Medical University of South Carolina

Institutional Biosafety Committee Meeting Minutes

Meeting Date	Thursday, May 14, 2026
Meeting Time	12:03 PM –1:03 PM
Meeting Type	Teams Meeting
IBC Members Present	1. Caroline Westwater, Ph.D., (IBC Chair) 2. Christina Voelkel-Johnson, Ph.D., (BSO) 3. Lisa Steed, Ph.D., (IBC Member) 4. Carlene Brandon, MS. (Local Non-affiliated Member) 5. Natalie Sutkowski, Ph.D. (IBC Member) 6. Ana Zimmerman, Ph.D. (Local Non-affiliated Member) 7. Logan Patterson, Ph.D. (IBC Member) 8. Daniel Eldridge, DVM (IBC Member, Animal Expert)
Quorum	Number of Members Present (Voting): 8 Number of Members Not Present: 3 Late Arrival of Voting Members: 0 Early Departure of Voting Members:0
Other Individuals in Attendance	Michael Smith, Ph.D., (IBC Manager) Gloriane Schnabolk Ph.D., (IACUC & IBC Senior Administrator)
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	Feb/March/April minutes pending revisions
Review of Prior Business	Discussion of training approval needed for Cryopreservation Lab storage protocol. IBC presentation to IDEA Class in May.
New IBC Registration and Amendments for Review (repeat for each registration)	

Protocol #	IBC-25-364
PI Name	Gowrishankar, Raajaram
Study Title	Gowrishankar Lab IBC protocol
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 recombinase, Cre-driven opsins, Cre-driven indicator reporter, Cre-driven biosensor reporter, Cre-driven fluorescence reporters, Cre-driven CRISPR constructs
Highest BSL	BSL2/ABSL2
Training	☒ Complete ☐ Pending
Risk Assessment of Procedures	PPE: ☐ BSL1 ☒ BSL2 ☒ ABSL1 ☒ ABSL2 Waste handling: ☒ Chemical inactivation ☒ Physical inactivation Aerosol handling: ☐ N/A ☒ Yes. BSC for aliquoting 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 intracranial delivery of recombinant constructs (fluorophores, opsins, biosensors, CRISPR/Cas9 systems, and Cre recombinase) in mice. AAV is a Risk Group 1 agent not associated with human disease; however, potential exposure routes include needlestick, mucous membrane contact, inhalation, or animal-related exposure, with theoretical risks including unintended gene expression or neuronal modulation following accidental exposure. Primary risks to personnel are associated with handling of viral vectors and injection procedures to animals. These risks are mitigated through BSL-2 practices during aliquoting of the vector, ABSL-2 containment during AAV administration, appropriate PPE, biosafety cabinet use, and adherence to sharps safety and animal handling protocols. AAV vectors are replication-incompetent and not propagated at MUSC, reducing overall risk. Environmental risks are minimal but include the stability of AAV particles; proper decontamination (e.g., bleach-based disinfectants) and containment measures are in place to prevent persistence and release. Overall risk is considered **low to moderate** and well-controlled with established biosafety and containment procedures.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Westwater
Second:	Voelkel-Johnson

Votes	
For:8 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-50
PI Name	Paczesny, Sophie
Study Title	Translating Novel Drug-Targetable Biomarkers to Treat Immunological Diseases
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, III-F
Modified microbes or vectors	Retro/lentiviral vectors
Transgene expression	Oncogene, fluorescent reporter, immunomodulator
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 propagation and use of replication-incompetent lentiviral and gamma-retroviral vectors, molecular-grade *Escherichia coli* (RG1), recombinant nucleic acids, human cell lines (including PBMCs), and gene-modified murine and human cells in mouse models under BSL-1/BSL-2 and ABSL-1/ABSL-2 conditions. RG1 *E. coli* presents low risk to healthy adults but may cause minor infection or digestive issues if overtly exposed. Primary risks to personnel include exposure to viral vectors via mucous membranes, broken skin, or inadvertent inoculation, with potential

	outcomes including insertional mutagenesis or oncogenic effects from retroviral/lentiviral integration. Additional risks include handling of human-derived materials and leukemia-inducing cell lines. Animal procedures (injection of gene-modified cells) introduce further exposure risks, though viral vectors are not directly administered to animals. Risks are mitigated through BSL-2 practices, biosafety cabinet use, sealed centrifugation, appropriate PPE, sharps precautions, and controlled preparation of cells prior to administration. ABSL-2 housing and handling procedures further reduce exposure risk, with some murine-only work eligible for downgrading after defined containment periods. Environmental risks are minimal, as viral vectors and modified cells are replication-incompetent and have limited survival outside controlled laboratory conditions. Overall risk is considered **moderate.**
Motion	☒ Straight approval-*protocol administratively cloned to correct format omissions. ☐ Conditional approval with administrative post-review ☐ Conditional approval with subcommittee post-review
First:	Voelkel-Johnson
Second:	Westwater
Votes	
For:8 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-26
PI Name	Hartman Jessica
Study Title	AAV8-Mediated Hepatic Expression of CYP2E1 in Mice
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-D4b
Modified microbes or vectors	AAV
Transgene expression	Cytochrome monooxygenase
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 replication-deficient AAV8 vectors for liver-targeted gene delivery (Cyp2e1) in mice under BSL-2/ABSL-2 conditions. AAV is a Risk Group 1 agent not associated with human disease; however, potential exposure routes include needlestick injury, mucous membrane contact, or contact with compromised skin. In a worst-case scenario, exposure could result in unintended transduction of human cells and transient expression of CYP2E1, with theoretical effects on cellular metabolism. Primary risks to personnel are associated with handling viral stocks and performing injection procedures. These risks are mitigated through BSL-2 practices, use of biosafety cabinets, appropriate PPE, sharps precautions, and controlled animal handling procedures. AAV vectors are replication-incompetent and not propagated at MUSC, reducing the risk of viral amplification. Environmental risks are minimal due to the inability of AAV to replicate without helper virus, although proper disinfection (e.g., bleach-based agents) is required due to viral stability. Overall risk is considered **low.**
Motion	☐ Straight approval ☒ Conditional approval with administrative post-review ☐ Conditional approval with subcommittee post-review
First:	Westwater
Second:	Zimmerman
Votes	
For:8 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-28
PI Name	Dolloff, Nathan
Study Title	Drug Discovery in Treatment Resistant 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	Lentiviral vectors
Transgene expression	Hydroxylase, cell death modulators, transcription factor, immunomodulators [redacted]
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 molecular-grade *Escherichia coli* (RG1), replication-incompetent lentiviral vectors, gene-modified mammalian cells, and recombinant fusion proteins containing cancer-associated antigens linked to the [redacted] RG1 *E. coli* presents low risk to healthy adults but may cause minor infection or digestive issues if accidentally exposed. Primary risks to personnel include exposure to lentiviral vectors with potential for insertional mutagenesis, and exposure to biologically active [redacted] fusion proteins, which may induce nonspecific T-cell activation and cytokine release if encountered at sufficient levels. Endogenous protein components [redacted] and plasmid DNA present minimal hazard. Animal procedures, including injection of gene-modified cells and recombinant proteins, introduce additional risks related to sharps use and potential exposure during handling. Risks are mitigated through BSL-1 (E coli) and BSL-2 (viral vectors) safety practices, including use of biosafety cabinets, appropriate PPE, sharps precautions, and adherence to ABSL-2 procedures for administration to animals. Animals may be housed at ABSL-1. Environmental risks are minimal due to the use of molecular grade strains of *E. coli*, replication-incompetent viral systems, and limited persistence of recombinant proteins outside controlled settings. Overall risk is considered **low to moderate** and well-controlled**,** with the primary concern being controlled handling of [redacted] fusion proteins under established biosafety practices.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Voelkel-Johnson

Second:	Steed
Votes	
For:8 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-42
PI Name	Engevik, Kristen
Study Title	Exploring the impact of [redacted] signaling on enteric infection
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	Clostridium difficile (not modified)
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 protocol involves the use of *Clostridioides difficile* (RG2), including wildtype and mutant strains, commercially available purified toxins (TcdA, TcdB, CDT), and transduced human organoid systems under BSL-2/ABSL-2 conditions. Primary risks to personnel include exposure via the fecal-oral route, ingestion, mucous membrane contact, or accidental contamination, with potential to cause gastrointestinal illness ranging from mild diarrhea to severe colitis. Commercially available purified toxins present additional hazards due to their cytotoxic activity.

	Animal work, including antibiotic treatment and oral inoculation of mice, introduces risks of environmental contamination through shedding of organisms. Risks are mitigated through BSL-2/ABSL-2 practices, including appropriate PPE, biosafety cabinet use for in vitro toxin work, containment housing, and strict adherence to SOPs for handling infectious materials and waste disposal. Environmental risks are controlled through proper containment, decontamination, and waste management, reducing the likelihood of organism spread. Overall risk is considered **moderate.**
Motion	☐ Straight approval ☒ Conditional approval with administrative post-review ☐ Conditional approval with subcommittee post-review
First:	Westwater
Second:	Patterson
Votes	
For:8 Against:0	Abstained: 0 Recused: 0

Meeting Adjournment	The IBC Chair called for the meeting to be adjourned at 1:03 PM