



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

December 18, 2025 Special IBC Meeting, 2:00 pm, MS Teams

### ATTENDANCE

#### MEMBERS

<i>Present</i>	<i>Absent</i>	
<input checked="" type="checkbox"/>	<input 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 checked="" type="checkbox"/>	<input 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 type="checkbox"/>	<input checked="" 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"/>	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 type="checkbox"/>	<input checked="" 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 type="checkbox"/>	<input checked="" 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"/>	Andrea Towler, HCRI Lab Director, <i>Member</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Allison Zelikoff MN, RN, COHN-S, Occupational Health Manager, <i>Member</i>

#### NON-MEMBERS

Jake White, Assistant Biosafety Officer, Environmental Health & Safety  
Cindy Wladyka, EH&S Specialist for Biosafety, Environmental Health & Safety

#### VISITORS

Michelle Choe MD, Study Principal Investigator  
Zoe Worthington PhD, IBC Consultant

Dr. Jerome, Chairperson, called the meeting to order at 2:01 pm.

### 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>
Choe	RG1125765	BSL-1	III-C
<b>Summary (including agents, manipulations, genes, hosts, proposed containment/biosafety levels):</b>			
<p>Dr. Choe attended the meeting, gave an overview of the trial and was available for questions from the committee. CAR manufacture is expected to take two weeks after apheresis, followed by participant lymphodepletion and infusion.</p> <p>Dr. Choe left the meeting prior to committee discussion and review.</p> <p>Committee discussion and review: Standard second generation CAR T study, manufactured here at FH. Phase I open label dose escalation study. Modification by third generation lentiviral vector manufactured at Indiana University Vector Production Facility. FOLR targeting has been used in various contexts without any severe toxicities. No reported cases of RCL in vectors used for modifying T cells.</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>	
Facilities have been inspected and are appropriate. Study PI training is up-to-date and complete.		Unanimously approved	

### 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 2:20 pm.

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