Institutional Biosafety Committee (IBC) Meeting Minutes

Institution:	**Wake Forest University School of Medicine**			
Meeting Date and Time:	November 19th 2025 at 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
	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
	Joseph Kim	AHWFB Teammate Health	☐ Present	☒ Absent
Quorum:	Yes			
Call to Order:	Meeting called to order at 12:39			
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:	Dr. Marini made motion to approve October meeting minutes, second by Dr. Blaeser			
Review of Prior Meeting Business (if applicable):	None			
New IBC Protocol				
PI Name:	Schaaf, Cecilia			
Registration Number:	B25-W-022			

IBC Registration Title:	NHP [redacted] model in Colorectal Cancer
Project Overview:	The goal of this project is to establish the effectiveness of our tumor-activated T cells [redacted] isolated from tumor biopsy, [redacted]) in killing tumor deposits within a non-human primate animal model as a first step towards ensuring therapeutic efficacy. Tumors will be surgically resected from animal models and processed to single-cells. Whole blood will be taken from the same tumor-bearing animal and peripheral blood mononucleated cells (PBMC) will be isolated. [redacted] The original tumor-bearing animal will then be treated by injection of [redacted] to calculate efficacy of the [redacted] in reducing tumor burden in an in vivo model.
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:	Clarification of the process for [redacted]. Summary of lab manipulations should be clearly described in the protocol. Human tumor component.
Training:	Annual Biosafety Retraining Animal Biosafety Emergency and Incident Response to Biohazard Spills and Releases OSHA Bloodborne Pathogens
Occupational Health Review (if applicable):	Semi Annual TB Testing for work with Primates Herpes B protocol for potential bloodborne exposures to NHP Tissues.
Biosafety Level: **Animal Biosafety Level:**	BSL 2/ABSL 2
IBC Vote:	Approve pending modifications at BSL 2
New IBC Protocol	

PI Name:	Schaaf, Cecilia
Registration Number:	B25-W-023
IBC Registration Title:	Testing Intestinal Epithelial Stem Cell Resiliency Through Aging
Project Overview:	Lab will be developing in vitro organoid models using intestinal epithelial materials from NHPs. Organoids will be used
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:	Indicate Risk Group on form Cells are not certified to be pathogen free. Need to clarify that the cells are not tested to be pathogen free.
Training:	Annual Biosafety Retraining Animal Biosafety Emergency and Incident Response to Biohazard Spills and Releases OSHA Bloodborne Pathogens
Occupational Health Review (if applicable):	Semi Annual TB Testing for work with Primates Herpes B protocol for potential bloodborne exposures to NHP Tissues.
Biosafety Level: **Animal Biosafety Level:**	BSL/ABSL 2
IBC Vote:	Approved at BSL 2
New IBC Registrations and Amendments for Review	
PI Name:	Turley, Christine
Registration Number:	B25-CT-C-018
IBC Registration Title:	A phase 3a, observer-blind, randomized, controlled study to demonstrate lot-to-lot consistency and evaluate the immunogenicity and safety of a varicella vaccine compared with Varivax, as a first dose, administered to healthy children, 12 to 15 months of age
Project Overview:	This study will assess efficacy of investigational varicella (chickenpox) vaccine against the currently licensed varicella vaccine in addition to the child's other age-specific routine

	vaccines. The objective of the study is to compare the strength of the immune response and the frequency and severity of reactions to multiple batches of the investigational vaccine versus the currently licensed varicella vaccine.
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	The VNS vaccine is a [redacted]
Types of Manipulations:	Any manipulations to IP conducted by Manufacturer
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:	Follow up on training for handling attenuated live virus.
Training:	Training for study provided by Study Sponsor.
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved at BSL 2
New IBC Protocol	
PI Name:	Ranken, Leslie
Registration Number:	B25-CT-C-010
IBC Registration Title:	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEX-TCAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)
Project Overview:	CAR-T Therapy for treatment of active systemic Lupus Erythematosus (SLE).
Applicable NIH Guidelines:	Section III-C-1
Agent Description:	Patient T cells modified [redacted]

e.g. virulence, pathogenicity, environmental stability	
Types of Manipulations:	Manipulations performed by IP manufacturer.
Source of nucleic (DNA/RNA) sequences: e.g. species	[redacted]
Nature of nucleic acid sequences: e.g. structural gene, oncogene	Protein expression
Host(s) and Vector(s):	Host: Patient T Cells Vector: [redacted]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Anti-CD19
Risk Assessment Discussion Points:	More information is needed on institutional policies regarding waste handling and disinfection practices.
Training:	Training provided by study sponsor.
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved Pending Modifications at BSL 2
New IBC Protocol	
PI Name:	Ranken, Leslie
Registration Number:	B25-CT-C-011
IBC Registration Title:	ALLO-329-101_a phase 1 study evaluating the safety and preliminary efficacy of allo-329, a dual anti-cd19 / anti-cd70 allogeneic car t cell product in autoimmune disease (resolution)
Project Overview:	CAR-T cell therapy for treatment of patients with autoimmune diseases. Patient T-Cells are modified [redacted] to express Anti-CD19 and CD-70 chimeric antigen receptors. This study will examine single doses of ALLO-329 to establish the recommended Phase 2 Cell Dose regimen in 3 B-cell mediated autoimmune diseases (Systemic lupus erythematosus, idiopathic inflammatory myopathy, and systemic sclerosis)
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	Patient T-Cells modified [redacted]
Types of Manipulations:	Manipulations performed by IP Manufacturer
Source of nucleic (DNA/RNA) sequences: e.g. species	N/A

Nature of nucleic acid sequences: e.g. structural gene, oncogene	Protein expression
Host(s) and Vector(s):	Host: Patient T-Cells Vector: [redacted]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	Anti-CD-19, Anti-CD-70
Risk Assessment Discussion Points:	More information is needed on institutional policies regarding waste handling and disinfection practices.
Training:	Training provided by sponsor
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved Pending Modifications at BSL 2
Resubmission	
PI Name:	Mougeot, Jean Luc
Registration Number:	B25-C-021
IBC Registration Title:	Use of human biological samples and cell lines to study the molecular mechanisms of oral or systemic disorders
Project Overview:	Molecular and cellular pathways involved in these diseases are studied in in vitro models using cell culture experiments. Oral, blood, skin, or other biological samples are collected into tubes containing buffers that release and stabilizes nucleic acid molecules. Samples undergo genomic and microbiomic analysis to identify genetic polymorphism and microbiome profiles associated with the disease. Additionally, cell lines are used for applications such as effects of drugs [redacted] and bacterial lysates on oral cavity derived cell lines. [redacted] to investigate wound healing using these cell lines. The plasmid will be delivered via [redacted] into the cell lines. The target sequence was designed manually and evaluated for off-site targets with the aid of the NCBI Primer-BLAST tool.
Applicable NIH Guidelines:	Section III-E
Agent Description: e.g. virulence, pathogenicity, environmental stability	[redacted]
Types of Manipulations:	Cells transfected with [redacted]
Source of nucleic (DNA/RNA) sequences: e.g. species	[redacted]
Nature of nucleic acid sequences:	Protein expression

e.g. structural gene, oncogene	
Host(s) and Vector(s):	Host: [redacted] Vector: [redacted]
Will a transgene be expressed? If so, what is the function of the protein that will be produced?	[redacted]
Risk Assessment Discussion Points:	None
Training:	Annual Biosafety Retraining NIH Recombinant DNA Guidelines Emergency and Incident Response to Biohazard Spills and Releases OSHA Bloodborne Pathogens
Occupational Health Review (if applicable):	None
Biosafety Level: **Animal Biosafety Level:**	BSL 2
IBC Vote:	Approved at BSL 2
Modification	
PI Name:	Berry, Laurel; Crane, Erin
Registration Number:	B25-CT-WS/C-019
IBC Registration Title:	Olvi-Vec-022/GOG-3076: A Randomized Phase 3 Study Assessing the Efficacy and Safety of Olvi-Vec followed by Platinum-doublet Chemotherapy and Bevacizumab Compared with Physician's Choice Chemotherapy and Bevacizumab in Women with Platinum-Resistant/Refractory Ovarian Cancer (OnPrime Study) (ClinicalTrials.gov Identifier: NCT05281471)
Project Overview:	Test safety and efficacy of Olvi-Vec for gynecologic cancers that have not responded to standard treatments. Olvi_Vec is an immunotherapy developed using vaccinia virus which has been genetically altered by the study sponsor. a
Applicable NIH Guidelines:	Section III-C-1
Agent Description: e.g. virulence, pathogenicity, environmental stability	Vaccinia virus
Types of Manipulations:	Manipulations to IP performed by the manufacturer.
Source of nucleic (DNA/RNA) sequences: e.g. species	[redacted]
Nature of nucleic acid sequences: e.g. structural gene, oncogene	Fluorescent protein expression and tumor marker.
Host(s) and Vector(s):	Host: [redacted] Vector: OlviVec [redacted]

Will a transgene be expressed? If so, what is the function of the protein that will be produced?	The following foreign proteins will be produced: [redacted]
Risk Assessment Discussion Points:	None
Training:	Training conducted by the study sponsor.
Occupational Health Review (if applicable):	None
Biosafety Level: Animal Biosafety Level:	BSL 2
IBC Vote:	Approved at BSL 2
Modification	
PI Name:	Martin, Jeff
Registration Number:	03.2020.Anesth.1100000.344.01a
IBC Registration Title:	AAV transfection of neurons in rats
Summary of Changes	Addition of 3 AAVs to IBC and IACUC protocols [redacted]
IBC Vote	Approved at BSL 1
Other	
New Business:	Controlled Substance Witnessed Destruction Event being held Dec 1st and 2nd for researchers. Biocontainment Facility Updates: HEPA Filters for exhaust and Blower Motor for BSC requires replacement. Building to remain out of service until repairs are made. Prospective studies for containment facility have not been finalized due to delays in government funding.
Review of Incidents:	NA
Lab Assessments Update:	NA
IBC Training:	NA
Public Comments:	NA
Adjournment:	Meeting adjourned at 1:20