



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

April 20, 2026 Special IBC Meeting, 11:30 am, MS Teams

**ATTENDANCE**

**MEMBERS**

<b>Present</b>	<b>Absent</b>	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Kevin Barry PhD, Public Health Sciences, <i>Member</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Elizabeth Cromwell, PDX Program Lead, <i>Member</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Bernadeta Dadonaite PhD, Staff Scientist, Basic Sciences, <i>Member</i>
<input checked="" type="checkbox"/>	<input 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 Esvelt DVM, Associate Director, Comparative Medicine, <i>Member</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Taran Gujral PhD, Human Biology, <i>Member</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Tony Han, BSL-3/ABSL-3 Facility Manager, <i>Member</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Alexandre 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-Gochmour 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 checked="" type="checkbox"/>	<input type="checkbox"/>	Joshua Schiffer MD, MSc, Clinical Researcher, <i>Member</i>
<input type="checkbox"/>	<input checked="" 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"/>	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

**VISITORS**

None

Dr. Jerome, Chairperson, called the meeting to order at 11:30 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**

None

**IV. REVIEW OF ACTION ITEMS**

None

**V. NEW BUSINESS**

**HUMAN GENE TRANSFER APPLICATIONS**

<b>Principal Investigator:</b>	<b>RG #:</b>	<b>Biosafety Level:</b>	<b>NIH Sections:</b>
McElrath	RG1123648	BSL-1	III-C
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<p>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 without HIV. The prime and first boost products have previously been approved by the Fred Hutch IBC and this version update is adding a new second mRNA-LNP boost.</p> <p>The mRNA-LNP formulation is made offsite.</p> <p>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.</p>			
<b>Comments &amp; Discussion:</b>			
<p>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.</p>			
<b>Training &amp; Facilities:</b>		<b>Vote &amp; Recusals:</b>	
<p>Facilities have been inspected and are appropriate. Study PI training is up-to-date and complete.</p>		<p>Unanimously approved 1 recusal</p>	

<b>Principal Investigator:</b>	<b>RG #:</b>	<b>Biosafety Level:</b>	<b>NIH Sections:</b>
Hirayama	RG1126232	BSL-1	III-C
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<p>The Investigational Drug Product (IDP) for this trial is a modified cell product, specifically T cells, for treatment of active systemic sclerosis.</p> <p>Modifications are made to the T cells offsite at the sponsor’s manufacturing facility by transduction with replication-incompetent lentiviral vector. The product undergoes replication competent lentivirus testing are part of product release.</p>			

<p>Modified cells are received by the FH Cellular Therapy lab (CTL), transported onsite and thawed at bedside by CTL personnel using clinic standard precautions.</p> <p>The modified cells are administered by Immunotherapy Clinic nurses using clinic standard precautions.</p>	
<p><b>Comments &amp; Discussion:</b></p> <p>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.</p> <p>Disinfection or spill clean-up of this product will be done with clinic quaternary ammonium/isopropyl alcohol-based germicidal wipes.</p>	
<p><b>Training &amp; Facilities:</b></p> <p>Facilities have been inspected and are appropriate. Study PI training is up-to-date and complete.</p>	<p><b>Vote &amp; Recusals:</b></p> <p>Unanimously approved 1 recusal</p>

CATEGORY "A" IBC REVIEWS

None

CATEGORY "B" IBC REVIEWS

None

CATEGORY "C" BSO REVIEWS

None

EMUA CLOSEOUTS

None

UPDATES/PROGRAM REVIEW

None

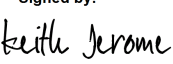
INCIDENTS, ACCIDENTS, AND PROBLEMS

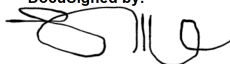
None

**VI. OTHER BUSINESS**

None

Meeting adjourned at 11:56 am.

Signed by:  
  
CB83B35EA7A9430  
 Keith Jerome, MD PhD  
 Vaccine and Infectious Disease  
 Institutional Biosafety Committee Chairperson

DocuSigned by:  
  
09CC928C5E494BB  
 Susan Parazzoli MS, RBP  
 Biosafety Officer

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