Vanderbilt University (Nashville, TN) Institutional Biosafety Committee (VU IBC)

Minutes
June 24, 2025
10:45am to 11:55am
Virtual Meeting

Voting Members Present:

Name	Affiliation	Role/Expertise	Present?	Notes
Julian Hillyer	Vanderbilt University	Chair, Arthropod Containment Expert	☒ Yes ☐ No	
Kyle Becker	Vanderbilt University	Biosafety Officer	☒ Yes ☐ No	
Chin Chiang	Vanderbilt University	Scientist, Developmental Biologist / RDNA Delivery Expert	☒ Yes ☐ No	
Abigail Holloway	Metro Nashville Public Health	Non-Affiliated Community Member	☒ Yes ☐ No	
Ethan Lippmann	Vanderbilt University	Scientist, Engineer / Drug Delivery and Stem Cell Expert	☐ Yes ☒ No	
Ryan Mason	Tennessee Department of Health	Non-Affiliated Community Member	☒ Yes ☐ No	
Lisa McCawley	Vanderbilt University	Scientist, Biologist / RDNA and Risk Assessment Expert	☒ Yes ☐ No	
Jenny Schafer	Vanderbilt University	Scientist, Microscopist / Core Representative	☒ Yes ☐ No	
Katherine Shuster	Vanderbilt University Medical Center (VUMC)	Animal Containment Expert	☒ Yes ☐ No	
Benjamin Spiller	Vanderbilt University	Scientist, Structural Biologist / Microbiology and Toxin Expert	☒ Yes ☐ No	Arrived at 11:17 am
William Wan	Vanderbilt University	Scientist, Biochemist / Molecular Biology and Virology Expert	☒ Yes ☐ No	
Jeanne Wallace	Vanderbilt University Medical Center	Alternate Animal Containment Expert	☐ Yes ☒ No	

Non-members in attendance:

Name	Affiliation	Title
Scott Bury	VUMC	Director, Office of Animal Welfare Assurance
Andrea George	Vanderbilt University	Assistant Vice Chancellor, Environmental Health Safety and Sustainability
Kendra Hoffsmith	Vanderbilt University	Safety Officer, Biosafety
Paul Liebman	Vanderbilt University	Senior Director, Office of General Counsel

Name	Affiliation	Title
Matt Loch	Vanderbilt University	Safety Officer, Biosafety
Greta Messer	Vanderbilt University	Associate General Counsel
Katrina Ngo	Vanderbilt University	Safety Officer, Biosafety
Ana Nobis	VUMC	Medical Director, Occupational Health Clinic
Cody Swilley	VUMC	Veterinary Resident, Division of Comparative Medicine
Anthony Tharp	Vanderbilt University	Assistant Dean, Facilities, Infrastructure, and Risk Management
Venita White	VUMC	Registered Nurse, Occupational Health Clinic

Quorum

Per the Vanderbilt University IBC Charter, at least five voting members of the Committee must be present to conduct business. Ten voting members were present, so quorum was met.

Call to Order / Introductions / Announcements

This meeting was held in a virtual format that included an internet-based video meeting platform. Using this platform, review materials were shared, and attendance and voting were confirmed and recorded.

The Chair called the meeting to order at 10:45 am.

Dr. Shuster introduced Dr. Cody Swilley, a veterinary resident with VUMC, who joined as a guest.

Dr. George provided an update on the status of the recruitment effort for a new Associate Director of Biosafety and BSO. There are several promising candidates and interviews are in progress. As candidates continue through the process, IBC members will be invited to meet with them.

The Chair reminded all members present to identify any conflicts of interest (COI) as each registration is reviewed. The Chair also reminded the Committee that the current missive of the IBC is to evaluate whether registrations comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), and that at present, the Committee does not specifically evaluate whether research constitutes dual use research of concern (DURC/PEPP) or gain of function research (GOF) since this is the function of the Institutional Review Entity (IRE).

Minutes Review / Approval

The Chair opened the floor for comments and proposed revisions of the minutes of the April 22, 2025, meeting. There was no substantive discussion because the minutes were deemed to accurately summarize the meeting. The Committee voted to approve the minutes as presented.
Motion to approve the minutes: For: 9; Against: 0; Abstain: 0.

Biosafety Officer's Incident Report

The BSO summarized a potential RDNA needlestick exposure sustained by a graduate student whose project involved the use of a beveled needle on one mL syringe to deliver saline to exposed murine brain during survival surgery. The animal had been administered an adeno-associated viral vector (AAVs) that delivered a calcium sensor two weeks prior to the incident and the lab member involved is unsure if during the saline flushing procedure, the needle contacted saline that had already been administered to the exposed site. After expelling saline from the device, the researcher placed the syringe on the benchtop and the researcher continued with subsequent steps of the surgery. In reaching for items on the bench for post-procedure cleanup, the researcher's hand contacted the exposed device. The student immediately removed their gloves, thoroughly flushed the site, reported the incident to their Principal Investigator (PI), and reported for post-exposure medical evaluation.

VU Biosafety met with the graduate student and the PI to review the procedure that resulted in the potential exposure. The researcher had completed and is current on all relevant institutional biosafety courses, had been trained and qualified on the procedure, and followed all appropriate steps for post-exposure follow-up. However, the researcher had not been added to the PI's biomaterials users roster which has now been rectified. It was determined that the root cause of the event was that a sharps container was not placed within arm's reach of the procedure for disposal of sharps immediately after use. Based on this meeting the BSO proposed recommendations to prevent future exposures. These included: (i) updating the procedure to implement alternatives to sharps where feasible (e.g., using a device that is a syringe with no needle) and stressing the need for placing a sharps container within arm's reach of procedures requiring sharps, (ii) requiring the PI and all lab members to review and discuss the "using sharps safely" document to reduce sharps injury potential associated with both existing and future procedures, and (iii) VU Biosafety will develop and implement a guidance document distributed to PIs receiving their initial IBC approval outlining events/timepoints likely to occur during the lab's first year that may result in the need to update the biomaterials registration (BMR), including the roster. This will serve as a tool for PIs to ensure that their BMR remains current. Because the potential exposure event included RDNA, the BSO reported the event to the National Institutes of Health Office of Science Policy (NIH OSP). NIH OSP evaluated the report and responded that no further information was required.

The committee discussed the incident, and the Chair noted that due to the nature of the procedure, it is unclear whether the student was exposed to RDNA; however, the incident was conservatively reported to the NIH to ensure compliance in case there was an RDNA exposure. Following the discussion, the Committee voted to endorse the BSO's recommendations. Although many of the recommended actions are already in motion, VU Biosafety will communicate these details to the PI, per the IBC incident review policy.

Motion to endorse recommended actions: For: 9 ; Against: 0; Abstain: 0.

Biomaterials Registration Reviews

VU-BMR	Review Type	PI	Department	Title
078	Modification	Plate, Lars	Chemistry	*Cell Culture and Flavivirus/Coronavirus Preparation for Protein Interactomics Studies*
Research Description (as stated by PI): The goal of research in the Plate Lab is to study the dynamics and coordination of protein-protein interactions involved in pathways of cellular protein folding, protein assembly, and during viral infection. The lab will culture and manipulate mammalian tissue culture cell lines and flavivirus or coronavirus infected cell lines to measure protein-protein interactions, protein trafficking, and turn-over using cell biological, biochemical, and proteomics methods.				
Project Overview: This modification involves activities to generate a stable cell line that, once generated, will produce non-replicating, single round-infectious virus-like particles (VLPs) of SARS-CoV-2 which contain a gene encoding a non-structural protein from another member of the *Orthocoronivirinae* subfamily. These VLPs will be used for downstream mass spectrometric and structural studies of the role of this gene in virus-host interactions. The system that will be used to generate these cells and resultant VLPs was previously reviewed by the Committee and approved by the NIH Office of Science Policy for BSL-2 containment. This modification was first discussed at the November 2024 meeting. At that time, the IBC endorsed contacting the Federal Select Agent Program to determine if the resultant VLPs would be considered a select agent. A decision letter was received from the CDC Division of Regulatory Science and Compliance (DRSC) on May 5, 2025 indicating that the VLPs described in this proposed work are not a select agent.				

Risk Assessment and Discussion: BSL-2 practices and containment were proposed for all activities involving RDNA from coronaviruses including cloning into non-pathogenic *E. coli* and the generation and use of resultant VLPs in experiments in rodent- and primate-derived cells.

A lab inspection was not required as the work contained in this modification does not expand the scope from the last biosafety inspection performed with this lab. The Committee verified that the facilities, procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

The Committee discussed the classification of SARS-CoV-2 as an RG2 agent following a communication from NIH OSP in December of 2024. The Committee also discussed the nature of the RDNA to be introduced into the VLPs. Finally, the Committee discussed that the Federal Select Agent Program determined that the VLPs described in these experiments do not constitute a select agent and that the lab has demonstrated that the original VLP system is unlikely to recombine and regain the ability to replicate.

Following the discussion, the Committee voted to approve the registration at the biosafety levels proposed.

NIHG Activity Categories: III-D-1-a, III-D-2-a, III-D-3-a

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (all personnel), Working Safely with Human-Derived Materials (all personnel), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Current Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:9	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
006	Modification	Walker, Allison	Chemistry	*Discovery of Antimicrobials Produced by Bacteria and Fungi and Engineering of Biosynthetic Gene Clusters*

Research Description (as stated by PI): The Walker Lab is focused on the discovery and engineering of bioactive natural products. In order to accomplish this, the lab cultures bacteria and extracts natural products that they produce. These molecules are then tested against a panel of bacteria and fungi to determine if they have antimicrobial activity. In addition to extracting natural products from their natural producing organism, the lab also heterologously expresses the genes required for production of the natural product in a heterologous host (*Escherichia coli*) which enables the lab to increase production of cryptic metabolites or produce metabolites for bacteria that are not culturable with current technologies. The lab also works on engineering biosynthetic gene clusters to produce new natural product like molecules and to understand the rules governing biosynthetic logic. To this end, the lab expresses mutant versions of biosynthetic genes in heterologous hosts. The lab also performs selections on these hosts to determine which gene clusters produce larger quantities of the desired product, or to select for more active natural products.

Project Overview: This registration modification includes the manipulation of plasmids in non-pathogenic *E. coli* and the knockout and expression of genes of interest (genes involved in natural product regulation/production) in several *Streptomyces spp.* This modification also includes the addition and use of modified Group B Streptococcus (*S. agalactiae)* strains for growth inhibition assays.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving non-pathogenic *E. coli* and *Streptomyces spp,* (i.e., *S. exfoliatus, S. flavochromogenes, S. globisporus, S. bicolor,* and *S. baarensis).* BSL-2 practices and containment were proposed for activities involving modification, culturing, and use of *S. agalactiae*.

A lab inspection was not required as the lab was recently inspected. The Committee verified that the facilities, procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

Since the *Streptomyces* species involved in this modification are not assigned a risk group in Appendix B of the NIH Guidelines, VU Biosafety contacted NIH OSP to assign containment for RDNA activities involving these agents. NIH OSP determined that experiments with these agents could occur at a minimum containment level of BSL1 but advised that "The IBC should also consider whether the species used in the research could cause human disease, and if so, whether these species are susceptible to therapeutically useful antibiotics other than the ones used as selection markers." The BSO shared that representatives from VUMC Occupational Health confirmed that while these bacteria can, in rare cases, infect immunocompromised individuals, the antibiotics used to treat those infections would differ from the antibiotics used as selection markers in this registration.

Following the discussion, the Committee voted to approve the registration at the biosafety levels proposed.

NIHG Activity Categories: III-D-1-a, III-E, III-F-8 / Appendix C-II

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (infectious agent users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only).

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:9	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
010	Modification	Osheroff, Neil	Biochemistry	*Function, Biology, and Drug Interactions of DNA Topoisomerases*

Research Description (as stated by PI): The Osheroff Laboratory studies the mechanism of action and cellular roles of DNA topoisomerases. The lab also studies the interactions of these enzymes with established and novel anticancer and antibacterial drugs and natural products. The lab prepares recombinant enzymes for study using bacterial and yeast expression systems. The lab also utilizes recombinant plasmids as substrates for enzyme reactions. Finally, the lab utilizes well-established human, yeast, and bacterial cell lines to characterize the cellular roles of DNA topoisomerases.

Project Overview: This registration modification involves the culturing and use of *Mycobacterium abscessus,* including the introduction of mutations targeting genes of interest for downstream growth inhibition assays.

Risk Assessment and Discussion: BSL-2 practices and containment were proposed for activities involving the culturing, use, and modification of *Mycobacterium abscessus.*

Representatives from the VU Biosafety team inspected the lab as part of the risk assessment process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

The Committee discussed the proposed mutations to *M. abscessus* that may confer resistance to antibiotics. The BSO reported to the Committee that the mutations introduced in these experiments are also found in nature and representatives from VUMC Occupational Health reported that they conferred with infectious disease clinicians at VUMC and the antibiotics used in this study are not front line treatments for *M. abscessus* infections. The Committee also discussed the training and qualification of individuals working with this agent, how the lab would limit access to the agent, and the biosafety briefing given by the graduate

student responsible for this project that would be provided to all lab members detailing this work and potential risks of this agent.

Following the discussion, the Committee voted to approve the registration at the biosafety levels proposed.

NIHG Activity Categories: III-D-1-a

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (HDM or infectious agent users only), Working Safely with Human-Derived Materials (HDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:9	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
105	Renewal	Lippmann, Ethan	Chemical and Biomolecular Engineering	*Engineering and Regenerative Medicine Strategies to Model, Understand, and Treat Disease*

Research Description (as stated by PI): The Lippmann Lab combines biomolecular and biomedical engineering principles with molecular biology techniques to model, understand, and treat diseases. The lab builds models of the vascularized brain using cultured human cells and combinations of mouse and human tissue. The lab probes these models using recombinant DNA technology via techniques such as cloning, viral transduction, and CRISPR. The lab performs validation work in mouse brain slice cultures and in living mice using viral transduction. The lab also complements these validations using primary human tissue samples.

Project Overview: This renewal registration includes cloning and expressing RDNA (fluorescent markers, antibiotic resistance markers for selection and genes involved in neuronal processes) in non-pathogenic *E. coli*. Mammalian cells, including human-derived cells, will be used in conjunction with expression plasmids and AAVs and lentiviral vectors. Human brain tissue will be used to create brain models for vascularization studies. Additionally, pertussis toxin and AAVs will be administered to animal models for downstream phenotypic studies.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving RDNA in K-12 strains of *E. coli.* BSL-2 practices and containment were proposed for activities involving human-derived materials, including the generation and use of AAVs and lentiviral vectors. BSL-2 was also proposed for the administration of AAVs to animal models. Chemical safety best practices will be followed for the handling and administration of pertussis toxin. ABSL-1 containment was proposed for subsequent animal maintenance.

Representatives from the VU Biosafety team inspected the lab as part of the risk assessment process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

No questions or concerns were raised by the Committee, and the registration was approved at the biosafety levels proposed.

NIHG Activity Categories: III-D-3, III-D-4-a, III-E, III-E-1, III-F-8 / Appendix C-II

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (all personnel), Working Safely with Human-Derived Materials (all personnel), 2025 Biosafety Refresher for

Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:10	Against:0	Abstain:0

VU-BMR	**Review Type**	**PI**	**Department**	**Title**
012	Renewal	Merrikh, Houra	Biochemistry	*Molecular Mechanisms of Mutagenesis and Dynamics of Replication-Transcription Conflicts in Bacterial and Mammalian Model Systems*

Research Description (as stated by PI): The Merrikh Lab's overarching goal is to understand with molecular detail how the DNA of different organisms mutates and how these mutations help them become resistant to antibiotics and chemotherapies. The lab uses bacteria and human cells as model organisms, introducing genetic mutations to proteins involved in DNA mutation, replication, and repair.

Project Overview: This registration involves the use of RDNA (fluorescent markers and genes involved in replication and transcription) in non-pathogenic *E. coli* and *Bacillus subtilis.* RG2 agents (*Salmonella enterica* serovar Typhimurium and *Staphylococcus aureus*) are also modified and used for downstream experiments involving genetic and protein analysis following infection in cell culture models. Additionally, immortalized human cell lines are utilized for generation of and modification by lentiviral vectors for use in subsequent experiments.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving non-pathogenic *E. coli* and *B subtilis.* BSL-2 practices and containment were proposed for experiments involving RG2 bacterial agents*,* lentiviral vectors, and human derived materials.

Representatives from the VU Biosafety team inspected the lab as part of the risk assessment process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

The Committee discussed a vortexing procedure and the BSO clarified how this procedure would be performed in the lab space with BSL-2 practices. The Committee also discussed the lab locations where experiments involving RG2 agents would occur; the BSO described which activities would occur in a BSC and which would occur on the open bench in small volumes. The lab uses a shared cell culture space but has a dedicated BSC and incubators for their work.

Following the discussion the Committee voted to approve the registration at the biosafety levels proposed.

NIHG Activity Categories: III-D-1-a, III-D-3, III-E, III-E-1, III-F-8 / Appendix C-II, C-V

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (all personnel), Working Safely with Human-Derived Materials (HDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:10	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
129	Modification	Mitchell, Douglas	Biochemistry	*Genome Mining, Characterization, and Engineering of Ribosomally Synthesized and Post-Translationally Modified Peptides*

Research Description (as stated by PI): The Mitchell Lab works on discovering and characterizing new ribosomally synthesized and post-translationally modified peptide natural products (RiPPs) to find new enzyme chemistry and therapeutic molecules. To accomplish this, various strains of non-pathogenic bacteria are used in heterologous expression of natural product biosynthetic enzymes. Other bacteria are grown to isolate RiPP natural products from the native organisms, or to test for the biological activities of purified compounds.

Project Overview: This registration modification includes the study of a protein complex found in the outer membrane of many bacteria that is used to assemble certain proteins on the cell surface (BAM complex). The lab will clone and express the genes of interest from this complex (which may originate from RG1 and RG2 bacteria) in non-pathogenic *E. coli* for use in downstream experiments. Additionally, this modification includes the use of RDNA to express genes of interest (glucagon receptor) in insect and human cell culture systems. RDNA will be expressed in insect culture via baculoviral vectors to produce a high yield of recombinant protein for downstream structural assays. Human cell culture will be modified via expression plasmids and treated with various peptides for downstream ligand binding assays.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RG1 RDNA in non-pathogenic *E. coli.* BSL-2 practices and containment are recommended for experiments involving RDNA from RG2 agents in non-pathogenic *E. coli*. (The Committee may vote to lower containment for these experiments to RG1, per Section III-D-2-a of NIHG). BSL-1 practices and containment were also proposed for experiments involving insect cell culture including modification by baculoviral vectors. BSL-2 practices and containment were proposed for experiments involving human-derived materials including modification by expression plasmids.

A lab inspection was not required as the lab was recently inspected. The Committee verified that the facilities, procedures, practices and expertise of personnel involved in this research were sufficient for the scope of work.

During the discussion regarding experiments involving RG2 RDNA in non-pathogenic *E. coli*, the Committee determined that the genes of interest are highly unlikely to affect virulence or pathogenicity as the BAM complex is homologous throughout many genera of bacteria, both pathogenic and non-pathogenic.

Following the discussion, the Committee voted to approve the registration at the biosafety levels proposed, including the lowering of containment to BSL-1 for activities involving the expression of genes of interest from RG2 agents in non-pathogenic *E. coli*.

NIHG Activity Categories: III-D-2-a, III-E, III-E-1, III-F-8 / Appendix C-II

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (HDM or infectious agent users only), Working Safely with Human-Derived Materials (HDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.

Motion to approve registration	For:10	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
127	Modification	Mahadevan-Jansen, Anita	Biomedical Engineering	Vanderbilt Biophotonics Center

Research Description (as stated by PI): The Biophotonics Center Laboratories are focused on the use of light to solve problems in medicine and biology. The Center typically develops technologies for ultimate clinical application such as cancer detection, nerve monitoring, surgical guidance, and pain management. The Center tests approaches in biological fluids, human cells, genetically modified animal cells, and human tissues before conducting *in vivo* human studies in collaboration at VUMC. All projects typically involve development and testing of the technology as well as experiments that evaluate the mechanism by which the approach works. Our Center encompasses a range of biological projects including:

1) Raman spectroscopy of human tissues and biological fluids;
2) Optical perturbation of neural tissues;
3) Development of imaging approaches for surgical guidance;
4) Microscopy of cells;
5) Photodynamic therapy and dosimetry of microbial species; and
6) Raman spectroscopy for the detection and characterization of infections, bacteria, and other microbial species.

Project Overview: This registration modification involves the receipt and use of biologically inactivated (formalin inactivation) tongue samples from animals previously exposed to an RG3 bacterial agent for *ex vivo* Raman spectroscopy. Tongue samples are obtained from a Vanderbilt University Medical Center collaborator who brought the samples from their previous institution. This modification also includes the use of dilute tetrodotoxin (TTX) aliquots for the inhibition of calcium signaling in a limited-use confocal microscopy experiment. Previously reconstituted aliquots will be acquired from a Vanderbilt University collaborator, with the transfer coordinated by VU Biosafety.

Risk Assessment and Discussion: BSL-2 practices and containment were proposed for activities involving the use of biologically inactivated samples containing an RG3 agent and activities involving TTX aliquots.

Representatives from the VU Biosafety team inspected the lab as part of the risk assessment process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

The Committee discussed the limited nature of the TTX experiments and emphasized that if the lab decides to continue TTX work beyond these limited use experiments they must contact VU Biosafety to modify their registration and receive a new approval from the IBC. The Committee also discussed the fixation process for the biologically inactivated samples, and it was noted by one committee member that this was a validated approach from a pathologist. It was also noted that the inactivation of these samples had already been approved by the collaborating PI's previous institution to remove them from the high containment facility. Representatives from Occupational Health confirmed that no additional medical surveillance would be required for this project.

Following the discussion the Committee voted to approve the registration at the biosafety levels proposed.

NIHG Activity Categories: N/A

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (all personnel), Working Safely with Human-Derived Materials (HDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.			
Motion to approve registration	For:10	Against:0	Abstain:0

VU-BMR	Review Type	PI	Department	Title
005	Renewal	Rook, Jerri	Pharmacology	Behavioral Pharmacology

Research Description (as stated by PI): The primary focus of research in the Rook Lab is to develop a detailed understanding of the circuitry involved in regulating neuronal signaling in the central nervous system. In electrophysiology studies, AAVs are used to regulate gene expression to help decipher which specific genes affect neurological disorders and behavior. TTX is also used in electrophysiology studies to block action potentials via voltage-gated sodium channels as a method to control neuronal activity. The lab also supports drug discovery efforts in the Warren Center for Neuroscience Drug Discovery by evaluating novel compounds in animal systems.

Project Overview: This renewal registration includes the administration of commercially acquired adeno-associated viral vectors (AAVs) in a rodent model. Additionally, the registration involves the preparation and use of tetrodotoxin in rodent cell and tissue studies.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for the *in vivo* administration of the viral vectors and ABSL-1 containment was proposed for the subsequent maintenance of animals. BSL-2 practices appropriate for biological toxin activities were proposed for the toxin work.

Representatives from the VU Biosafety team inspected the lab as part of the risk assessment process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

No questions or concerns were raised by the Committee, and the registration was approved at the biosafety levels proposed.

NIHG Activity Categories: III-D-4-a

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (toxin users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all personnel), and Know Your Responsibilities: Biomaterials Safety Standards for Principal Investigators (PI only)

All required trainings are complete for all lab staff listed in the registration.

Conflict of interest: No IBC members declared a conflict of interest.			
Motion to approve registration	For:10	Against:0	Abstain:0

Prior Business/Outstanding Actions

There were no biomaterials registrations with conditional approvals or outstanding actions.

The BSO provided an update regarding an RDNA needlestick exposure incident first discussed at the April 2025 meeting. The BSO informed the Committee that a report was sent on May 7, 2025 to NIH OSP regarding the incident and that NIH OSP responded on May 30, 2025 indicating no further action or information was requested.

Administrative Reviews

Principal Investigator	VU BMR#	Administrative Amendment Summary
Bhowmick, Rahul	092-R2	Roster update
Boutaud, Olivier	023-R6	Roster update
Castiglione, Gianni	021-R10	Roster update
Chiang, Chin	009-R3	Addition of human cells for *in vivo* administration (M1600177) in conjunction with IACUC 3-year renewal; previously approved for similar materials.
Cigliola, Valentina	112-R1	Roster update
Coate, Katie	130-R1	Roster update
Duvall, Craig	035-R3	Addition of RG1-based viral vectors for *in vivo* administration (M1600107) in conjunction with IACUC 3-year renewal; previously approved for similar materials; roster update.
Hiebert, Scott	096-R2	Roster update
Hillyer, Julian	074-R2	Roster update
Karbstein, Katrin	114-R3	Roster update
Lee, Ethan	037-R3	Roster update
Linkous, Amanda	118-R2	Roster update
Locke, Andrea	089-R1	Roster update
Meydan, Sezen	119-R1	Roster update
Niswender, Colleen	175-R1	Roster update
Rafat, Marjan	083-R2	Roster update
Ren, Yi	107-R1	Roster update
Weaver, Alissa	069-R3	Space and roster update
Wilson, John	077-R5	PI confirmed no changes associated with IACUC 3-year review (M2200023, M2200035, M2200026); including updated letter signifying no use of toxin.
Zaganjor, Elma	060-R3	Addition of RG2-based viral vectors for *in vitro* experiments; previously approved for similar materials; roster update.

Following discussion of the items on the administrative review table, the Committee voted to approve the administrative reviews as specified above.

Julian Hillyer declared a conflict of interest as his lab had a roster update that is included as an administrative update and he did not vote.

Motion to approve the administrative reviews: For: 9; Against: 0; Abstain: 0.

New Business

The BSO introduced new requirements from NIH OSP for transparency for IBC Committee Meeting minutes which will now be posted publicly on the IBC's website following approval. The BSO also shared updates to the IBC Meeting minutes template which included changes to attendance information, the addition of quorum and conflict of interest statements, and changes to the biomaterials registration reviews that better align with the minutes template provided by NIH OSP.

The BSO also provided a summary of the completion metrics for the 2025 Biosafety Refresher module. The rate of completion for the refresher exceeds that of the previous year, at this time, and efforts to increase compliance will continue as part of registration renewals.

Public Comments

There were no public comments.

Adjournment

The Chair adjourned the meeting at 11:58 am. The next meeting of the IBC will be held via Zoom on July 22, 2025, at 10:45 am.