



## MINUTES OF THE FRED HUTCHINSON CANCER CENTER INSTITUTIONAL BIOSAFETY COMMITTEE

November 20, 2025, IBC Meeting, 10:00 am, M1-A303

### ATTENDANCE

#### MEMBERS

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

#### 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  
 Liz Kindred, Director, Environmental Health & Safety  
 David Creed, Chemical Hygiene Officer, Environmental Health & Safety

#### VISITORS

Melinda Houdak, Regulatory Affairs, HVTN  
 Janine Maenza MD, HVTN

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Dr. Jerome, Chairperson, called the meeting to order at 10:00 am.

## I. ANNOUNCEMENTS AND UPDATES

- NIH launches an initiative to “Modernize and Strengthen Biosafety Oversight” on September 9<sup>th</sup>.
- We welcome back Michael Emerman as a member of the IBC

## 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 the meeting held on September 18, 2025, were reviewed and approved.

## IV. REVIEW OF ACTION ITEMS

- None

## V. NEW BUSINESS

### HVTN TRIAL UPDATES

- HVTN 307
  - Received updates, including a revised summary of clinical data and details of a serious adverse event due to the underlying conditions of the participant. Inclusion/Exclusion criteria were updated to prohibit participants at risk of developing thrombosis.

### CATEGORY “A” IBC REVIEWS

Principal Investigator:	EMUA Type:	EMUA Number & Title:	NIH Sections:
McElrath	Clinical	HVTN 312 Amendment	III-C
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<ul style="list-style-type: none"> <li>• Addition of a boost with a different mRNA-LNP encoding an alternate Env protein (CH505 w24) from the one previously approved by the IBC (CH505M5 N197D)</li> </ul>			
<b>Comments &amp; Discussion:</b>		The IBC noted that the only change is the sequence composition of the mRNA in the added boost. Risk to staff remains small.	
<b>Training &amp; Facilities:</b>		<b>Vote &amp; Recusals:</b>	
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.		Approved unanimously	

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Thomas	New	E425.1 Thomas lab at FHCC	Section III-D-3, III-D-4, III-D-7, III-E-1, III-F-1, III-F-8
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<ul style="list-style-type: none"> <li>The lab aims to define the roles of different cellular subsets and cytokines in the generation of immune responses to viral infections, their effector activity, and how they persist. They will utilize different viral models, such as influenza and cytomegalovirus, to understand which components of the host immune response contribute to immune protection, pathology, and recovery.</li> <li>Lab strains of <i>E. coli</i> for routine cloning will be handled at BSL-1.</li> <li>Routine culturing of human cell lines will be done at BSL-2.</li> <li>Gene targets include human immune system genes, viral proteins and reporters]; modifications will be made using viral transduction and CRISPR/Cas editing.</li> <li>Production and use of [lentiviral vectors and gammaretroviral vectors for transduction of human cell lines will be done at BSL-2.</li> <li>Nanoparticles composed of a lipid with a mRNA nucleic acid will be used to transfect human cells in a BSC at BSL-2.</li> <li>Lab-adapted influenza strains (PR8 backbone) are produced by reverse genetics to create recombinant viruses that express different T cell epitopes in HA and NA proteins at BSL-2 and administered to rodents at ABSL-2</li> <li>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.</li> <li>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.</li> <li>Nanoparticles SOP was provided</li> </ul>			
<b>Comments &amp; Discussion:</b>			
Provided nanoparticle SOP. 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.			
<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>		
Facilities inspections will be done before work begins, once the lab is moved-in. New personnel training is up-to-date and complete.	Approved unanimously		

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Alvarez	Renewal	E425.2 Alvarez lab at FHCC	III-D-3, III-D-4, III-E-1, III-F-1, III-F-2, III-F-8
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<ul style="list-style-type: none"> <li>The overall goal of the lab is to identify mechanisms of cancer progression using a combination of in vitro and in vivo approaches, with the goal of identifying pathways that can be targeted to kill cancer cells and prevent tumor progression.</li> <li>Gene targets include human, mouse, and synthetic oncogenes, enzymes, and reporters; modifications will be made using viral transduction and CRISPR/Cas editing.</li> <li>Lab strains of <i>E. coli</i> for routine cloning will be handled at BSL-1.</li> <li>Breeding and handling of transgenic mice will be done at ABSL-1.</li> <li>Administration of modified human and mouse cell lines that have tested negative for vivarium-excluded pathogens will be done within a BSC followed by housing at ABSL-1.</li> <li>Routine culturing of human and mouse cell lines will be done at BSL-2.</li> <li>Production and use of lentiviral and adenoviral vectors for transduction of human and mouse cell lines will be done at ABSL-2.</li> <li>FACS will be performed on modified human and mouse cells at BSL-2 and BSL-2+.</li> </ul>			
<b>Comments &amp; Discussion:</b>			

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

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
Facilities have been inspected and unresolved findings were communicated to the lab. Training is up-to-date and complete.	Approved unanimously

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Gujral	Renewal	E425.4 Gujral lab at FHCC	III-D-3, III-D-4, III-E, III-E-1, III-F-1

<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>
<ul style="list-style-type: none"> <li>The overall goal of the lab is to understand how cancer cells communicate with their surrounding environment and leverage this knowledge to discover new therapies, particularly for rare and hard-to-treat cancers like fibrolamellar carcinoma and ependymoma. The lab achieves this by developing advanced preclinical models that preserve the 3D structure of tumors and integrating them with computational tools, helping to predict drug responses and identify novel therapeutic strategies.</li> <li>Gene targets include human kinases and genes involved in signaling pathways; modifications will be made using viral transduction and CRISPR/Cas editing.</li> <li>Lab strains of <i>E. coli</i> for routine cloning will be handled at BSL-1.</li> <li>Handling of transgenic <i>Drosophila melanogaster</i> will be done at BSL-1.</li> <li>Administration of modified and unmodified human cells and tissues, mouse cells, and lipid nanoparticles carrying siRNA will be done within a BSC followed by housing at ABSL-1.</li> <li>Routine culturing of human and mouse cell lines will be done at BSL-2.</li> <li>Production and use of lentiviral and gammaretroviral vectors for transduction of human and mouse cell lines will be done at BSL-2.</li> <li>Human tissues will be handled at BSL-2 for processing, phenotypic assays, and isolating nucleic acids.</li> <li>FACS will be performed on modified human cells at BSL-2.</li> </ul>

<b>Comments &amp; Discussion:</b>
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.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
Facilities have been inspected and unresolved findings were communicated to the lab. Training is up-to-date and complete.	Approved unanimously, 1 recusal

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Markey	Renewal	E425.6 Markey lab at FHCC	III-D-4, III-E-3, III-F-1, III-F-5, III-F-8

<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>
<ul style="list-style-type: none"> <li>The overall goal of the Markey lab is to delineate how the gut microbiome can be leveraged to improve outcomes after allo-HCT.</li> <li>Routine culturing of human and mouse cancer cell lines that express fluorescent reporter genes and that have been previously transduced with oncogenes by collaborators will be done at BSL-2.</li> <li>Human blood and stool samples will be handled at BSL-2 for protein and nucleic acid isolation.</li> <li>Breeding/handling transgenic mice will be done at ABSL-1.</li> <li>Administering mouse cells from wild-type or transgenic mice and previously modified human or mouse cancer cell lines that have tested negative for vivarium-excluded pathogens will be done within a BSC followed by housing at ABSL-1.</li> <li>FACS will be performed on fixed (BSL-1) and unfixed (BSL-2) previously modified mouse cancer cells or unfixed transgenic mouse model hematopoietic cells (BSL-1).</li> </ul>

- Unmodified commensal gut bacteria strains will be propagated and administered to mice by oral gavage. These activities will be done at A/BSL-1 or A/BSL-2 depending on the strain.

**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:**

Facilities have been inspected and all findings resolved.  
Training is up-to-date and complete.

**Vote & Recusals:**

Approved unanimously

Principal Investigator:	EMUA Type:	EMUA Number & Title:	NIH Sections:
Prlic	Renewal	E425.7 Prlic lab at FHCC	III-D-1, III-D-3, III-D-4, III-F-1

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

- This research investigates how different T cell subsets contribute to host immunity under conditions such as infection, inflammation, vaccination, and cancer. The work aims to uncover mechanisms underlying T cell function to enable therapeutic manipulation of immune responses. To achieve this, the team uses mouse models for in vivo studies, human cells and tissues for ex vivo experiments, and develops antibodies for targeted interventions.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Routine culturing of human, mouse cell lines will be done at BSL-2.
- Gene targets include non-oncogenic human immune genes and modifications will be made using viral transduction.
- Production and use of lentiviral vectors for transduction of human cell lines will be done at BSL-2.
- Genetically modified RG2 bacteria expressing T-cell epitopes or lacking genes that enable it to spread from cell to cell will be generated, used and administered to mice at (A)BSL-2.
- Genetically modified RG2 virus expressing chicken OVA will be produced, used and administered to mice at (A)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 human 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 IBC requests updates for wording for agents in storage. To say "make an amendment to the EMUA" rather than "reach out to EH&S"

**Training & Facilities:**

Facilities have been inspected and all findings resolved.  
Training is up-to-date and complete.

**Vote & Recusals:**

Approved contingent on minor change listed in the comments and discussion.

Principal Investigator:	EMUA Type:	EMUA Number & Title:	NIH Sections:
Rajan	Renewal	E425.8: Rajan lab at FHCC	III-E, III-F-1, III-F-8

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

- The overall goal of the Rajan lab is to understand the basic cellular and molecular mechanisms that underlie maintenance of energy balance. The specific aims are to use *Drosophila* as a discovery tool to identify precise mechanisms involved in nutrient sensing and storage.
- 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 and culture of *Drosophila* cell lines will be at BSL-1.
- Gene targets include invertebrate cytokines and metabolism genes as well as fluorescent reporters; modifications will be made using non-viral transient transfection.

**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.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Salama	Renewal	E425.9: Salama lab at FHCC	III-D-1, III-D-2, III-D-3, III-D-4, III-E-1, III-E-3, III-F-1, III-F-3, III-F-4, III-F-8

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

- The lab studies mechanisms by which *H. pylori* establishes chronic infection in the stomach and the host and bacterial factors that promote disease.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.
- Routine culturing of human, mouse, and canine cell lines will be done at BSL-2.
- Gene targets include non-oncogenic, non-tumor suppressive human and *H.pylori* bacteria virulence genes. Modifications will be made using viral transduction and CRISPR/Cas editing.
- Production and use of 2<sup>nd</sup> and 3<sup>rd</sup> gen lentiviral vectors for transduction of human cell lines and mouse cells will be done at BSL-2.
- Culturing, propagation and mouse infection with modified RG2 bacteria will be done at BSL-2
- Genetic modifications by cloning to RG2 bacteria include virulence genes and fluorescent reporters

**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.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Talbot	Renewal	E425.10: Talbot lab at FHCC	III-D-2, III-D-3, III-D-4, III-E-1, 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 the Talbot lab is to study the crosstalk between nervous system and the immune system. In particular, how gut neurons maintain intestinal and systemic homeostasis through interactions with the immune system. Current research in the lab studies how neuronal control of the immune system leads to changes in intestinal permeability, host-microbiota interactions, intestinal inflammation, nutrient absorption and systemic metabolism.
- Gene targets include non-oncogenic human, mouse, invertebrate and viral proteins along with fluorescent reporters; modifications will be made using viral transduction.
- Lab strains of *E. coli* for routine cloning will be handled at BSL-1.

- Routine culturing of human, mouse, feline, rabbit and rat cell lines will be done at BSL-2.
- Production and use of replication incompetent lentiviral vectors, pseudorabies vector and AAV for transduction of human and mouse cell lines will be done at BSL-2.
- Administering unmodified mouse cells or cells from transgenic mouse models that have tested negative for vivarium-excluded pathogens to mice will be done within a BSC followed by housing at ABSL-1.
- Administering viral vectors or unmodified risk group 2 bacterial agents to mice will be done within a BSC followed by housing at ABSL-2.
- FACS will be performed on fixed virally modified human and mouse cells at BSL-1 and on unfixed mouse cells exposed to bacterial or viral agents 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 that the research is clearly described, the associated risks are recognized, and appropriate biosafety practices are implemented in accordance with institutional and regulatory standards.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
Facilities have been inspected and all findings resolved. Training is up-to-date and complete.	Approved unanimously

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Bloom	Amendment	E325.3 Adding CRISPR lentivirus system	III-D-3

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

- The lab would like to use the CRISPR-Cas9 system to knock down the expression of mucin gene in human bronchial epithelial cells
- Lentiviral delivery of CRISPR will occur at BSL2

**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.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment	Approved unanimously

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Boonyaratanaornkit	Amendment	E223.2 Production and Use of Genetically Modified Rhinovirus in-vitro and in-vivo	III-D-2, III-D-3, III-D-4

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

- The project goal is to study the immune response to rhinoviruses and identify and develop antibodies that could be used to protect against rhinovirus infections.
- Rhinovirus will be produced by reverse genetics from nucleic acids in human cells at BSL-2.
- Engineered virus will be administered to rodents at ABSL-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.

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

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
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 will be done at BSL-2.

**Comments & Discussion:**

- Clarification is needed on the handling procedures for the EBV-conditioned supernatant during viral batch production.

<b>Training &amp; Facilities:</b>	<b>Vote &amp; Recusals:</b>
N/A - no changes to personnel, facilities, or maximum approved containment level due to this amendment.	Vote deferred, pending additional information required for appropriate risk assessment

<b>Principal Investigator:</b>	<b>EMUA Type:</b>	<b>EMUA Number &amp; Title:</b>	<b>NIH Sections:</b>
Hill	Amendment	E323.10 Engineered commensal microbes expressing defined murine epitopes to modulate antigen presentation and donor T cell responses in graft-versus-host disease	III-D-4, III-E

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

- This project aims to harness engineered microbes to modulate antigen presentation and microbe-specific T cell responses in graft-versus-host disease (GVHD)
- Modification of non-pathogenic E. coli to express murine peptides will occur at BSL-1
- Gene targets also include reporter genes
- Administration of modified E. coli to mice will occur at ABSL-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.

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

## CATEGORY "B" IBC REVIEWS

<b>Principal Investigator:</b>	<b>EMUA Number:</b>	<b>NIH Sections:</b>	<b>Summary:</b>
Bloom (1)	E325.3	III-E, III-F-8	<ul style="list-style-type: none"> <li>Adding PiggyBac Transposon System</li> </ul>
Bloom (2)	E325.3	III-D-2, III-D-3, III-F-1	<ul style="list-style-type: none"> <li>Adding Measles H and F pseudoviruses and receptor cell lines.</li> </ul>
Cheung	E125.3	III-D-3	<ul style="list-style-type: none"> <li>Adding new 2nd generation lentiviral vectors and non- oncogenic inserts for sorting.</li> </ul>
Ha	E425.5	III-F-1	<ul style="list-style-type: none"> <li>Renewal of full EMUA, with all work exempt from NIH Guidelines</li> </ul>
Headley	E223.5	III-D-4	<ul style="list-style-type: none"> <li>Add Poly I:C for administration to mice.</li> </ul>
Kugel	E421.4	III-D-3, III-E-1	<ul style="list-style-type: none"> <li>Add new modified pancreatic, liver and lung cancer cell lines.</li> <li>Add new histone gene targets.</li> <li>Add new 2nd generation lentiviral vector system to modify the added cell lines.</li> <li>Modified cell lines will be subjected to FACS.</li> </ul>
Lee	E125.6	III-D-4	<ul style="list-style-type: none"> <li>Add modified human T cells (provided by collaborator lab) for administration to mice.</li> <li>Add alternate routes of administration to mice for previously approved agents.</li> </ul>
Stephan	E322.6	III-D-3	<ul style="list-style-type: none"> <li>Adding a new 3rd generation lentivirus expressing Anti-Mesothelin.</li> </ul>
<b>Batch Comments &amp; Discussion:</b>			
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.			
<b>Batch Vote &amp; Recusals/Abstentions:</b>			
Approved unanimously, 2 recusals			

## CATEGORY "C" BSO REVIEWS

<b>Principal Investigator:</b>	<b>EMUA Number:</b>	<b>Approval Date:</b>	<b>NIH Sections:</b>	<b>Summary:</b>
Mayers	E424.2	9.23.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Cheung (1)	E125.3	9.29.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Cheung (2)	E125.3	10.2.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Esvelt	E423.1	10.3.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Ring	E223.4	10.9.25	N/A	Add unmodified human cells for in vivo administration. Facilities are confirmed appropriate.
Eisenman	E123.12	10.10.25	N/A	Add FACS procedure on approved cells. Facilities are confirmed appropriate.
Campbell	E125.10	10.21.25	N/A	Add personnel. New personnel training is up-to-date and complete. Update TC room location. Facilities are confirmed appropriate.

Koch	E125.12	10.24.25	N/A	Add personnel. New personnel training is up-to-date and complete. Add funding.
Tapscott	E224.3	10.30.25	N/A	Add funding.
MacPherson	E322.4	11.4.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Bleakley	E225.4	11.7.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Ghajar	E125.4	11.10.25	N/A	Add personnel. New personnel training is up-to-date and complete.
Bloom	E325.3	11.10.25	N/A	Add personnel. New personnel training is up-to-date and complete.

## EMUA CLOSEOUTS

- None

## UPDATES/PROGRAM REVIEW

- Transition from CITI to a new Biosafety training launched in August which is in-house and required every 3 years

## INCIDENTS, ACCIDENTS, AND PROBLEMS

- 8/12/2025 – Mouse bite, potential exposure to lentiviral vector
- 10/28/2025 (1) – Needlestic following serial injections
- 10/28/2025 (2) – Needlestic while injecting modified T cells

**VI. OTHER BUSINESS**

- None

Meeting adjourned at 11:47 am.

Signed by:

  
keith Jerome

CB83B35EA7A9430

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

DocuSigned by:

  
Susan Parazzoli

09CC928C5E494BB...

Susan Parazzoli MS, RBP  
Biosafety Officer

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