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

December 9, 2025
10:45am to 11:55am
Hybrid Meeting

Voting Members Present:

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

Non-voting members in attendance:

Name	Affiliation	Title
Kyle Becker	VU	Senior Safety Officer, Biosafety, Environmental Health, Safety, and Sustainability (EHSS)
Andrea George	VU	Assistant Vice Chancellor, EHSS
Kendra Hoffsmith	VU	Safety Officer, Biosafety, EHSS
Matt Loch	VU	Safety Officer, Biosafety, EHSS
Katrina Ngo	VU	Safety Officer, Biosafety, EHSS

Selene Colon	VU	Assistant Dean for Research, Dean's Office, School of Medicine Basic Sciences
Scott Bury	VUMC	Director of Office of Animal Welfare Assurance
Venita White	VUMC	Infectious Disease Nursing Program Manager, Occupational Health Clinic (OHC)

Quorum

Per the VU IBC Charter, at least five voting members of the IBC must be present to conduct business. Nine voting members were present; therefore, quorum was met.

Call to Order / Introductions / Announcements

This meeting was held in a hybrid format at VU Stevenson Center 5502, Nashville, TN 37240. The IBC meeting included an internet-based video meeting platform for those unable to attend in person. Using a presentation screen for those in person and the virtual platform for those not in person, the IBC meeting materials were shared. Attendance and voting were confirmed and recorded using the virtual platform for those not in person.

Dr. Hillyer was unable to attend this meeting; as such, Dr. Schafer served as chair pro tempore.

The IBC chair called the meeting to order at 10:46 am.

The IBC chair reminded all members present to identify any conflicts of interest (COI) as each registration is reviewed. The IBC chair also reminded the IBC 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* (NIHG), and that at present, the IBC does not specifically evaluate whether research constitutes dual use research of concern or gain of function research since this is the function of an Institutional Review Entity.

The BSO reminded those attending the IBC meeting that in January 2026, they will receive a communication regarding updating their COI disclosures for 2026.

Minutes Review / Approval

The IBC chair opened the floor for comments and proposed revisions to the minutes of the November 11, 2025 meeting. The IBC voted to approve the minutes as presented with no changes.

Dr. McCawley abstained from the vote because she was not present at the November meeting.

Motion to approve the November 2025 IBC minutes: For: 8; Against: 0; Abstain: 1.

Biosafety Officer's Incident Report

There were no incidents to report.

Biomaterials Registration Reviews

VU-BMR	Review Type	PI	Department	Title
023	Renewal	Boutaud, Olivier	Pharmacology	*Development of Novel Therapeutics for CNS Disorders*

Research Description (as stated by PI): The primary focus of research in the Drug Metabolism and Pharmacokinetics and Molecular Pharmacology labs is to characterize novel small molecules synthesized at the Warren Center for Neuroscience Drug Discovery (WCNDD). This is done by using animal brain/plasma proteins, and target protein expressing mammalian cells, respectively. These research activities support the drug discovery efforts of the WCNDD by allowing for the screening of these novel compounds in multiple assays.

Project Overview: This renewal registration includes the cloning and expression of genes of interest (neurotransmitter receptors, their isoforms, and associated proteins) in non-pathogenic *E. coli* to clone plasmids that are introduced to mammalian cells for the expression of proteins. Modified and unmodified human-derived cell lines are treated with compounds for downstream functional assays. Additionally, commercially acquired human- and macaque-derived plasma, tissue, and hepatocytes are used in downstream protein binding and compound screening experiments.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RDNA in non-pathogenic *E. coli.* BSL-2 practices and containment were proposed for experiments involving human- and macaque-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.

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

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

Training: Biosafety 101: Standard Microbiological Practices (all researchers), Biosafety 201: BSL-2 Principles (HDM and MDM users only), Working Safely with Human-Derived Materials (HDM and MDM users only), Macaque-Derived Materials and Herpes B Exposure Response for Lab Activities (MDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all researchers), and Know Your Responsibilities: Biomaterials Safety Standards for New Principal Investigators (PI only).

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

COI: 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
035	Renewal	Duvall, Craig	Biomedical Engineering	*Targeted Drug Delivery via Smart Polymer Carriers and Carrier-Free Designs for Enhanced Therapeutic Efficacy*

Research Description (as stated by PI): The Duvall Laboratory applies "smart", environmentally-responsive polymers to develop novel approaches for overcoming pharmacological barriers. A variety of projects are currently underway for development of polymeric and carrier-free systems that respond to one or more stimuli, such as pH, temperature, oxidative stress, and enzymatic activity, in order trigger polymer functionalities. Approaches are aimed at enhanced drug and nanoparticle targeting, intracellular biomacromolecular delivery, and systems for controlled release of growth factors and other extracellular-acting molecules. Therapeutic applications include cancer, wound healing and tissue regeneration, arthritis, and long-term patency in vascular bypass grafts.

Project Overview: This renewal registration includes cloning and expressing RDNA (fluorescent markers and genes related to cancer, wound healing and tissue regeneration, arthritis, etc.) in non-pathogenic *E. coli*. Mammalian cells, including human-derived cells, will be used in conjunction with expression plasmids, adeno-associated viral vectors (AAVs) and lentiviral vectors. Resultant cell lines are used for downstream genetic and biomolecular experiments. Human blood from healthy donors will be used for hemolysis assays. Additionally, modified and unmodified cell lines, plasmids, and AAVs are 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 of and transduction by AAVs and lentiviral vectors. BSL-1 was proposed for the administration of murine cell lines, plasmids, and AAVs to animal models. BSL-2 was proposed for the administration of modified or unmodified human cells to animal models. 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.

During the discussion, an IBC member inquired about the laboratory's disinfectant for work with HDM, the use of glass pipettes in conjunction with HDM, and training requirements. A member of the VU Biosafety team confirmed that an appropriate disinfectant is being used in conjunction with HDM, clarified that the lab is switching to plastic pipettes and will no longer purchase glass ones, and confirmed all required biosafety training requirements have been completed.

Following the discussion, the IBC voted to approve the registration 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 researchers), Biosafety 201: BSL-2 Principles (HDM users only), Working Safely with Human-Derived Materials (HDM users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all researchers), and Know Your Responsibilities: Biomaterials Safety Standards for New Principal Investigators (PI only).

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

COI: 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 R3	Modification	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 laboratory combines biomolecular and biomedical engineering principles with molecular biology techniques to model, understand, and treat diseases. They build models of the vascularized brain using cultured human cells and combinations of mouse and human tissue. These models are probed using recombinant DNA technology via techniques such as cloning, viral transduction, and CRISPR. The laboratory performs validation work in mouse brain slice cultures and in living mice using viral transduction. They also complement these validations using primary human tissue samples.

Project Overview: This registration modification involves the receipt and use of recombinant human alpha-synuclein pre-formed fibrils (a-syn PFFs) from a collaborator outside of VU for the development of an *in vitro* neuronal cell-based assay. This modification does not include RDNA.

Risk Assessment and Discussion: BSL-2 practices and containment with additional Prion-Like Protein (PLP) practices were proposed for activities involving a-syn PFFs.

VU Biosafety met with the PI and key study personnel to discuss the new project, proposed spaces, and potential additional biosafety practices. From this discussion, it was determined that a laboratory inspection was not required as the work contained in this modification does not significantly expand the laboratory requirements beyond the last biosafety inspection performed, which took place during the PIs last renewal. The IBC verified that the facilities, procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work.

This modification was first discussed at the November 2025 VU IBC meeting. At that time, the BSO introduced PLP biosafety practices for this project and requested that the IBC review and provide feedback. The IBC further discussed these practices within the scope of this project at the December 2025 IBC meeting. At this meeting, an IBC member asked if the biosafety procedures are similar to protocols for work with a-syn PFFs at other institutions and the BSO stated the biosafety practices were developed using five sources that are annotated references and published approaches for PLP work risk reduction at other institutions. Additional adjustments were discussed and made to the biosafety practices related to specifying eye protection as “safety” eye protection and including the disinfection procedure for the safety eye protection. Additionally, there was a discussion on the use of surgical masks for the PLP work. The BSO clarified that the PLP biosafety practices are currently specific to work that will occur within this project, which is all contained within a certified biosafety cabinet (BSC); therefore, the use of a surgical mask may not be necessary. The IBC decided to not include the use of surgical masks for this project but will revisit their use in future proposals that include work outside of a primary containment device. The IBC agreed to amend the protocol to include the use of safety eye protection and additional steps for disinfecting PPE. VU Biosafety implemented these changes to the PLP biosafety practices and will communicate these changes to the laboratory.

Following the discussion, the IBC voted to approve the registration at the biosafety levels proposed with the additional PLP biosafety practices.

NIHG Activity Categories: N/A

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

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

COI: 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
028	Renewal	Nakagawa, Terunaga	Molecular Physiology and Biophysics	*Molecular Mechanism of Synaptic Signaling*

Research Description (as stated by PI): To study their functional mechanism, the Nakagawa Lab will express proteins in non-neuronal and neuronal cells that function in regulating synaptic signaling in the central nervous system. To do this, the lab will conduct recombinant DNA experiments and use plasmid vectors and lentiviral vectors. The lab will also use pharmacological reagents that block the activity of these proteins.

Project Overview: This registration renewal includes the use of expression plasmids and third-generation lentiviral vectors to express proteins of interest (fluorescent markers or ion channel proteins) or mutated proteins in non-pathogenic *E. coli* and mammalian cells, including human cells. These proteins are then purified for use in biochemical and electrophysiological experiments. This registration also includes the storage of dilute aliquots of tetrodotoxin (TTX) for future electrophysiological studies. The TTX is currently only being stored and not used. The laboratory has indicated they will notify VU Biosafety prior to removal from storage for either disposal or experimental use.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RDNA in non-pathogenic *E. coli* and rodent cells. BSL-2 practices and containment were proposed for experiments involving human-derived materials and dilute TTX.

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.

During the discussion, the BSO was asked to clarify the laboratory's use of a Bunsen burner (in conjunction with ethanol) inside a BSC for the disinfection of instruments used in their research. The BSO explained that, during consultation with the PI, it was strongly advised to find an alternative disinfection method that does not involve an open flame due to fire risks and the potential to compromise the BSC HEPA filters, and/or laminar flow. The PI considered the recommendation but believed the use of a flame in a BSC was a scientific necessity for their work. The PI drafted a justification for the scientific necessity of a Bunsen burner for inclusion in the IBC review packet and agreed to store ethanol outside of the BSC to decrease the probability of a fire. An IBC member asked for clarification regarding whether the IBC had purview over fire safety issues. Dr. George and the BSO clarified that the IBC has purview only if the flame affects biosafety aspects of the laboratory. The BSO stated that the flame has been used for over a decade and to date has not influenced the annual certification of the BSC. In congruence with the December 2022 IBC meeting, where flames in the BSC were initially discussed, the IBC strongly encourages the PI to seek alternatives to the use of flames in BSCs.

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

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

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

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

COI: No IBC members declared a conflict of interest.

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

Administrative Reviews

Principal Investigator	VU BMR#	Administrative Amendment Summary
Douglas McMahon	068 R2	Roster update.

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

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

Prior Business/Outstanding Actions

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

Dr. McAllister provided an update regarding the submission to update VU NIH IBC roster that designates him as the institutional BSO. The website (https://ibc-rms.od.nih.gov/Contents/IBC_HOME.aspx) to submit the IBC roster adjustment was unavailable due to the U.S. government shutdown between Dr. McAllister joining VU on October 20, 2025, and November 13, 2025. The biosafety office found the website to be functional on November 13, 2025, and a request to update the VU IBC roster was submitted on the same day. This request was approved on November 19, 2025, and the VU IBC roster was updated to reflect Dr. Ryan McAllister as VU's Institutional Biosafety Officer.

Dr. McAllister also updated the IBC on the NIH initiative to modernize and strengthen biosafety oversight (https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight), first described at the October 2025 VU IBC meeting. Dr. McAllister reminded the IBC of the initiative's primary goals to work with the research community and create a modernized biosafety framework that revamps biosafety oversight to include risks beyond RDNA, decrease oversight for widely used low-risk activities, and strengthen partnerships between the IBC and other oversight bodies. In this update, Dr. McAllister informed the IBC of the date for the upcoming region 2 (southeast region) listening session, reminded the IBC that this listening session prioritizes speaking spots to those who reside and/or work within region 2, and that the listening sessions are free and open to the public. He noted that IBC members may comment on their own if they wish. An IBC member asked for clarification regarding the scope of the changes OSP is planning to make to the guidelines. The BSO clarified that the NIHG in its entirety is being reevaluated and he also gave clarification on the type of feedback that was observed at the region 1 listening session.

New Business

Dr. George introduced a new EHSS website format, which is expected to launch in December 2025. She showed the IBC the layout of the EHSS homepage and the biological safety page of the upcoming website. She noted that the URL for the new website will be different, and the previous website URL will automatically forward to the new website URL. Dr. George also informed the IBC that the content of the website is unchanged; however, in the process of changing the website, the VU Biosafety team made minor administrative changes (contact information, dates of documents, etc.) to some materials on the website.

The BSO presented edited IBC policy materials that were circulated before the IBC meeting for the IBC to review. This included updates to the IBC policies regarding human-derived materials, acutely hazardous biological toxins, high-risk biological agents, macaque-derived materials, exposure incidents and spills, and temporary trainee researchers and infectious agent activities. The changes made to the documents did not include modifications that would result in operational changes. The changes to the documents included minor language adjustments, contact information, updating the permissible amounts of conotoxin, and footer dates.

No questions or concerns were raised by the IBC and the IBC voted to endorse the updated documents.

Motion to batch endorse the updated policy documents and post them on the EHSS website: For: 9; Against: 0; Abstain: 0.

Public Comments

There were no public comments.

Adjournment

The Chair adjourned the meeting at 11:37 am. The next meeting of the IBC will be held via an internet-based video meeting platform on January 13, 2026, at 10:45 am.

List of Abbreviations

AAV	Adeno-Associated Viral Vector
ABSL	Animal Biosafety Level
a-syn PFFs	alpha-synuclein pre-formed fibrils
BSC	Biosafety cabinet
BSL	Biosafety Level
BSO	Biosafety Officer
COI	Conflict of Interest
E. coli	*Escherichia coli*
EHSS	Environmental Health, Safety, and Sustainability
HDM	Human-Derived Materials
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
MDM	Macaque-Derived Materials
NIH	National Institutes of Health
NIHG	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
OHC	Occupational Health Clinic
OSP	Office of Science Policy
PI	Principal Investigator
PLP	Prion-Like Proteins
RDNA	Recombinant DNA
RG	Risk Group
TTX	Tetrodotoxin
VU	Vanderbilt University
VUMC	Vanderbilt University Medical Center
WCNDD	Warren Center for Neuroscience Drug Discovery