Medical University of South Carolina

Institutional Biosafety Committee Meeting Minutes

Meeting Date	Thursday, March 12, 2026
Meeting Time	12:03 PM –1:11 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. Aimee McRae-Clark, Pharm.D., BCPP (IBC Alternate Member; Office of Research Integrity Director) 7. Ana Zimmerman, Ph.D. (Local Non-affiliated Member) 8. Logan Patterson, Ph.D. (IBC Member) 9. Daniel Eldridge, DVM (IBC Member, Animal Expert) 10. Eric Meissner, M.D., Ph.D. (IBC Member)
Quorum	Number of Members Present (Voting): 10 Number of Members Not Present: 1 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	February 12, 2026 IBC meeting minutes were discussed and approved. Voting: For: 10; Against: 0; Abstain: 0
Review of Prior Business	Discussed requirements for amendments to shell protocols. Any FCR amendments will require a new protocol to be submitted. Discussed reaching out to OSP about redaction requirements.
New IBC Registration and Amendments for Review (repeat for each registration)	

Protocol #	IBC-25-353
PI Name	Judge, Daniel
Study Title	A Phase 1 Dose Escalation Trial Evaluating an Intravenously Administered Recombinant [redacted] Vector Containing [redacted] Gene Coding Sequence ([redacted] in Subjects with Dilated Cardiomyopathy Arising from Pathogenic [redacted] Variants ([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	AAV
Transgene expression	[redacted]
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:** The investigational product [redacted] consists of a replication-deficient AAV expressing a functional copy of the [redacted] gene under control of a [redacted]-specific promoter. A single dose will be delivered to via i.v infusion to replace the faulty gene in subjects with dilated cardiomyopathy (DCM). The IP will be stored and prepared in the IDS pharmacy. It will be delivered to subjects via a single i.v. infusion through extension tubing attached to IV catheter. BSL-2 precautions are used during preparation and administration. The AAV is replication-deficient and poses minimal risk to healthy adults but pregnant women are advised not to handle the IP. Shedding will be monitored as part of the study but due to low risk of AAV and tissue-specific expression of the transgene, isolation of subjects is not required. Risk is further mitigated though education of subjects and their close contacts. No DURC-PEPP concern.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Westwater

Second:	Meissner
Votes	
For:10 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-06
PI Name	Otis, James
Study Title	Neuroadaptation Produced by Acute PTSD-like Stress Create Vulnerability for Cannabis
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 recombinase, DREADD receptors, fluorescent reporters, opsins
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: 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**: Minimal risk. AAV is a RG1 agent and does not pose a significant risk to healthy adults. Insert genes have minimal risk and are expressed from neuron- or glia-specific promoters. AAV will be purchased and not propagated in the lab. Volumes administered to rats intracranially are small and are not expected to shed. Risk during administration is mitigated by ABSL-2 safety precaution. ABSL-1 precautions are sufficient for housing. No DURC-PEPP concern.

Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Woodward
Second:	Westwater
Votes	
For:10 Against:0	Abstained: 0 Recused: 0

Protocol #	IBC-26-21
PI Name	Sahin, Ozgur
Study Title	Molecular Mechanisms of Drug Resistance and Metastasis
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	lentivirus
Transgene expression	Large number of transgenes, including some with elevated risk such as oncogenes, immune-modulating genes, growth factors, and cell death regulators. Overexpression, knock down or both will be evaluated (more than 30 gene entries). More than 20 genes will be edited using CRISPR/Cas9 technology.
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 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: Plasmid amplification in molecular grade Escherichia coli poses minimal risk to healthy adults. Exposure during propagation and use of replication-deficient lentiviral vectors is mitigated through BSL-2 precautions. The highest risk is exposure to a lentiviral vector that expresses an insert carrying elevated risk (i.e. oncogene) or off-target effects (i.e., CRISPR editing). This risk is minimized by avoiding sharp use during procedures and substitution of glassware for plasticware. Needlestick injury is possible during administration of gene modified cells to animals. This is mitigated by training and following safe needle handling practices. No DURC-PEPP concern.
Motion	☐ Straight approval ☐ Conditional approval with administrative post-review ☒ Conditional approval with subcommittee post-review
First:	Voelkel-Johnson
Second:	Westwater
Votes	
For:10 Against:0	Abstained: 0 Recused: 0

Meeting Adjournment	The IBC Chair called for the meeting to be adjourned at 1:11 PM