

## Institutional Biosafety Committee (IBC) Meeting Minutes

<b>Institution:</b>	<b>Wake Forest University School of Medicine</b>			
<b>Meeting Date and Time:</b>	August 20 <sup>th</sup> at 12:30			
<b>Meeting Type:</b>	Online via Microsoft Teams			
	Name	Role and Department	Attendance	
<b>IBC Members Present:</b>	Frank Marini, PhD	IBC Chair, WFIRM	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Anthony Blaaser, PhD	IBC Vice Chair Musculoskeletal Department	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Samuel Centanni, PhD	Voting Member, Translational Neuroscience	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Ji Hyun Kim, PhD	Voting Member, WFIRM	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Elizabeth Palavecino, MD	Voting Member, Pathology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	David Ornelles, PhD	Voting Member, Microbiology and Immunology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Marlena Westcott, PhD	Voting Member, Microbiology and Immunology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Brian Strittmatter, PharmD, MSCR	Voting Member, Pharmacy Clinical Trial Services, Pharmacy Manager	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Patrick McNutt, PhD	Voting Member, WFIRM,	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Linda Metheny-Barlow, PhD	Voting Member, Radiation Oncology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Swapn Das, PhD, MSc	Voting Member, IM. Endocrinology & Metabolism	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Caryn Gee Morse, MD, PhD	Voting Member, IM, Infectious Diseases	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Drew Kiraly, MD	Voting Member, Translational Neuroscience	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Robert Hampson, PhD	Voting Member, WFIRM	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Farah Mougeot, PhD, MS	Voting Member, Translational Research – Oral Medicine	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Kimberly Woodward, MD, MPH	Voting Member, Pathology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Paris Charilaou, MD, FACP	Voting Member, Gastroenterology and Hepatology	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent

	Yuming Jiang, MD, PhD	Voting Member, Radiation Oncology	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Dan Hurley	Local Non-Affiliated Community Member (Charlotte)	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Jeanette Bennett	Community Member (Charlotte)	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Kara Milton	Community Member (Winston Salem)	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Adam Bray	Community Member (Winston Salem)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Christopher Ohl, MD	Voting Member, IM, Infectious Diseases (Ad-Hoc)	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Scott Gamble, DVM	Voting Member, Animal Expert	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Lisa Colvin	Voting Contact, IBC Administrator	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Emylee Pedersen	Voting Contact, IBC Administrator	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Bernadette Menuey	Voting Member, Biosafety Officer	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Jessica Baker	Voting Member, IACUC Representative	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Katy Heide	Voting Member, EHS, Environmental Compliance	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Ex Officio W/O Vote			
	Suzy Mounsey	Animal Resources Program	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Gaye Hodges	Animal Resources Program	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Stephen Fisenne	WFU Representative	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
	Morgan Lawson	Environmental Health & Safety	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Jennifer Williams	Environmental Health & Safety	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Paul Haliburton	EHS, AVP	<input checked="" type="checkbox"/> Present	<input type="checkbox"/> Absent
	Joseph Kim	AHWFB Teammate Health	<input type="checkbox"/> Present	<input checked="" type="checkbox"/> Absent
<b>Quorum:</b>	Yes			
<b>Call to Order:</b>	Meeting called to order at 12:33			
<b>Conflicts of Interest:</b>	Chair reminded all members present to identify any conflicts of interest as protocols are reviewed. No COIs to disclose for this meeting.			
<b>Review and Approval of Previous Meeting Minutes:</b>	Motion to approve by Dr. Marini, second by Dr. Blaeser			
<b>Review of Prior Meeting Business (if applicable):</b>	Committee vote on IBC Bylaws.			

New IBC Registrations and Amendments for Review	
<b>PI Name:</b>	Kiraly, Drew
<b>Registration Number:</b>	B25-W-004
<b>IBC Registration Title:</b>	Influence of murine (b) (4) on opioid seeking behaviors.
<b>Project Overview:</b>	Mice will be infected with (b) (4) and exposed to behavioral paradigms such as self-administration and conditioned place preference, aiming to uncover how persistent viral presence in the CNS affects motivation for opioid and reward sensitivity.
<b>Applicable NIH Guidelines:</b>	Section III-D: rDNA from Risk Group 2, 3, 4, or restricted agents as vector systems; Infectious or defective DNA or RNA viruses; Whole animals and plants; Large volumes
<b>Agent Description:</b> e.g. virulence, pathogenicity, environmental stability	<p>Ecotropic murine leukemia virus (MLV) envelope, (b) (4) chimera on the backbone of clade NDK</p> <p>Ecotropic murine leukemia virus (MLV) envelope, (b) (4) chimera on the backbone of clade (b) (4)</p> <p>Collaborator develops plasmids using recombination-deficient strains for plasmid amplification in addition to the deletion of human-specific viral replication genes. This viral plasmid has not been found capable of infecting any type of human cell tested (Potash MJ, et.al., 2005. A mouse model for studying systemic (b) (4) infection, antiviral immune responses, and neuroinvasiveness. PNAS)</p>
<b>Types of Manipulations:</b>	None
<b>Source of nucleic (DNA/RNA) sequences:</b> e.g. species	(b) (4) Ectopic MLV
<b>Nature of nucleic acid sequences:</b> e.g. structural gene, oncogene	N/A
<b>Host(s) and Vector(s):</b>	<p>(b) (4) - Lentiviral vector (based on (b) (4) backbone); envelope is murine Ecotropic MLV gp80</p> <p>(b) (4) - Lentiviral vector (based on (b) (4) backbone); envelope is murine Ecotropic MLV gp80</p> <p>E. coli, DH5alpha (plasmid amplification); Hek293FT (viral packaging)</p>
<b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b>	SV40 Early promoter (stable transcription provided by additional packaging vector); (b) (4) Long terminal repeats (LTRs)
<b>Risk Assessment Discussion Points:</b>	<p>ABSL 2 facility in Hanes is currently under renovation. Project cannot begin until project is complete.</p> <p>Clarification needed on where agent will be administered to animals, where animals will be housed, and where behavioral testing will take place.</p>

<b>Training:</b>	Awaiting training certifications from PI for: <ul style="list-style-type: none"> <li>• Initial Biosafety Training</li> <li>• Biosafety Retraining</li> <li>• Animal Biosafety</li> <li>• Emergency and Incident Response to Biohazard Spills and Releases</li> <li>• NIH Recombinant DNA Guidelines</li> <li>• OSHA Bloodborne Pathogens</li> </ul>
<b>Occupational Health Review (if applicable):</b>	Standard precautions for bloodborne pathogens and PPE for working at BSL/ABSL 2.
<b>Biosafety Level:</b> <b>Animal Biosafety Level:</b>	BSL/ABSL2
<b>IBC Vote:</b>	Approved pending modifications
<b>New IBC Registrations and Amendments for Review</b>	
<b>PI Name:</b>	Dr. Justin Matulay
<b>Registration Number:</b>	B25-CT-C-003
<b>IBC Registration Title:</b>	A Phase 2, Multi-Arm, Multi-Cohort, Open Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle Invasive Bladder Cancer (ClinicalTrials.gov ID NCT06567743)
<b>Project Overview:</b>	Treatment for Non-Muscle Invasive Bladder Cancer with oncolytic immunotherapy with dual mechanism of action that selectively replicates and lyses cancer cells while simultaneously amplifying the immune response against bladder tumors.
<b>Applicable NIH Guidelines:</b>	Section III-C-1
<b>Agent Description:</b> e.g. virulence, pathogenicity, environmental stability	The study agent cretostimogene grenadenorepvec ("cretostimogene", (b) (4) ) is a (b) (4) . In cretostimogene, the (b) (4) .
<b>Types of Manipulations:</b>	Manipulations performed by manufacturer of study agent.
<b>Source of nucleic (DNA/RNA) sequences:</b> e.g. species	N/A
<b>Nature of nucleic acid sequences:</b> e.g. structural gene, oncogene	(b) (4)
<b>Host(s) and Vector(s):</b>	Host: (b) (4)

<b>Will a transgene be expressed? If so, what is the function of the protein that will be produced?</b>	(b) (4)
<b>Risk Assessment Discussion Points:</b>	If unused product will be returned to study sponsor, teammates shall receive training for proper shipping procedures for biological materials.
<b>Training:</b>	
<b>Occupational Health Review (if applicable):</b>	N/A
<b>Biosafety Level: Animal Biosafety Level:</b>	BSL2
<b>IBC Vote:</b>	Approved
<b>New IBC Registrations and Amendments for Review</b>	
<b>PI Name:</b>	Dr. Jonathan Lambird Dr. Cindy Varga
<b>Registration Number:</b>	B25-CT-WS/C-001
<b>IBC Registration Title:</b>	Kite Pharma KT-US-679-0788: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma (iMMagine-3) (ClinicalTrials.gov Identifier: NCT06413498)
<b>Project Overview:</b>	Comparing the safety and efficacy of anitocabtagene autoleucel (b) (4) ) versus standard of care therapy (SOCT) in treating patients with multiple myeloma who have received 1 to 3 prior lines of therapy.
<b>Applicable NIH Guidelines:</b>	Section III-C-1
<b>Agent Description:</b> e.g. virulence, pathogenicity, environmental stability	The (b) (4) system derived from (b) (4) (b) (4)
<b>Types of Manipulations:</b>	Manipulations performed by manufacturer of study agent.
<b>Source of nucleic (DNA/RNA) sequences:</b> e.g. species	n/a
<b>Nature of nucleic acid sequences:</b> e.g. structural gene, oncogene	(b) (4)
<b>Host(s) and Vector(s):</b>	Host: (b) (4) (b) (4)
<b>Will a transgene be expressed? If so, what is the function of the</b>	(b) (4)

<b>protein that will be produced?</b>	
<b>Risk Assessment Discussion Points:</b>	If unused product will be returned to study sponsor, teammates shall be receive training for proper shipping procedures for biological materials.
<b>Training:</b>	
<b>Occupational Health Review (if applicable):</b>	N/A
<b>Biosafety Level:</b>	BSL 2
<b>Animal Biosafety Level:</b>	
<b>IBC Vote:</b>	Approved
<b>Other</b>	
<b>New Business:</b>	None
<b>Review of Incidents:</b>	None
<b>Lab Assessments Update:</b>	Lab assessment cycle 2024-2025 is complete. Next inspection cycle will start September 2025. No biological related issues to report.
<b>IBC Training:</b>	N/A
<b>Public Comments:</b>	None
<b>Adjournment:</b>	1:30 PM