UNIVERSITY OF South Carolina

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING MINUTES

DATE: *December 10, 2025*
TIME: *3:00 PM*
LOCATION: *Virtual Meeting via Microsoft Teams*

The meeting for the University of South Carolina's Institutional Biosafety Committee (IBC) was called to order by the Chair, Dr. Doug Pittman at 3:01pm.

Approved IBC minutes will be posted on the university's IBC website. This website includes meeting dates, times, locations, and guidance for the public to request to attend an IBC meeting.

MEETING ATTENDANCE

IBC Member	Member Role / Position / Department	Attendance
Doug Pittman	IBC Chair; Director, Graduate Studies in Drug Discovery & Biomedical Sciences	☑
Mark Robbins	Research Safety Bureau Chief & Senior Biosafety Officer in EH&S	☑
Shayne Barlow	Associate Vice President for Research; Director, Animal Resource Facilities	☑
Beth Krizek	Plant Expert; Professor in Biological Sciences	☑
Sujit Pujhari	Viral Vector Core Director in Pharmacology, Physiology & Neuroscience	☑
Jason Kubinak	Associate Professor in Pathology, Microbiology, and Immunology	ABSENT
Michael Shtutman	Associate Professor in Drug Discovery & Biomedical Sciences	ABSENT
Daping Fan	Professor in Cell Biology and Anatomy	☑
Sean Norman	Director, Molecular Microbial Ecology Lab in Environmental Health Sciences	☑
Anna Blenda	Clinical Professor in Biomedical Sciences at USC SOM Greenville	☑
William Jackson	Professor/Chair in Biological, Environmental & Earth Sciences at USC Aiken	☑
Ben Montgomery	Associate Professor in Natural Sciences and Division Chair at USC Upstate	☑
Amanda Moore	Community member; SC Department of Public Health	ABSENT
Vida Mingo	Community member; Senior Lecturer of Biology at Columbia College	ABSENT
Kris Kaigler	Research Specialist staff in Pharmacology, Physiology and Neuroscience	☑

I. APPROVAL OF PREVIOUS MEETING MINUTES

IBC minutes from the meeting on October 22, 2025, were approved by committee vote.

- Votes: For = 11 / Against = 0 / Abstain = 0

II. ANNOUNCEMENTS

A. IBC CHAIR

i. Dr. Montgomery will no longer serve on the IBC after this year. The Chair recognized the many valuable contributions he has made as an IBC member.

ii. The committee discussed the option for an in-person meeting next year to meet new IBC members and possible alternative locations for easier parking.

B. RESEARCH SAFETY BUREAU CHIEF / SENIOR BIOSAFETY OFFICER

i. The committee voted to approve the updated IBC Charter that includes the new members that will begin attending meetings starting in early 2026.

III. OLD BUSINESS

No old business was discussed.

IV. PROTOCOL REVIEWS

Protocol #	1-0140-1225
Protocol Type	Renewal
PI Name	Jeff Twiss
Project Title	In vivo approaches to modulate axonal mRNA transport and translation
Section of NIH Guidelines	Section III-D-1 & III-D-4, Section III-E-1 & III-E-3, Section III-F-3 & III-F-8
Characteristics of Agent(s) or Material(s)	Adeno-associated viruses (AAV) are small, non-enveloped viruses with single-stranded linear DNA. AAV vectors are non-pathogenic and can infect dividing and non-dividing cells. Although no known diseases are associated with any AAV human serotype, insertional mutagenesis is a theoretical possibility (AAV integrates into the host cell genome). Mucous membrane exposure, parenteral inoculation, ingestion, and

	inhalation of aerosols are the primary routes of transmission. Lentivirus (HIV) is a medium sized, enveloped retrovirus that can integrate into the host's genome. Lentivirus (HIV) only infects humans. The primary routes of transmission are parenteral inoculation, mucous membrane contact, and potentially ingestion. Aerosol transmission is unknown. The major risks with HIV-1 based lentivirus vectors are the potential for generation of replication-competent lentivirus (RCL) and potential for oncogenesis depending on the genes of interest. To mitigate risk of generating RCL, only 3rd generation LV will be used. Transgene derivatives used are not a well-known safety hazard (e.g., no oncogenes). Consequences of expression of gene products are limited to neurons and LV particles (poor retrograde transport for neuronal infection in humans). No anticipated consequences of expression in non-neuronal cells. cDNAs from rat and mouse and genomic DNA from mouse will be used. Lab will engineer sequences of mRNAs for overexpression or altered transport of their mRNAs into axons or altered translation within axons. A second approach is for down regulation of proteins using polycistronic shRNA-GFP constructs. Standard plasmids used for cloning, expression in mammalian cells, and generation of replication-deficient lentivirus (LV) and AAV. Viral titer is typically 10 to -10 to -12 MOI and < 5 µl viral preparation solution. LV and AAV are generated by Viral Vector Core facilities. Third approach is genome editing using CRISPR/Cas9. Plasmids will be amplified in non-pathogenic *E. coli* K-12 strains. Non-neuronal cells are used to troubleshoot constructs showing low expression in neuronal contexts & validate functionality of Crispr/Cas9. Replication-deficient LV and AAV preparations used to transduce primary mouse and rat neuron cultures. For cDNAs cloned into LV shuttle vectors, site-directed-mutagenesis is used to remove the poly-adenylation element(s).
Manipulations/Procedures & Risk Assessment	BL2 containment is used for handling virus. Aerosol-resistant centrifuge rotors are used. All staff use PPE (gloves, lab coat, face shield/glasses) while handling virus. Viral preparations pipetted with aerosol resistant pipets (i.e., plugged) in a biosafety cabinet. Microliter quantities are used and all surfaces for virus work are decontaminated with 10% bleach. Experimental procedures used for transducing exogenous transgenes into cultured cells and anesthetized mice and rats. Techniques for cultured cells are pipetting viral solution into culture dish – µl quantities of virus (generally < 10 µl) with ml quantities of culture medium are used (< 2 ml). Culture vessels are placed into secondary containers and incubated. Electroporation used to transiently transfect neuronal-like cell lines and primary cultures of neurons from adult mice/rats. For transducing animals, ≤ 5 µl aliquot of viral solution is aspirated into a Hamilton microsyringe fitted with a needle within a biosafety cabinet. Injection of AAV into the vitreous humor is performed under a dissecting microscope in a Class I Safety Enclosure. Injection of LV and AAV into the neurons is performed in a biosafety cabinet. Hamilton microsyringe & needle are rinsed three times with 10% bleach. Bleach is drawn up into the syringe then put into a waste container (repeated for 3 cleanings). Syringe is then rinsed with water 3X using the same technique. After the

<table>
<tr><td></td><td>water rinse, the syringe is allowed to dry and is stored in the original puncture-resistant container before being used again.

Animals are transported to and from the animal facility is a large soft-sided cooler (method was approved by the IACUC/veterinarian). After infection, animals are transported back to the animal facility in the same cooler. Animals are moved to the cage used for the biohazard rack. Dirty cages are bagged as hazardous and placed on the dirty cage side to be autoclaved and washed. Biohazard waste transported to the autoclave room in a durable, leak-proof container and secured for transport.</td></tr>
<tr><td>Source(s) and Nature of Nucleic Acid Sequences

Transgene Expression & Function of Protein</td><td>The source of nucleic acid sequences includes rat, mouse & synthetic.

The nature of nucleic acids and function of proteins produced include structural proteins, GTPase, phosphoinositide 5-phosphatase, RNA binding proteins, stress granule complex, mutant blocks and enhances stress granule aggregation, facilitates axon growth, retrograde signaling molecule, GPI-anchored protein, transmembrane protein, RNA interference, transcription factor, and biotinylation enzyme</td></tr>
<tr><td>Host(s) & Vector(s) Used</td><td>Hosts: E. coli used to amplify plasmids.
Replication-deficient lentivirus (LV) and adeno-associated virus (AAV) – lab only generate shuttle vectors. Lab uses Viral Vector Core facilities for generation and initial testing that verifies replication deficiency and titer.
Plasmids for initial cloning of PCR products and for expression in mammalian cells in culture, and shuttle vector for generation of LV.
Shuttle vector for generation of AAV was modified to allow lab to better manipulate sites of protein expression.
Expression plasmid for Cas9 protein for genome editing in mice/rat cells.</td></tr>
<tr><td>Viral Vectors</td><td>Adeno-Associated Virus (AAV not packaged in PI’s lab)

Retrovirus / Lentivirus (3rd generation, not packaged in PI’s lab)</td></tr>
<tr><td>Biosafety Level(s)</td><td>BL1 (amplification of plasmids in E. coli K-12 strains)

BL2 (experiments involving lentiviral and AAV vectors)</td></tr>
<tr><td>Work Practices</td><td>Verified proper work practices for experiments conducted at BL1 & BL2.</td></tr>
<tr><td>Laboratory Facilities</td><td>Verified proper lab facilities for experiments conducted at BL1 & BL2.</td></tr>
<tr><td>Training and Expertise of Research Personnel</td><td>PI provided CV/biosketch for IBC to verify PI’s training and expertise.

PI completed training on NIH Guidelines for Principal Investigators.

PI indicated plans to make biosafety protocols available to lab staff and train lab staff in safe work practices and procedures for incidents.

Lab personnel that will administer viral vectors in animals have received training to follow all procedures in the SOP for Biohazards in Animals.</td></tr>
<tr><td>IACUC Approval</td><td><table><tr><th>IACUC Approval Number</th><th>IACUC Approval Date</th></tr><tr><td>2633-101765-012023</td><td>1/20/2023</td></tr><tr><td>2741-101976-120624</td><td>5/19/2025</td></tr></table></td></tr>
</table>

		2780-102060-091525	9/15/2025	
Major Discussion Points	PI added description for handling microsyringe after injections to prevent exposure and procedures for transporting animals between lab & DLAR.			
Motion to Approve	A motion was made to approve this protocol as is			
	Votes For:	Votes Against:	Abstained:	Conflict of Interest:
	11	0	0	None

Protocol #	1-0143-1225
Protocol Type	Renewal
PI Name	April DeLaurier
Project Title	Use of recombinant DNA in zebrafish developmental biology research
Section of NIH Guidelines	Section III-D-4, Section III-F-7 & III-F-8
Characteristics of Agent(s) or Material(s)	CRISPR DNA and RNA materials are synthesized in vitro using PCR and other amplification methods. This includes guide RNAs, short oligo nucleotides, and mRNA. Genetic material is microinjected into 1 cell stage zebrafish embryos and zebrafish are raised to adulthood. Recombinant DNA is integrated into the host genome and stably transmitted by parents to offspring. Plasmid DNA containing portions of zebrafish genes & other transgenes (e.g. GFP) & antibiotic resistance (e.g. transformed in *E. coli* K-12 cells) Recombinant materials are minimal risk and non-pathogenic.
Manipulations/Procedures & Risk Assessment	Plasmid DNA is made recombinant by inserting sections of zebrafish DNA or jellyfish-derived GFP or RFP into vectors at cloning sites. Circular/linear DNA may be injected in zebrafish eggs for recombination into genomes to mis-express a gene or express a transgene. Genetic constructs will be synthesized in the lab - e.g. digestion, ligation, propagation in *E. coli* K-12 strains, purification from *E. coli*, PCR, and RT-PCR; and injected into 1-cell stage zebrafish embryos. Transgenic zebrafish used for time-lapse imaging of cell behaviors. No genetic constructs made will have pathogenic potential. Short genetic constructs synthesized by PCR such as gRNAs for CRISPR. Short gRNAs used for injection in 1-cell stage zebrafish embryos. Users of genetically modified material will wear gloves to prevent exposure to recombinant DNA. Waste (bacteria containing vectors, including bacterial growth culture plates and media, and purified plasmid stored in micro-centrifuge tubes) containing recombinant DNA will be autoclaved prior to disposal. There are no exposure risks associated with this work if safety

<table>
<tr><td></td><td>precautions are followed. Sharps used for microinjections are disposed of in a puncture-resistant sharps container and microinjection device is setup to mitigate the risk of a sharps exposure (i.e., injection). Potentially contaminated surfaces wiped with 70% ethanol and PPE is used. Tissues from recombinant zebrafish are disposed of as biohazardous waste. Containers are clearly labelled in fridges, freezers, and on benchtops.</td></tr>
<tr><td>Source(s) and Nature of Nucleic Acid Sequences
Transgene Expression & Function of Protein</td><td>The source of nucleic acid sequences includes jellyfish and zebrafish.
The nature of nucleic acids include green & red fluorescence, guide RNA constructs, and a modified DNA sequence to induce mutation.</td></tr>
<tr><td>Host(s) & Vector(s) Used</td><td>E. coli K-12 strains as vectors are microinjected into zebrafish embryos</td></tr>
<tr><td>Viral Vectors</td><td>None</td></tr>
<tr><td>Biosafety Level(s)</td><td>BL1 (digestion, ligation, propagation in E. coli K-12 strains, injections into zebrafish embryos and use of transgenic zebrafish)</td></tr>
<tr><td>Work Practices</td><td>Verified proper work practices for experiments conducted at BL1.</td></tr>
<tr><td>Laboratory Facilities</td><td>Verified proper lab facilities for experiments conducted at BL1.</td></tr>
<tr><td>Training and Expertise of Research Personnel</td><td>PI provided CV/biosketch for IBC to verify PI’s training and expertise.
PI completed training on NIH Guidelines for Principal Investigators.
PI indicated plans to make biosafety protocols available to lab staff and train lab staff in safe work practices and procedures for incidents.</td></tr>
<tr><td>IACUC Approval</td><td><table><tr><th>IACUC Approval Number</th><th>IACUC Approval Date</th></tr><tr><td>USCA-IACUC-001</td><td>03/26/24</td></tr></table></td></tr>
<tr><td>Major Discussion Points</td><td>No major issues were discussed by the committee.</td></tr>
<tr><td>Motion to Approve</td><td>A motion was made to approve this protocol as is<table><tr><td><u>Votes For:</u>
11</td><td><u>Votes Against:</u>
0</td><td><u>Abstained:</u>
0</td><td><u>Conflict of Interest:</u>
None</td></tr></table></td></tr>
</table>

Protocol #	1-0149-1225
Protocol Type	Renewal
PI Name	Nicholas Truex
Project Title	Engineering molecular immunotherapies
Section of NIH Guidelines	Section III-D-1 & III-D-2, Section III-E, Section III-F-1, F-2, F-3, F-8
Characteristics of	<u>Artificial Transcription Factors (ATFs):</u> DNA-targeting proteins for

Agent(s) or Material(s)	regulating gene expression of human and mouse genomes, including oncoproteins, cytokines and chemokines, growth factors, and homing receptors. The ATFs are DNA-encoded into mammalian and bacterial expression plasmids. Yeast Surface Display**:** screening platform for discovering new binding proteins. Two protein libraries are screened on the surface of yeast cells. One library is derived from human antibodies, and the other library is derived from a *Sulfolobus solfataricus* protein. Both libraries are encoded in a yeast expression plasmid amplified in bacterial cells. Antibody Engineering: several plasmids for antibody expression in mammalian and bacterial cells. Most are human-derived antibodies and the other antibodies are murine-derived antibodies. Bacterial expression is performed in an expression vector by transformation. Anthrax-mediated Protein Delivery: *Bacillus anthracis* strains are identical or equivalent to, or derived from, the widely used Sterne strain. The Sterne strain contains the large pXO1 plasmid that encodes the anthrax toxin proteins but lacks the pXO2 plasmid that encodes the poly-gamma-D-glutamic acid capsule. Loss of either plasmid decreases virulence by manyfold. The Sterne strain (pXO1+, pXO2-), and versions known generically as "Sternetype", are used world-wide as veterinary vaccines and in Russia and China as a human vaccine. A suspension of Sterne (34F2) spores is sold in the USA as the veterinary vaccine. In contrast, those *B. anthracis* strains containing the pXO2 plasmid are classified and regulated as Select Agents. No pXO2-containing Select Agent *B. anthracis* strains will be acquired or used in the lab. The *B. anthracis* strain BH500 lacks pXO2 and pXO1, further decreasing risk. The *B. anthracis* BH500 strains used for experiments secrete a protective antigen (PA), which can be used as a molecular syringe to inject therapeutics into cancer cells. Because *B. anthracis* secretes the protein, the protein preparation procedure is more convenient than expression in *E. coli*. The BH500 strain has several endogenous proteases knocked out and serves as an effective host for production of recombinant proteins. Nonetheless, *B. anthracis* can produce spores that allow the organism to persist for long periods, withstanding heat and drying, until the return of more favorable conditions for vegetative growth. Studies also indicate that very few spores are required for cutaneous infection. Lentiviral-Derived Gene Delivery: Lab will use a gene-delivery system derived from HIV-1, a 3rd generation system that is significantly modified to remove replication capability and reduce biosafety concerns. Each experiment uses a 4-plasmid approach, in which three plasmids encode gag, pol, rev, and env genes but are separated across multiple plasmids to prevent self-sustaining viral replication. The fourth plasmid encodes the transgene for gene expression but lacks LTR repeats and the ψ (psi) packaging signal and is not designed to mediate canonical lentiviral genome packaging or integrative transduction. Instead, the fourth plasmid relies on high RNA abundance to allow RNA encapsulation by HIV-1 Gag, as previously reported, and particle-mediated delivery. Transgene plasmids encode gene products that include ATF proteins,

	fluorescent proteins, and inflammatory cytokines and chemokines. Although these proteins are nonpathogenic, over-expression can potentially be harmful due to: (a) oncogenic effects from ATF-mediated stimulation of immune genes, which can affect cell cycle regulation, proliferation, or apoptosis; (b) toxic effects from excessive protein expression or ATF-mediated immune activation; and (c) physiological effects from the ATF-mediated unanticipated modulation of signaling proteins, which can affect growth factors, immune responses, and cellular behavior. (d) allergenic affects from ATF-mediated immune activation. Inherent hazards include: (a) mutagenesis from integration into the host genome, which could disrupt regulatory regions of endogenous genes, potentially leading to oncogenesis; (b) high doses to cells can cause cytotoxic effects or an immune response; (c) cells with stable expression of a transgene that has oncogenic properties can cause uncontrolled cell proliferation; (d) possible disruption of cell homeostasis due to gene over-expression, immune activation or dysregulation of cell function. The lentiviral gene delivery system has been pseudotyped with the VSV-G envelope protein, which enables applications in most mammalian cells. The vector titer and amount for experiments are relatively small in scale.
Manipulations/Procedures & Risk Assessment	Some r/s NA sequences used in the lab comprise transgenes from pathogens (RG 2), including *B. anthracis* and *C. diphtheriae*. Genetically modified *B. anthracis*) are used for protein expression. Work with these molecules and pathogens does not increase toxicity or pathogenicity. r/s NAs usage includes: (1) direct transfection for protein expression, (2) manipulation through mutagenesis and gene editing, (3) direct treatment to mammalian cells as an immunogenic adjuvant. r/s NA transfection into cells includes mammalian cell transfection (BL2), bacterial transformation (BL2), and yeast transformations (BL1), and lentiviral-derived gene delivery (BL2) The procedures include PCR, RT-qPCR, cloning, recombinant protein expression (*B. anthracis*), and lentivirus transduction in mammalian cells. Besides using plastic pipette tips for work with mammalian cells, no other sharps are used. Work with mammalian cells in the biosafety cabinet. Bacteria requiring BL2 containment will be centrifuged using safety cups to contain aerosols and a 10-minute settling time will be allowed before opening safety cups while the user is wearing proper PPE, including lab coat, safety glasses, and a face mask. Animals and plants will not be used in any experiments. If material must be transported between rooms, it will be placed in a durable leak-proof container and secured for transport. Work surfaces will be routinely decontaminated as well as after any spills using freshly prepared 10% bleach or 70% ethanol solutions. Possible modes of transmission for *B. anthracis* include respiratory, cutaneous (via broken skin), gastrointestinal (via ingestion), and inhalation. Eye and face protection (i.e., goggles, masks, or face shields) will be used when splashes or sprays are possible. To reduce the risk of cutaneous exposures, gloves will be worn when handling samples and no sharps will be used. The risk of gastrointestinal exposures will be

	minimized by handling less than 3 liters of culture at a time and using appropriate PPE (gloves, lab coat, safety glasses or goggles) and safe work practices. When working with larger volumes (>500 mL), a surgical mask will also be worn to minimize risk of contact with the mouth. *B. anthracis* can produce spores that allow the organism to persist for long periods and are resistant to many disinfectants. For decontamination, a freshly prepared 20% bleach solution will be used to decontaminate all work surfaces and spills after each protein expression. If a spill occurs involving *B. anthracis*, the Biosafety Officer will be notified. *B. anthracis* has the highest exposure risk through inhalation. If a *B. anthracis* spill occurs, lab personnel will immediately evacuate the lab for 1 hour to allow potential aerosols to settle. Afterward, the PI and lab personnel will enter the room to clean up the spill. These procedures will also be described and posted throughout the lab. High concentrations of *B. anthracis* cultures will not be used. The primary lentivirus exposure risks are mucous membrane exposure and parenteral inoculation. No sharps will be used, so there is no risk of parenteral inoculation. The risk of mucous membrane exposure will be minimized by working in a biosafety cabinet and wearing face and eye protection if materials must be handled outside of the biosafety cabinet.
Source(s) and Nature of Nucleic Acid Sequences **Transgene Expression & Function of Protein**	The source of nucleic acid sequences includes *B. anthracis*, *Staph. aureus*, human, Discosoma, Aequoera Victoria, Mus musculus, Tobacco Etch Virus, Thosea asigna virus, *S. cerevisiae*, *Sulfolobus acidocaldarius* The nature of nucleic acids and function of proteins produced include pore-forming protein, inhibition of protein synthesis, transpeptidase, cell receptor, fluorescent proteins, protease for cleaving, affibody, nanobody, Single-chain variable fragment, self-cleaving peptide, ASMTNMELM peptide, mAb, mouse IgG2c antibody, fluorescein binding antibody, sumo protease, chemokine, and for discovering novel binding proteins
Host(s) & Vector(s) Used	Bacterial expression (*E. coli*, *B. anthracis*) of proteins and antibody fragments Mammalian expression of proteins, antibodies, and antibody fragments Yeast display of protein libraries (antibody fragments and small binding proteins) Lentiviral-derived gene delivery
Viral Vectors	None
Biosafety Level(s)	BL1 (yeast transformations) BL2 (mammalian cell transfection, bacterial transformation, lentiviral-derived gene delivery)
Work Practices	Verified proper work practices for experiments conducted at BL1 & BL2.
Laboratory Facilities	Verified proper lab facilities for experiments conducted at BL1 & BL2.

<table>
<tr><td>Training and Expertise of Research Personnel</td><td colspan="4">PI provided CV/biosketch for IBC to verify PI's training and expertise.
PI completed training on NIH Guidelines for Principal Investigators.
PI indicated plans to make biosafety protocols available to lab staff and train lab staff in safe work practices and procedures for incidents.</td></tr>
<tr><td>Major Discussion Points</td><td colspan="4">The IBC discussed the classification of the gene delivery system used.</td></tr>
<tr><td rowspan="3">Motion to Approve</td><td colspan="4">A motion was made to approve this protocol, pending the PI adding clarifications about the lentiviral gene delivery. The IBC discussed the absence of LTRs and the Ψ packaging signal means the construct does not constitute a canonical lentiviral vector or a non-integrating lentiviral vector (NILV). While Gag-mediated assembly and encapsulation of non-Ψ RNAs has been reported, such particles are considered non-canonical and non-genome-defined and fall outside standard lentiviral vector classifications. The protocol was revised to use the term "lentiviral-derived gene delivery" and to explicitly state that the fourth plasmid lacks LTRs and the ψ packaging signal. The protocol was approved after the PI made the required revisions to address this issue.</td></tr>
<tr><td><u>Votes For:</u></td><td><u>Votes Against:</u></td><td><u>Abstained:</u></td><td><u>Conflict of Interest:</u></td></tr>
<tr><td>11</td><td>0</td><td>0</td><td>None</td></tr>
</table>

V. New Business / Additional Topics

No new business was introduced.

VI. Review of Incidents

No new incidents were reported.

VII. Inspections/Ongoing Oversight

Each PI's protocol includes a link to their last lab safety inspection report for IBC review.

VIII. IBC Training

New members that will be joining the IBC will complete training in January.

IX. Public Comments

No public comments were received.

X. Meeting Adjournment

The IBC meeting was adjourned at 3:50pm.