

## Medical University of South Carolina

### Institutional Biosafety Committee Meeting Minutes

<b>Meeting Date</b>	Thursday, October 9, 2025
<b>Meeting Time</b>	12:05 PM –1:19 PM
<b>Meeting Type</b>	Teams Meeting
<b>IBC Members Present</b>	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. Eric Meissner, M.D., (IBC Member) 6. Carlene Brandon, MS. (Local Non-affiliated Member) 7. Anastasia Zimmerman, Ph.D. (Local Non-affiliated Member) 8. Aimee McRae-Clar, Pharm.D., BCPP (IBC Alternate Member; Office of Research Integrity Director) 9. Logan Patterson, Ph.D. (IBC Member)
<b>Quorum</b>	Number of Members Present (Voting): 9 Number of Members Not Present: 2 Late Arrival of Voting Members: 2 Early Departure of Voting Members:1
<b>Other Individuals in Attendance</b>	Michael Smith, Ph.D., (IBC Manager) Gloriane Schnabolk Ph.D., (IACUC & IBC Senior Administrator)
<b>Call to Order</b>	The IBC Chair called the meeting to order at 12:05 PM
<b>Conflicts of Interests</b>	The IBC Chair reminded all members present to identify any conflicts of interest before each registration is reviewed.
<b>Review and Approval of Previous Meeting Minutes</b>	July 10, 2025, August 14, 2025, September 11, 2025 IBC meeting minutes will be discussed.
<b>Review of Prior Business</b>	Introduction of new IBC member, Dr. Patterson NIH launched Initiative to Modernize and Strengthen Biosafety Oversight. Revised meeting minutes template
<b>New IBC Registration and Amendments for Review (repeat for each registration)</b>	

<b>Protocol #</b>	IBC-25-300
<b>PI Name</b>	Flume, Patrick
<b>Study Title</b>	An Open-label, Phase 1/2 Trial of Gene Therapy ██████ in Adults with Cystic Fibrosis
<b>Agent</b>	<input checked="" type="checkbox"/> Plasmid DNA/mRNA <input type="checkbox"/> CRISPR/Cas9 technology <input type="checkbox"/> Molecular grade Escherichia coli <input type="checkbox"/> Laboratory grade strains Saccharomyces cerevisiae

	<input checked="" type="checkbox"/> Replication-deficient viral vectors <input type="checkbox"/> RG1 microbes <input type="checkbox"/> RG2 microbes <input type="checkbox"/> Biological toxins <input type="checkbox"/> Gene modified mouse cells <input type="checkbox"/> Gene modified human cells <input type="checkbox"/> Other		
<b>rDNA Category</b>	III-C		
<b>Genetically modified microbes or vectors</b>	adeno-associated viral vector		
<b>Transgene expression</b>			
<b>Highest BSL</b>	BSL2		
<b>Training</b>	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Pending		
<b>Risk Assessment of Procedures</b>	PPE is appropriate for <input type="checkbox"/> BSL1 <input checked="" type="checkbox"/> BSL2 <input type="checkbox"/> ABSL1 <input type="checkbox"/> ABSL2 Waste handling: <input checked="" type="checkbox"/> Chemical inactivation <input checked="" type="checkbox"/> Physical inactivation Aerosol handling: N/A <input type="checkbox"/> Yes <input checked="" type="checkbox"/> negative pressure room Centrifugation: N/A <input checked="" type="checkbox"/> Sealed rotors/safety caps <input type="checkbox"/> Sharps handling: N/A <input checked="" type="checkbox"/> Standard sharps precautions <input type="checkbox"/> Transport: N/A <input type="checkbox"/> Double sealed, durable leak-proof container with biohazard label <input checked="" type="checkbox"/> Any special considerations No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		
<b>Motion</b>	<input type="checkbox"/> Straight approval <input type="checkbox"/> Conditional approval with administrative post-review <input checked="" type="checkbox"/> Conditional approval with subcommittee post-review		
<b>First:</b>	Westwater	<b>Second:</b>	Woodward
<b>Votes</b>			
<b>For:8</b>	Against:0	Abstained:0	Recused:0

<b>Protocol #</b>	IBC-25-303
<b>PI Name</b>	Mingora, Christina
<b>Study Title</b>	: A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate Nebulized Bacteriophage Treatment in Outpatient Adult Subjects with Chronic Pseudomonas aeruginosa (PsA) Pulmonary Infection
<b>Agent</b>	<input checked="" type="checkbox"/> Plasmid DNA/mRNA <input type="checkbox"/> CRISPR/Cas9 technology <input type="checkbox"/> Molecular grade Escherichia coli <input type="checkbox"/> Laboratory grade strains Saccharomyces cerevisiae <input checked="" type="checkbox"/> Replication-deficient viral vectors <input checked="" type="checkbox"/> RG1 microbes <input type="checkbox"/> RG2 microbes <input type="checkbox"/> Biological toxins <input type="checkbox"/> Gene modified mouse cells <input type="checkbox"/> Gene modified human cells

	<input type="checkbox"/> Other		
<b>rDNA Category</b>	III-D1a, III-D-4-b		
<b>Genetically modified microbes or vectors</b>	bacteriophages		
<b>Transgene expression</b>	N/A		
<b>Highest BSL</b>	BSL2		
<b>Training</b>	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Pending		
<b>Risk Assessment of Procedures</b>	PPE is appropriate for <input type="checkbox"/> BSL1 <input checked="" type="checkbox"/> BSL2 <input type="checkbox"/> ABSL1 <input type="checkbox"/> ABSL2 Waste handling: <input checked="" type="checkbox"/> Chemical inactivation <input checked="" type="checkbox"/> Physical inactivation Aerosol handling: N/A <input type="checkbox"/> Yes <input checked="" type="checkbox"/> negative pressure room Centrifugation: N/A <input checked="" type="checkbox"/> Sealed rotors/safety caps <input type="checkbox"/> Sharps handling: N/A <input checked="" type="checkbox"/> Standard sharps precautions <input type="checkbox"/> Transport: N/A <input type="checkbox"/> Double sealed, durable leak-proof container with biohazard label <input checked="" type="checkbox"/> Any special considerations No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		
<b>Motion</b>	<input type="checkbox"/> Straight approval <input type="checkbox"/> Conditional approval with administrative post-review <input checked="" type="checkbox"/> Conditional approval with subcommittee post-review		
First:	Voelkel-Johnson	Second:	Meissner
<b>Votes</b>			
For:9	Against:0	Abstained:0	Recused:0

<b>Protocol #</b>	IBC-25-270
<b>PI Name</b>	Green, Kimberly
<b>Study Title</b>	Phase 1b Dose Expansion Study of [REDACTED] for the Treatment of Patients with Relapsed or Refractory [REDACTED]
<b>Agent</b>	<input type="checkbox"/> Plasmid DNA/mRNA <input type="checkbox"/> CRISPR/Cas9 technology <input type="checkbox"/> Molecular grade Escherichia coli <input type="checkbox"/> Laboratory grade strains Saccharomyces cerevisiae <input type="checkbox"/> Replication-deficient viral vectors <input type="checkbox"/> RG1 microbes <input type="checkbox"/> RG2 microbes <input type="checkbox"/> Biological toxins <input type="checkbox"/> Gene modified mouse cells <input type="checkbox"/> Gene modified human cells <input type="checkbox"/> Other
<b>rDNA Category</b>	III-D1a, III-C
<b>Genetically modified microbes or vectors</b>	
<b>Transgene expression</b>	[REDACTED]

<b>Highest BSL</b>	BSL2		
<b>Training</b>	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Pending		
<b>Risk Assessment of Procedures</b>	PPE is appropriate for <input type="checkbox"/> BSL1 <input checked="" type="checkbox"/> BSL2 <input type="checkbox"/> ABSL1 <input type="checkbox"/> ABSL2 Waste handling: <input checked="" type="checkbox"/> Chemical inactivation <input checked="" type="checkbox"/> Physical inactivation Aerosol handling: N/A <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Centrifugation: N/A <input checked="" type="checkbox"/> Sealed rotors/safety caps <input type="checkbox"/> Sharps handling: N/A <input checked="" type="checkbox"/> Standard sharps precautions <input type="checkbox"/> Transport: N/A <input type="checkbox"/> Double sealed, durable leak-proof container with biohazard label <input checked="" type="checkbox"/> Any special considerations No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		
<b>Motion</b>	<input type="checkbox"/> Straight approval <input type="checkbox"/> Conditional approval with administrative post-review <input checked="" type="checkbox"/> Conditional approval with subcommittee post-review		
First:	Woodward	Second:	Westwater
<b>Votes</b>			
For:9	Against:0	Abstained:0	Recused:0

<b>Protocol #</b>	IBC-25-289		
<b>PI Name</b>	Strange, Charlie		
<b>Study Title</b>	[REDACTED]: A Phase 1/2 dose-exploration and dose-expansion study to evaluate the safety and efficacy of [REDACTED] in adult patients with [REDACTED] associated lung disease and/or liver disease.		
<b>Agent</b>	<input checked="" type="checkbox"/> Plasmid DNA/mRNA <input checked="" type="checkbox"/> CRISPR/Cas9 technology <input type="checkbox"/> Molecular grade Escherichia coli <input type="checkbox"/> Laboratory grade strains Saccharomyces cerevisiae <input type="checkbox"/> Replication-deficient viral vectors <input type="checkbox"/> RG1 microbes <input type="checkbox"/> RG2 microbes <input type="checkbox"/> Biological toxins <input type="checkbox"/> Gene modified mouse cells <input type="checkbox"/> Gene modified human cells <input type="checkbox"/> Other		
<b>rDNA Category</b>	III-C		
<b>Genetically modified microbes or vectors</b>	N/A		
<b>Transgene expression</b>	[REDACTED]		
<b>Highest BSL</b>	BSL2		
<b>Training</b>	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Pending		
<b>Risk Assessment of Procedures</b>	PPE is appropriate for <input type="checkbox"/> BSL1 <input checked="" type="checkbox"/> BSL2 <input type="checkbox"/> ABSL1 <input type="checkbox"/> ABSL2 Waste handling: <input checked="" type="checkbox"/> Chemical inactivation <input checked="" type="checkbox"/> Physical inactivation Aerosol handling: N/A <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		

	Centrifugation: N/A <input checked="" type="checkbox"/> Sealed rotors/safety caps <input type="checkbox"/> Sharps handling: N/A <input type="checkbox"/> Standard sharps precautions <input checked="" type="checkbox"/> Transport: N/A <input type="checkbox"/> Double sealed, durable leak-proof container with biohazard label <input checked="" type="checkbox"/> Any special considerations No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		
<b>Motion</b>	<input type="checkbox"/> Straight approval <input type="checkbox"/> Conditional approval with administrative post-review <input checked="" type="checkbox"/> Conditional approval with subcommittee post-review		
First:	Westwater	Second:	Voelkel-Johnson
<b>Votes</b>			
For:8	Against:0	Abstained:0	Recused:0

<b>Protocol #</b>	IBC-25-330
<b>PI Name</b>	Spencer-Smith, Russell
<b>Study Title</b>	Exploring drug repurposing for the treatment of RASopathy syndromes cells to increase fetal hemoglobin production.
<b>Agent</b>	<input checked="" type="checkbox"/> Plasmid DNA/mRNA <input type="checkbox"/> CRISPR/Cas9 technology <input type="checkbox"/> Molecular grade Escherichia coli <input type="checkbox"/> Laboratory grade strains Saccharomyces cerevisiae <input type="checkbox"/> Replication-deficient viral vectors <input type="checkbox"/> RG1 microbes <input type="checkbox"/> RG2 microbes <input type="checkbox"/> Biological toxins <input type="checkbox"/> Gene modified rodent cells <input type="checkbox"/> Gene modified human cells <input type="checkbox"/> Other
<b>rDNA Category</b>	III-D4b
<b>Genetically modified microbes or vectors</b>	N/A
<b>Transgene expression</b>	RASopathy genes include: BRAF, CBL, HRAS, KRAS, NRAS, LZTR1, MEK1, MEK2, MRAS, PPP1CB, PTPN11, RAF1, RASA2, RIT1, RRAS, RRAS2, SHOC2, SOS1, SOS2.
<b>Highest BSL</b>	BSL1, ABSL1
<b>Training</b>	<input checked="" type="checkbox"/> Complete <input type="checkbox"/> Pending
<b>Risk Assessment of Procedures</b>	PPE is appropriate for <input checked="" type="checkbox"/> BSL1 <input type="checkbox"/> BSL2 <input checked="" type="checkbox"/> ABSL1 <input type="checkbox"/> ABSL2 Waste handling: <input checked="" type="checkbox"/> Chemical inactivation <input checked="" type="checkbox"/> Physical inactivation Aerosol handling: N/A <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Centrifugation: N/A <input checked="" type="checkbox"/> Sealed rotors/safety caps <input type="checkbox"/> Sharps handling: N/A <input type="checkbox"/> Standard sharps precautions <input checked="" type="checkbox"/> Transport: N/A <input type="checkbox"/> Double sealed, durable leak-proof container with biohazard label <input checked="" type="checkbox"/> Any special considerations No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>

<b>Motion</b>	<input checked="" type="checkbox"/> Straight approval <input type="checkbox"/> Conditional approval with administrative post-review <input type="checkbox"/> Conditional approval with subcommittee post-review
First:	Voelkel-Johnson
<b>Votes</b>	Second: Westwater
For:8	Against:0
	Abstained:0
	Recused:0

<b>Meeting Adjournment</b>	The IBC Chair called for the meeting to be adjourned at 1:19 PM
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