

July 17, 2025, IBC Meeting, 10:00 am, E1-101

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, Human Biology, *Member*
☐	☒	Marian Esvelt DVM, Associate Director, Comparative Medicine, *Member*
☐	☒	Taran Gujral PhD, Human Biology, *Member*
☒	☐	Tony Han, BSL-3/ABSL-3 Facility Manager, *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 Research, *Member*
☒	☐	Susan Strenk, Research Technician III, Vaccine and Infectious Disease, *Member*
☐	☒	Andrea Towlerton, HCRI Lab Director, *Member*
☒	☐	Allison Zelikoff MN, RN, COHN-S, Occupational Nurse Manager, *Member*

NON-MEMBERS

Dagmar Achtelik, Administrative Coordinator, EH&S, *Committee Secretary*
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 10:03 am.

I. ANNOUNCEMENTS AND UPDATES

- Presentation regarding the availability of IBC member rosters on the NIH website and the new requirement for public posting of IBC Meeting Minutes.

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

IBC minutes for meetings held on May 15, 2025, and May 28, 2025, were reviewed and approved by all committee members during the month of June to facilitate approval and signature by the departing IBC chairperson.

IV. REVIEW OF ACTION ITEMS

- None

V. NEW BUSINESS

HVTN TRIAL UPDATES

- None

CATEGORY "A" IBC REVIEWS

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Simeonov	New	E325.1: Simeonov lab at FHCC	III-D-3, III-D-4, III-E, III-E-1, III-F-1, III-F-2, III-F-8

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

- The overall goal of this work is to study cancer evolution by tracing the history of individual tumor cells using specialized genetic barcodes. The work may give insight into which cells mediate metastasis and treatment resistance and thus lead to improved therapies.
- Gene targets include human, mouse, bacteria and invertebrate reporters, transposase and CRISPR/Cas guides; modifications will be made using transient 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.
- Production and use of lentiviral vectors for transduction of mouse cell lines will be done 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.
- 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.
Remove all embedded links to the lab's plasmid maps, since they do not work without access permissions. Relevant plasmid maps are included at the end of the EMUA document.

Training & Facilities:	***Vote & Recusals:***
Facilities inspections will be done before work begins, once the lab is moved in. New personnel training is up-to-date and complete.	Approved, no recusals.

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Aprikyan	Renewal	E325.2 Aprikyan lab at FHCC	III-D-4, III-F-1

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

- The purpose of these experiments is to make and test nanoparticles that deliver several biologically active drugs simultaneously to restore the function of abnormal genes, and to test the delivery of these drugs to cells with minimal cell toxicity, largely in glioblastoma. At the Hutch, they aim to test in mouse models.
- Administering modified human cells to mice at BSL-2.
- Recombinant nucleic acids with human gene targets will be delivered by nanoparticle to mice in a BSC followed by ABSL-1 housing

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.
The term “primary” should be removed from the Procedures section in reference to the cells being used. They are cell lines only, not primary samples.

Training & Facilities:	*Vote & Recusals:*
Personnel training is up-to-date and complete. Facilities are confirmed appropriate.	Approved, no recusals.

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Bloom	Renewal	E325.3 Bloom Lab at FHCC	III-D-1, III-D-2, III-D-3, III-D-7, III-E-1, III-F-1, III-F-2, III-F-3, III-F-4, III-F-5, III-F-8

REVIEW AND VOTE DEFERRED
Due to a necessary recusal, quorum was lost.

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Malik	Renewal	E325.4: Malik lab at FHCC	III-D-1, III-D-2, III-D-3, III-D-4, III-E-1, III-F-1, III-F-2, III-F-3, III-F-4, III-F-5, III-F-7, III-F-8

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

- The overall goal of this work is to 1) investigate the role of evolutionary changes in chromosomal and mitochondrial proteins on the function of these proteins and 2) study the evolutionary arms race in host-virus interactions to understand what evolutionary pressures drive changes in both viral and antiviral proteins.
- Gene targets include human, yeast and drosophila reporter, cell cycle, and histone dynamics genes, as well as viral packaging/transport/polymerase and antiviral genes; 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.

- Yeast strains for routine fungal culture and protein expression will be handled at BSL-1.
- Routine manipulation of *Drosophila* strains and cell lines will be done at BSL-1.
- Routine culturing of human and non-human primate cell lines will be done at BSL-2.
- Production and use of lentiviral vectors for transduction of cell lines will be done at BSL-2.
- FACS will be performed on yeast and *Drosophila* cells at BSL-1 and on human and non-human primate cells at BSL-2.
- Nucleic acids from risk group 2 viruses will be studied in non-replicating systems at BSL-2.
- The EMUA also 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, no recusals

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Parkhurst	Renewal	E325.5	III-D-4, III-E, III-F-1

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

- The overall goal of this project is to determine the biological basis of single cell and tissue wound repair in order to guide further design of tissue repair therapies to enhance healing speed and prevent scarring.
- Gene targets include a wide variety of *Drosophila* genes; modifications will be made using CRISPR/Cas editing.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Yeast strains for routine fungal culture will be handled at BSL-1.
- Breeding and handling of transgenic *Drosophila* will be done at BSL-1.
- Recombinant synthetic nucleic acids or molecules will be administered to *Drosophila* at BSL-1.
- Routine culturing of *Drosophila* cell lines will be done at BSL-1.

Comments & Discussion:

Clarify the methods used for the generation and breeding of transgenic *Drosophila*.
Clarify the absence of risk of a gene drive.

Training & Facilities:	***Vote & Recusals:***
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Vote deferred, pending additional information required for appropriate risk assessment

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Strong	Renewal	E325.6 Strong Lab at FHCC	III-D-3, III-E, III-F-1, III-F-2, III-F-8

REVIEW AND VOTE DEFERRED
Due to a necessary recusal, quorum was lost.

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Waghmare	Renewal	E325.7	III-F-1

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

- The overall goal of this project is to identify biomarkers and immune correlates of susceptibility to the acquisition, progression, and severity of viral infections through studies of humoral and cellular immunity.
- Lab strains of *E. coli* for bacteriophage production will be handled at BSL-1.
- Human tissue samples and primary cells will be handled at BSL-2 for processing.
- 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, no recusals.

Principal Investigator:	*EMUA Type:*	*EMUA Number & Title:*	*NIH Sections:*
Dhodapkar	Amendment	E225.1: Nanoparticles into mice	III-D-4

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

- The goal of this project is to test a lipid nanoparticle system as a novel approach to modify cells *in vivo*.
- New gene targets include human T cell receptors.
- Nanoparticles composed of lipids and gene target mRNA payload will be administered to mice 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.
Provide lab with Fred Hutch SOP for Nanoparticles.

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

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

Koch	Amendment	E125.12	Section III-D-4

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

- The purpose of this amendment is to add a new genetically modified commensal E. coli strain which would help track T cell responses to this bacteria in mice.
- Commensal strains of genetically modified E. coli will be administered to mice at ABSL-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, no recusals

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Mayers	Amendment	E424.2	III-D-1, III-D-4

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

- This amendment adds additional strains of risk group 2 bacteria, RG1 E.coli with single cell deletions and genetic modifications to other risk group 2 bacteria to explore the impairment of the fitness of the bacteria in setting an infection.
- Culturing of risk group 2 bacteria will occur at BSL-2.
- Administration of risk group 2 genetically modified bacteria will occur at ABSL-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.	Approval, no recusals

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Nabet	Amendment	E321.11: HHV-8 cell lines and new lentivirus & CRISPR/Cas constructs	III-D-3

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

- The goal of this project is to dissect the molecular mechanisms that drive HHV-8 lytic replication and tumorigenesis.
- Routine culturing of human cell lines will be done at BSL-2.
- New gene targets include human non-receptor tyrosine kinases; modifications will be made using viral transduction, nucleofection and CRISPR/Cas editing.
- Production and use of lentiviral and AAV 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:***
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.	Approved, no recusals

Principal Investigator:	***EMUA Type:***	***EMUA Number & Title:***	***NIH Sections:***
Tam	Amendment	E324.1 mRNA lipid Nanoparticle Administrations	III-D-4, III-E

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

- This is an antibody core seeking approval to immunize mice with RNA encapsulated in lipid nanoparticles (LNPs) on behalf of an external client. The purpose is to discover antibodies against the human target protein. The target protein is considered upregulated in many cancers; therefore, extra precautions will be in place to ensure worker safety.
- mRNA LNP will be delivered ready to use to the antibody core.
- Nanoparticles will be administered to mice 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.
Provide lab with Fred Hutch SOP for Nanoparticles.

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

CATEGORY “B” IBC REVIEWS

Principal Investigator:	***EMUA Number:***	***NIH Sections:***	***Summary:***
Kugel	E421.4	III-D-3, III-E-1	• Adding new human cell lines and routine culturing will be done at BSL-2. • Adding new lentiviral vector system and production and use of lentivirus for transduction of human cell lines will be done at BSL-2. • New gene targets include human chromatin compactors. • Adding FACS to be performed on modified human cell lines at BSL-2.
Peterson	E323.8	III-D-4, III-E-1	REVIEW AND VOTE DEFERRED Due to a necessary recusal, quorum was lost.

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:
Kugel – approved, no recusals

CATEGORY "C" BSO REVIEWS

Principal Investigator:	***EMUA Number:***	***Approval Date:***	***NIH Sections:***	***Summary:***
Mian	E424.3	5.19.25	N/A	Add FACS procedure on approved modified cells. Facilities are confirmed appropriate.
Hadland	E123.12	5.20.25	N/A	Update lab locations. Facilities are confirmed appropriate.
Dey	E322.2	5.29.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Alvarez	E321.2	5.29.25	N/A	Update lab locations. Facilities are confirmed appropriate.
Termini	E122.2	5.29.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Dey	E322.2	6.12.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Mayers	E424.2	6.13.25	N/A	Update lab locations. Facilities are confirmed appropriate.
Cheung	E125.3	6.18.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Mian	E424.3	6.26.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Gujral	E321.6	7.2.25	N/A	Add drosophila host model system. Facilities are confirmed appropriate.
Termini	E122.2	7.2.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Dhodapkar	E225.1	7.3.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Lin	E124.7	7.8.25	N/A	Update lab locations. Facilities are confirmed appropriate.
Dey	E322.2	7.8.25	N/A	Add personnel. New personnel training is up-to-date and complete.

EMUA CLOSEOUTS

- Vasioukhin, Brent, Cooper, Avgousti, Hatch, Adair, Emerman

UPDATES/PROGRAM REVIEW

- None

INCIDENTS, ACCIDENTS, AND PROBLEMS

- Exposure to genetically modified cell lines via needlestick injury

VI. OTHER BUSINESS

- None

Meeting adjourned at 12:00 pm.

DocuSigned 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