Medical University of South Carolina

Institutional Biosafety Committee Meeting Minutes

Meeting Date	Thursday, April 9, 2026
Meeting Time	12:03 PM –1:43 PM
Meeting Type	Teams Meeting
IBC Members Present	1. Caroline Westwater, Ph.D., (IBC Chair) 2. John Woodward, Ph.D. (IBC Vice Chair) 3. Christina Voelkel-Johnson, Ph.D., (BSO) 4. Lisa Steed, Ph.D., (IBC Member) 5. Carlene Brandon, MS. (Local Non-affiliated Member) 6. Natalie Sutkowski, Ph.D. (IBC Member) 7. Ana Zimmerman, Ph.D. (Local Non-affiliated Member) 8. Logan Patterson, Ph.D. (IBC Member) 9. Daniel Eldridge, DVM (IBC Member, Animal Expert)
Quorum	Number of Members Present (Voting): 9 Number of Members Not Present: 2 Late Arrival of Voting Members: 0 Early Departure of Voting Members: 0
Other Individuals in Attendance	Michael Smith, Ph.D., (IBC Manager)
Call to Order	The IBC Chair called the meeting to order at 12:03 PM
Conflicts of Interests	The IBC Chair reminded all members present to identify any conflicts of interest before each registration is reviewed.
Review and Approval of Previous Meeting Minutes	March minutes pending revisions
Review of Prior Business	Discussed hazard signage updates. Reviewed discussion with NIH OSP about redaction requirements and modifications to meeting minutes template.
New IBC Registration and Amendments for Review (repeat for each registration)	

Protocol #	IBC-25-269
PI Name	Baratam, Praneeth
Study Title	[redacted]: Autologous Enriched T Cells Transduced with a Lentiviral Vector to Express a Novel Anti-[redacted] Chimeric Antigen Receptor ([redacted]
Agent	☐ Plasmid DNA/mRNA ☐ CRISPR/Cas9 technology ☐ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☐ Replication-deficient viral vectors ☐ RG1 microbes ☐ RG2 microbes ☐ Biological toxins

	☐ Gene modified mouse cells ☒ Gene modified human cells ☐ Other
rDNA Category	III-D-1a, III-C
Modified microbes or vectors	N/A
Transgene expression	anti-[redacted] CAR ([redacted] [CAT] CAR)
Highest BSL	BSL2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☐ BSL1 ☒ BSL2 ☐ ABSL1 ☐ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling: ☐ N/A ☒ Yes. BSC during preparation Centrifugation: ☒ N/A ☐ Sealed rotors/safety caps ☐Other: Sharps handling: ☐ N/A ☒ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment:** This protocol involves the handling and administration of a sponsor manufactured lentivirus-transduced CAR T cell therapy [redacted] under BSL-2 conditions. The product consists of autologous human T cells genetically modified ex vivo using a replication-deficient lentiviral vector, with no viral manipulation performed at MUSC. Primary risks to personnel include exposure to human-derived cellular material and potential sharps injury during preparation and administration. Although there is a theoretical risk of replication-competent lentivirus (RCL), this is minimized through vector design (split plasmid system, self-inactivating vector) and extensive testing prior to product release. Risk mitigation includes BSL-2 practices, use of appropriate PPE, biosafety procedures for handling human-derived materials, and standard sharps precautions. The product is handled in closed systems, transported in sealed, labeled secondary containers, and prepared only by trained personnel. Additional precautions are in place for potential occupational exposure, including enhanced reporting requirements for exposures involving pregnancy. Overall risk is considered **low to moderate** and well-controlled through established clinical and biosafety procedures.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Westwater
Second:	Voelkel-Johnson
Votes	
For:9	Abstained: 0

Against:0	Recused: 0

Protocol #	IBC-26-14
PI Name	Cowan, Chris
Study Title	Molecular Mechanisms of Addiction and Neural Developmental Disease-Related Plasticity
Agent	☒ Plasmid DNA/mRNA ☒ CRISPR/Cas9 technology ☒ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☒ Replication-deficient viral vectors ☐ RG1 microbes ☒ RG2 microbes ☒ Biological toxins ☐ Gene modified mouse cells ☒ Gene modified human cells ☐ Other
rDNA Category	III-D1a, III-D4b
Modified microbes or vectors	AAV, lentiviral vectors, herpes viral vectors
Transgene expression	Cre/Flpo recombinases, optogenetic constructs, chemogenetic constructs, biosensors, fluorescent reporters
Highest BSL	BSL2/ABSL-2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☒ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling: ☐ N/A ☒ Yes: Aliquoting in BSC Centrifugation: ☐ N/A ☒ Sealed rotors/safety caps ☐Other: Sharps handling: ☐ N/A ☒ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment**: This protocol involves the use of replication-incompetent viral vectors (AAV, lentivirus, HSV-1–derived), molecular-grade *Escherichia coli* (RG1), tetrodotoxin (RG2), recombinant nucleic acids, and in vivo mouse studies under BSL-2/ABSL-2 conditions. Primary risks to personnel include exposure to viral vectors via mucosal contact, injection, or accidental autoinoculation, with potential outcomes including mild viral effects, insertional mutagenesis (lentivirus), or in rare cases central nervous system effects (HSV). AAV presents minimal risk but has theoretical reproductive concerns. Tetrodotoxin poses a toxicity risk (e.g., respiratory paralysis) upon inhalation, ingestion, or mucosal exposure.

	RG1 *E. coli* presents low risk but may cause minor infection if accidentally introduced. Animal procedures (intracranial injections) introduce additional risks associated with sharps use and handling of infected animals. Recombinant genes (e.g., Cre, transcription factors, reporters, CRISPR/Cas9 components) are considered minimal hazard, with gene-specific effects limited to experimental systems. Risks are mitigated through BSL-2/ABSL-2 practices, including appropriate PPE, biosafety cabinet use, sharps precautions, secure transport in labeled secondary containment, and adherence to SOPs for waste inactivation. Viral vectors are handled in small volumes and are replication-deficient, limiting environmental persistence and spread. Overall risk is considered **moderate** but well-controlled with established biosafety and containment practices.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Woodward
Second:	Westwater
Votes	
For:9 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-05
PI Name	Rinker, Jennifer
Study Title	Rinker Lab IBC - AAV Transgene Delivery
Agent	☐ Plasmid DNA/mRNA ☐ CRISPR/Cas9 technology ☐ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☒ Replication-deficient viral vectors ☐ RG1 microbes ☐ RG2 microbes ☐ Biological toxins ☐ Gene modified mouse cells ☐ Gene modified human cells ☐ Other
rDNA Category	III-D1a, III-D4b
Modified microbes or vectors	AAV
Transgene expression	Cre/Flpo recombinases, optogenetic constructs, chemogenetic constructs, biosensors, fluorescent reporters
Highest BSL	BSL2/ABSL-2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☒ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling:

	☐ N/A ☒ Yes. Aliquoting in BSC Centrifugation: ☒ N/A ☐ Sealed rotors/safety caps ☐Other: Sharps handling: ☐ N/A ☒ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment:** This protocol involves the use of replication-deficient AAV vectors (multiple serotypes) for neuronal gene delivery in mice, including expression of recombinases (Cre/Flpo), optogenetic/chemogenetic tools, biosensors, and fluorescent reporters. AAV is a Risk Group 1 agent not associated with human disease, though potential exposure routes include aerosol, mucosal contact, ingestion, or needlestick, with theoretical risks including reproductive effects. The recombinant constructs used are considered minimal hazard and designed for cell-type-specific expression. Primary risks to personnel are associated with intracranial injections (sharps use) and handling of viral vectors. These risks are mitigated through ABSL-2 practices during administration, appropriate PPE, stereotaxic procedures, and secure handling and transport (double-contained, labeled materials). AAV vectors are replication-incompetent and handled in small volumes, limiting environmental persistence, although proper disinfectants (e.g., bleach) are required due to capsid stability. Overall risk is considered **low to moderate** and well-controlled with established biosafety, animal handling, and containment practices.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Woodward
Second:	Voelkel-Johnson
Votes	
For:9 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-24
PI Name	Jiang, Wei
Study Title	The Role of Live Microbial Translocation and Microbiome in Disease Pathogenesis
Agent	☐ Plasmid DNA/mRNA ☐ CRISPR/Cas9 technology ☐ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☐ Replication-deficient viral vectors ☒ RG1 microbes ☒ RG2 microbes ☐ Biological toxins ☐ Gene modified mouse cells

	☐ Gene modified human cells ☐ Other
rDNA Category	N/A
Modified microbes or vectors	N/A for this IBC but see also IBC-2022-01472 for EcoHIV (microbe/virus combination experiment)
Transgene expression	N/A
Highest BSL	BSL2/ABSL-2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☒ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling: ☐ N/A ☒ Yes. BSC Centrifugation: ☐ N/A ☒ Sealed rotors/safety caps ☐Other: Sharps handling: ☒ N/A ☐ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment:** This study involves propagation and handling of multiple bacterial species, including commensal organisms and opportunistic pathogens (RG1/RG2). Primary risks to personnel include exposure via ingestion, inhalation, skin contact, vortexing, centrifugation, and transport. Some organisms present potential for invasive or disseminated disease, particularly in immunocompromised individuals. Risks are mitigated through BSL-2/ABSL-2 containment practices, use of appropriate PPE, biosafety cabinet procedures for aerosol-generating activities, sealed centrifugation, and secure transport in leak-proof secondary containers. Proper waste disposal and SOP adherence further reduce environmental exposure. EcoHIV. See IBC-2022-01472. Microbes in this protocol will be administered to EcoHIV-infected mice (single or multiple microbial combinations). EcoHIV infects CD4 positive T cells and F4/80 positive macrophages systemically as well as brain microglia. Therefore, if EcoHIV infected mice were accidentally released into the environment, there is the risk that the infected mice could spread the infection to other mice. This risk is minimized by preventing infected mice from being moved outside the housing room. Mice will only be relocated to another housing room in cases of emergencies. Overall risk is considered **moderate** but adequately controlled by established biosafety practices and containment measures.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review

First:	Westwater
Second:	Steed
Votes	
For:9 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-25
PI Name	Vasu, Chenthamarakshan
Study Title	Studies on modulation of autoimmunity, inflammation and cancer
Agent	☒ Plasmid DNA/mRNA ☐ CRISPR/Cas9 technology ☒ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☒ Replication-deficient viral vectors ☒ RG1 microbes ☒ RG2 microbes ☐ Biological toxins ☒ Gene modified mouse cells ☒ Gene modified human cells ☐ Other
rDNA Category	III-D1a, III-D4b
Modified microbes or vectors	Retro/Lentiviral vectors
Transgene expression	Cytokines, growth factors, immune receptors, transcription factors, centriolar and vesicular proteins, fluorescent reporters
Highest BSL	BSL2/ABSL-2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☒ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling: ☐ N/A ☒ Yes. BSC Centrifugation: ☐ N/A ☒ Sealed rotors/safety caps ☐Other: Sharps handling: ☐ N/A ☒ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment:** This protocol involves the use of RG1 and RG2 bacteria, molecular-grade *Escherichia coli*, lentiviral and retroviral vectors, human stool-derived microbial communities, and gene-modified mouse and human cells in murine models under BSL-1/BSL-2 and ABSL-1/ABSL-2 conditions. Primary risks to personnel include exposure via ingestion, inhalation, skin contact, or sharps injury, as well as potential opportunistic infections from RG2 microbes and unknown pathogens in human stool samples. Viral vectors introduce additional risks of insertional

	mutagenesis, oncogenesis, and generation of replication-competent virus, though these risks are minimized through established vector design. Animal work, including oral microbial delivery and injection of gene-modified cells, presents additional exposure risks and requires appropriate animal handling and containment practices. Recombinant genes (e.g., cytokines, immune regulators, transcription factors) may alter cellular growth, immune responses, or differentiation but are confined to experimental systems. Risks are mitigated through appropriate BSL-1/BSL-2 and ABSL-1/ABSL-2 practices, including PPE, biosafety cabinet use, sealed centrifugation and transport, sharps precautions, and proper chemical and physical waste inactivation. Donor screening and post-donation monitoring reduce risks associated with human-derived materials. Overall risk is considered **moderate but well-controlled** with established biosafety procedures and SOP compliance.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Voelkel-Johnson
Second:	Woodward
Votes	
For:8 Against:0	Abstained: 0 Recused: 1

Protocol #	IBC-25-176
PI Name	Meissner, Eric
Study Title	Regulation of Lambda Interferon Signaling by Canonical and Non-canonical IFNLR1 Variants
Agent	☒ Plasmid DNA/mRNA ☒ CRISPR/Cas9 technology ☒ Molecular grade Escherichia coli ☐ Laboratory grade strains Saccharomyces cerevisiae ☒ Replication-deficient viral vectors ☐ RG1 microbes ☒ RG2 microbes ☐ Biological toxins ☐ Gene modified mouse cells ☒ Gene modified human cells ☐ Other
rDNA Category	III-D1a, III-D4b
Modified microbes or vectors	Lentiviral vector, Hepatitis B virus (HBV), G-deleted vesicular stomatitis virus (VSV)
Transgene expression	Immunomodulators, fluorescent reporter genes, microbial DNA, endonuclease
Highest BSL	BSL2/ABSL-2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☒ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation

	Aerosol handling: ☐ N/A ☒ Yes. BSC Centrifugation: ☐ N/A ☒ Sealed rotors/safety caps ☐Other: Sharps handling: ☒ N/A ☐ Standard sharps precautions ☐Other: Transport: ☐ N/A. ☒ Double sealed, leak-proof container with biohazard label Special considerations: none **Risk Assessment:** This protocol involves the use of HBV-producing cell lines, replication-deficient lentiviral vectors, VSV-ΔG-EGFP, molecular-grade *Escherichia coli* (RG1), recombinant nucleic acids (including CRISPR/Cas9 and plasmids), and human cell lines/iPSC-derived systems under primarily BSL-2 conditions. Primary risks to personnel include exposure to bloodborne pathogens (HBV) via mucous membranes or broken skin, viral vector exposure, and potential insertional mutagenesis from lentiviral systems. VSV-ΔG-EGFP is limited to a single round of infection and is environmentally fragile, reducing transmission risk. RG1 *E. coli* presents minimal risk in healthy adults. Risk mitigation includes adherence to appropriate BSL practices, use of appropriate PPE, biosafety cabinets for aerosol containment, and avoidance of sharps. Recombinant nucleic acids and transgenes are considered minimal hazard. All infectious materials are inactivated (e.g., paraformaldehyde fixation) prior to removal from the laboratory, and transport is conducted in sealed, labeled containers. Proper waste disposal procedures are in place to minimize environmental exposure. Overall risk is considered **moderate** but well-controlled with established biosafety measures and SOP compliance.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Westwater
Second:	Voelkel-Johnson
Votes	
For:9 Against:0	Abstained: 0 Recused: 0

Meeting Adjournment	The IBC Chair called for the meeting to be adjourned at 1:43 PM