Institutional Biosafety Committee (IBC) Meeting Minutes

Institution:	**Wake Forest University School of Medicine**			
Meeting Date and Time:	September 17th @ 12:30 pm			
Meeting Type:	Online via Microsoft Teams			
	Name	**Role and Department**	**Attendance**	
IBC Members Present:	Frank Marini, PhD	IBC Chair, WFIRM	☒ Present	☐ Absent
	Anthony Blaeser, PhD	IBC Vice Chair Musculoskeletal Department	☒ Present	☐ Absent
	Samuel Centanni, PhD	Voting Member, Translational Neuroscience	☒ Present	☐ Absent
	Ji Hyun Kim, PhD	Voting Member, WFIRM	☐ Present	☒ Absent
	Elizabeth Palavecino, MD	Voting Member, Pathology	☒ Present	☐ Absent
	David Ornelles, PhD	Voting Member, Microbiology and Immunology	☒ Present	☐ Absent
	Marlena Westcott, PhD	Voting Member, Microbiology and Immunology	☒ Present	☐ Absent
	Brian Strittmatter, PharmD, MSCR	Voting Member, Pharmacy Clinical Trial Services, Pharmacy Manager	☒ Present	☐ Absent
	Patrick McNutt, PhD	Voting Member, WFIRM,	☒ Present	☐ Absent
	Linda Metheny-Barlow, PhD	Voting Member, Radiation Oncology	☐ Present	☒ Absent
	Swapan Das, PhD, MSc	Voting Member, IM. Endocrinology & Metabolism	☒ Present	☐ Absent
	Caryn Gee Morse, MD, PhD	Voting Member, IM, Infectious Diseases	☒ Present	☐ Absent
	Drew Kiraly, MD	Voting Member, Translational Neuroscience	☐ Present	☒ Absent
	Robert Hampson, PhD	Voting Member, WFIRM	☒ Present	☐ Absent
	Farah Mougeot, PhD, MS	Voting Member, Translational Research – Oral Medicine	☐ Present	☒ Absent
	Kimberly Woodward, MD, MPH	Voting Member, Pathology	☒ Present	☐ Absent
	Paris Charilaou, MD, FACP	Voting Member, Gastroenterology and Hepatology	☒ Present	☐ Absent

	Yuming Jiang, MD, PhD	Voting Member, Radiation Oncology	☒ Present	☐ Absent
	Dan Hurley	Local Non-Affiliated Community Member (Charlotte)	☐ Present	☒ Absent
	Jeanette Bennett	Community Member (Charlotte)	☐ Present	☒ Absent
	Kara Milton	Community Member (Winston Salem)	☒ Present	☐ Absent
	Adam Bray	Community Member (Winston Salem)	☒ Present	☐ Absent
	Christpher Ohl, MD	Voting Member, IM, Infectious Diseases (Ad-Hoc)	☐ Present	☐ Absent
	Scott Gamble, DVM	Voting Member, Animal Expert	☒ Present	☐ Absent
	Lisa Colvin	Voting Contact, IBC Administrator	☒ Present	☐ Absent
	Emylee Pedersen	Voting Contact, IBC Administrator	☒ Present	☐ Absent
	Bernadette Menuey	Voting Member, Biosafety Officer	☒ Present	☐ Absent
	Jessica Baker	Voting Member, IACUC Representative	☒ Present	☐ Absent
	Katy Heide	Voting Member, EHS, Environmental Compliance	☒ Present	☐ Absent
	Ex Officio W/O Vote			
	Suzy Mounsey	Animal Resources Program	☒ Present	☐ Absent
	Gaye Hodges	Animal Resources Program	☒ Present	☐ Absent
	Stephen Fisenne	WFU Representative	☒ Present	☐ Absent
	Morgan Lawson	Environmental Health & Safety	☒ Present	☐ Absent
	Jennifer Williams	Environmental Health & Safety	☒ Present	☐ Absent
	Paul Haliburton	EHS, AVP	☐ Present	☒ Absent
	Joseph Kim	AHWFB Teammate Health	☐ Present	☒ Absent
Quorum:	Yes			
Call to Order:	Dr. Marini called the meeting to order at 12:30			
Conflicts of Interest:	Chair reminded all members present to identify any conflicts of interest as protocols are reviewed. No COIs to disclose for this meeting.			
Review and Approval of Previous Meeting Minutes:	Motion to approve by Dr. Marini, second by Dr. Blaeser			
Review of Prior Meeting Business (if applicable):	NA			

New IBC Registrations for Review	
PI Name:	Shah
Registration Number:	B25-CT-WS-004
IBC Registration Title:	A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-1)
Project Overview:	4D-150 is a recombinant AAV-based gene replacement therapy in development for the treatment of Neovascular Age-related Macular Degeneration (nAMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR). This study recruiting patients with treatment naive nAMD.
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	4DMT utilizes a discovery platform termed Therapeutic Vector Evolution to invent novel AAV capsids for the treatment of diseases involving specific target tissues in vivo. In this process, [redacted] Using Therapeutic Vector Evolution, 4DMT invented the AAV capsid variant [redacted] for development of intravitreal (IVT) gene therapeutics for retinal diseases.
Types of Manipulations:	Manipulations performed by manufacturer of study agent.
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	Vascular endothelial growth factor blocker.
Host(s) and Vector(s):	Host: patient vitreous Vector: Wild-type AAV capsid
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	4D-150 expression to suppress intraocular angiogenic signaling through expression of aflibercept and reduction of vascular endothelial growth factor
Risk Assessment Discussion Points:	Confirm with project manager that providers and care staff have received training from study sponsor on how to appropriately handle AAV.
Training:	Study specific training from Sponsor.
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL-2
IBC Vote:	Approve Pending Modifications

New IBC Registrations for Review	
PI Name:	Grunwald/Weiduwilt
Registration Number:	B25-CT-WS-C-006
IBC Registration Title:	Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia (NCT06799221)
Project Overview:	The purpose of this study is to provide patients the opportunity to be treated with Obecabtagene Autoleucel (obe-cel) Out of Specification (OOS) for treating Acute Lymphoblastic Leukemia through an expanded access program (EAP). Obe-cel (brand name AUCATZYL) is a type of CAR-T cell therapy. [redacted] In this study the tests to decide whether obe-cel from the patient's cells are okay to use, show that the product is outside of the range of known standards (so called "Out of Specification", abbreviated as "OOS").
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	Obe-cel will be generated by [redacted]
Types of Manipulations:	Manipulations performed by manufacturer of study agent.
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	DNA Coding for Anti-CD19 CAR expression to target and kill cancer cells.
Host(s) and Vector(s):	Host: Patient-derived T-Cells Vector: [redacted] containing the CD19 CAR expression cassette.
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Anti-CD19 CAR expression
Risk Assessment Discussion Points:	Confirm with project manager that providers and care staff have received training from study sponsor on how to appropriately handle lentivirus.
Training:	Study specific training from Sponsor.
Occupational Health Review (if applicable):	None

Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved Pending Modifications
New IBC Registrations for Review	
PI Name:	Paul/McKay
Registration Number:	B25-CT-WS-C-007
IBC Registration Title:	BMS CA0881007: A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety ofBMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma (NCT06615479)
Project Overview:	This is a randomized, open label, multicenter, Phase 3 trial comparing the safety and efficacy of arlo-cel (BMS-986393) versus standard of care (SOC) regimens. This study is designed to help us learn whether the study drug works to treat people with relapsing or refractory multiple myeloma (MM). BMS-986393 is a chimeric antigen receptor (CAR) T-cell therapy. In this study the safety and efficacy of BMS-986393 will be compared to 2 current standard of care (SOC) treatments. If this CAR T-cell therapy shows a meaningful benefit, this trial would allow BMS-986393 to be approved as a treatment option earlier in the course of MM. Approximately 440 participants will be randomized in a 1:1 ratio to Arm A (BMS-986393) or Arm B (SOC). Subjects will undergo 3 periods: screening (eligibility), treatment (administration of arlo-cel or SOC regimen, as applicable), and post-treatment (every 3 month follow-up for safety and disease status assessment) periods.
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	BMS-986393 is an investigational GPRC5D-targeted CAR T-cell product. [redacted]
Types of Manipulations:	Manipulations performed by manufacturer of study agent.
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	DNA coding for GPRC5D-Directed CAR
Host(s) and Vector(s):	Host: Patient-derived T-Cells Vector: Third generation lentiviral vector

Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Viral expression of BMS-986393 to target GPRC5D an orphan transmembrane G protein-coupled receptor that is expressed on malignant plasma cells.
Risk Assessment Discussion Points:	Confirm with project manager that providers and care staff have received training from study sponsors on how to appropriately handle lentivirus.
Training:	Study specific training from Sponsor.
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved Pending Modifications
New IBC Registrations for Review	
PI Name:	Delbono
Registration Number:	B25-W-014
IBC Registration Title:	Sympathetic Nervous System and Sarcopenia
Project Overview:	Injection of [redacted] engineered to express specific neurons in the CNS that can be studied to determine their role in the development of sarcopenia. This will define the role of a group of neurons in the brain and the communication between nerves, muscles, muscle mass, and strength in an animal model for aging.
Applicable NIH Guidelines:	Section III-E
Agent Description: e.g. virulence, pathogenicity, environmental stability	[redacted]
Types of Manipulations:	N/A
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	Biological marker of norepinephrine neurons and channelrhodopsin expression
Host(s) and Vector(s):	Host: C57Bl/6 and PS19 mice from colony Vector: [redacted]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	GFP and Channelrhodopsin
Risk Assessment Discussion Points:	N/A
Training:	• Initial Biosafety Training • Biosafety Retraining • Animal Biosafety • Emergency and Incident Response to Biohazard Spills and Releases • NIH Recombinant DNA Guidelines

Occupational Health Review (if applicable):	N/A
Biosafety Level: Animal Biosafety Level:	BSL/ABSL 1
IBC Vote:	Approve Pending Modifications
New IBC Registrations for Review	
PI Name:	Zhang, Y
Registration Number:	B25-W-006
IBC Registration Title:	PEDF-Rich Exosomes for Post-Prostatectomy Urinary Incontinence
Project Overview:	Our research focuses on [redacted]. We believe that by delivering [redacted] to the area of the damaged urethral sphincter after prostate surgery, we can help these muscles regenerate. Stem cells will be isolated from urine samples collected from prostatectomy patients and age-matched healthy donors. To enhance [redacted] Our collaborators will then [redacted] We will establish 2 animal models to evaluate the treatment. [redacted] These models will allow us to assess both the neuromuscular regenerative effects of the treatment and its anticancer capabilities. We'll test different dosages, and compare single versus multiple injections to optimize the treatment strategy. Finally, we will conduct in-vitro studies to better understand how [redacted] promote neuromuscular regeneration. [redacted]
Applicable NIH Guidelines:	Section III-E
Agent Description: e.g. virulence, pathogenicity, environmental stability	Plasmids with [redacted],
Types of Manipulations:	In vitro transfection of urine-derived stem cells
Source of nucleic (DNA/RNA) sequences: e.g. species	Plasmids with [redacted]
Nature of nucleic acid sequences:	Induction of nerve and muscle regeneration, prevention of cancer cells proliferation and metastasis. [redacted]

e.g. structural gene, oncogene	
Host(s) and Vector(s):	Host: Urine-Derived Stem Cells Vector: [redacted]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	N/A
Risk Assessment Discussion Points:	None
Training:	• Initial Biosafety Training • Biosafety Retraining • Animal Biosafety • Emergency and Incident Response to Biohazard Spills and Releases • NIH Recombinant DNA Guidelines
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL/ABSL 2
IBC Vote:	Approve Pending Modifications
New IBC Registrations for Review	
PI Name:	Orlando, G
Registration Number:	B25-W-016
IBC Registration Title:	Transplantation of encapsulated human islet [redacted]
Project Overview:	Fresh and cryopreserved human islets will be tested in vitro for their health and implanted in vivo [redacted] to assess their ability to reverse [redacted], after short-, medium- and long-term cryopreservation.
Applicable NIH Guidelines:	N/A
Agent Description: e.g. virulence, pathogenicity, environmental stability	N/A
Types of Manipulations:	N/A
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	NA
Host(s) and Vector(s):	N/A
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	NA

Risk Assessment Discussion Points:	Protocol lists materials as BSL 1. Protocol will be approved at BSL 2 unless PI provides proof of testing for pathogens. Provide better description for how cells will be transported from lab to the animal facility. Include correct room numbers for location of work taking place.
Training:	Initial Biosafety Training • Biosafety Retraining • Animal Biosafety • Emergency and Incident Response to Biohazard Spills and Releases
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved Pending Modifications
New IBC Registrations for Review	
PI Name:	Asthana
Registration Number:	B25-W-020
IBC Registration Title:	3D bioprinting of human islets
Project Overview:	Human islets will be 3D bioprinted in bioinks and implanted in the [redacted] to assess the 3D bioprinted construct's ability to [redacted].
Applicable NIH Guidelines:	N/A
Agent Description: e.g. virulence, pathogenicity, environmental stability	N/A
Types of Manipulations:	N/A
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A
Nature of nucleic acid sequences: e.g. structural gene, oncogene	N/A
Host(s) and Vector(s):	N/A
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	N/A
Risk Assessment Discussion Points:	Testing of cells for [redacted] needs to be provided for work to be conducted at BSL1
Training:	Initial Biosafety Training Biosafety Retraining Animal Biosafety Emergency and Incident Response to Biohazard Spills and Releases Bloodborne Pathogens Training

Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved Pending Modifications
Modifications for Review	
PI Name:	Sun, P
Registration Number:	07.2021.100200.1100000.676
IBC Registration Title:	Role of the [redacted] pathway in oncogene-induced senescence, DNA damage responses and tumor suppression/Analysis of Cellular Senescence and [redacted] in Xenograft models.
Modification Overview:	Update to PI contact information Addition of human lung cancer cell lines to study
Applicable NIH Guidelines:	NA
Agent Description: e.g. virulence, pathogenicity, environmental stability	NA
Types of Manipulations:	NA
Source of nucleic (DNA/RNA) sequences: e.g. species	NA
Nature of nucleic acid sequences: e.g. structural gene, oncogene	NA
Host(s) and Vector(s):	NA
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	NA
Risk Assessment Discussion Points:	NA
Training:	NA
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved
Other	
New Business:	N/A
Review of Incidents:	None
Lab Assessments Update:	N/A
IBC Training:	N/A
Public Comments:	None

Adjournment:	1:42 pm