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

October 28, 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	
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	Vanderbilt University	Scientist, Developmental Biologist / recombinant DNA (RDNA) Delivery Expert	☒ Yes ☐ No	
Ethan Lippmann	Vanderbilt University	Scientist, Engineer / Drug Delivery and Stem Cell Expert	☒ 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	
Jeanne Wallace	VUMC	Alternate Animal Containment Expert	☐ Yes ☒ No	
William Wan	Vanderbilt University	Scientist, Biochemist / Molecular Biology and Virology Expert	☒ Yes ☐ No	

Non-voting members in attendance:

Name	Affiliation	Title
Andrea George	Vanderbilt University	Assistant Vice Chancellor, Environmental Health, Safety, and Sustainability (EHSS)
Kendra Hoffsmith	Vanderbilt University	Safety Officer, Biosafety, EHSS
Matt Loch	Vanderbilt University	Safety Officer, Biosafety, EHSS
Ryan McAllister	Vanderbilt University	Associate Director of Biosafety, EHSS
Katrina Ngo	Vanderbilt University	Safety Officer, Biosafety, EHSS
Selene Colon	Vanderbilt University	Assistant Dean for Research, Dean's Office, School of Medicine Basic Sciences

Name	Affiliation	Title
Greta Messer	Vanderbilt University	Associate General Counsel, Office of the General Counsel
Scott Bury	VUMC	Director of Office of Animal Welfare Assurance
Ana Nobis	VUMC	Medical Director, Occupational Health Clinic (OHC)
Venita White	VUMC	Infectious Disease Nursing Program Manager, OHC

Quorum

Per the Vanderbilt University IBC Charter, at least five voting members of the Committee must be present to conduct business. 11 voting members were present; therefore, 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 10:46 am.

The BSO introduced Dr. Ryan McAllister (Ph.D.), the new Associate Director of Biosafety; Ryan will serve as the BSO at future IBC meetings once he is added to the roster on file with the NIH Office of Science Policy (NIH OSP).

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 recombinant and synthetic nucleic acid research, 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 an Institutional Review Entity (IRE).

Minutes Review / Approval

The Chair opened the floor for comments and proposed revisions of the minutes of the September 23, 2025 meeting. The Committee voted to approve the minutes as presented with no changes.

Motion to approve the minutes: For: 11; Against: 0; Abstain: 0.

Biosafety Officer's Incident Report

The BSO summarized a potential RDNA exposure sustained by a staff researcher whose project involved the use of HEK293 immortalized human cell lines modified to over-express a G-protein coupled receptor (GPCR). These cells are stored in cryovials within a liquid nitrogen dewar. While removing the plastic vials, one 2.0 mL Nalgene plastic cryogenic tube ruptured, presumably from the rapid evaporation of liquid nitrogen that had seeped into the vial. A piece of the vial hit the staff researcher in the chin causing a break in the skin. At the time of the incident, the staff researcher was wearing fluid resistant nitrile gloves, cryogenic-protective gloves, and a body covering. The staff researcher let others present know what happened, proceeded to the sink to flush the affected area, and then reported to OHC for post-exposure medical evaluation.

VU Biosafety met with the staff researcher and the Principal Investigator (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 working with these cells, and followed all appropriate steps for post-exposure follow-up. However, the researcher was not wearing appropriate eye or face protection at the time of the incident. It was determined that the root cause of the event was the rupture of the plastic cryogenic vial, likely because of liquid nitrogen seeping into the vial when stored in the liquid phase of the dewar.

Based on this meeting, the BSO proposed recommendations to prevent future similar events. These included: (i) updating the lab's procedure to emphasize the importance of wearing adequate eye and face protection when

removing vials from the dewar, (ii) requiring the PI and all lab members to review and discuss the Cryogen Best Practices document which includes guidance regarding storing cells in the gaseous phase of liquid nitrogen dewars to minimize liquid nitrogen intrusion into vials, and (iii) VU Biosafety will highlight Cryogen best practices in the next annual refresher training (anticipated first quarter 2026). Because the potential exposure event included RDNA, the BSO reported the event to NIH OSP and is awaiting a response.

The Committee discussed the incident and the Committee Chair clarified that he and Dr. George reviewed the incident report before it was sent to the NIH. One Committee member commented on the importance of appropriate personal protective equipment (PPE) usage. 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: 11; Against: 0; Abstain: 0.

Biosafety Registration Reviews

VU-BMR	Review Type	PI	Department	Title
026	Renewal	Cortez, David	Biochemistry	*Mechanisms of Genome Stability*
Research Description (as stated by PI): The Cortez Lab studies the mechanisms by which cells replicate and repair their DNA. Approaches include biochemistry, genetics, and cell biology. These approaches utilize recombinant DNA, bacterial cell expression, and *in vitro* mammalian cell culture.				
Project Overview: This renewal registration includes cloning and expressing RDNA (fluorescent markers, and genes involved in eukaryotic replication and repair) in non-pathogenic *E. coli***.** Human-derived cells will be used in conjunction with retroviral vectors and third-generation lentiviral vectors to express genes of interest for downstream biochemical, genetic and cell biology experiments.				
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 retroviral vectors and lentiviral vectors. 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-D-3, 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 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: 11	Against: 0	Abstain: 0	

VU-BMR	Review Type	PI	Department	Title
001	Renewal	Gu, Guoqiang	Cell and Developmental Biology	*Endocrine Islet Production and Function in Diabetes*

Research Description (as stated by PI): The Gu Lab studies why endocrine islet beta cells fail in obese people causing diabetes. The lab obtains mouse and human islets, manipulates their DNA and mRNA, and tests how those manipulations affect beta-cell function in culture as well as in transplantation.

Project Overview: This renewal registration includes cloning and expressing RDNA (fluorescent markers and genes involved in beta cell function) in non-pathogenic *E. coli*. Mammalian cells, including human-derived cells, will be used in conjunction with expression plasmids and adenoviral and third-generation lentiviral vectors. Transgenic mice that express diphtheria receptors on islet cells and Cre-lox transgenic mice generated at the Vanderbilt Genome Editing Resource facility to control expression of GSTO1 or DDIT4L will be used by the lab for downstream phenotypic studies. Additionally, diphtheria toxin (DT) will be used for cell ablation experiments in transgenic animals, lentiviral vectors will be used to deliver short hairpin RNA (shRNA) affecting beta cell function, and normal or diabetic human pancreatic islets 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,* and modification of cultured rodent cell lines via transduction with an adenoviral vector. BSL-1 was also proposed for the creation and use of transgenic rodents. BSL-2 practices and containment were proposed for activities involving human-derived materials, including the generation and use of lentiviral vectors. BSL-2 was also proposed for the handling and administration of DT and human pancreatic islets 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 questioned whether new DT users would reach out to VU Biosafety for training and the BSO clarified that any new DT users would need to reach out to the Biosafety team to receive the appropriate training before being authorized to work with the toxin.

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-1, III-E-3, III-F-8 / Appendix C-II

Training: Biosafety 101: Standard Microbiological Practices (all researchers), Biosafety 201: BSL-2 Principles (HDM and toxin users only), Working Safely with Human-Derived Materials (HDM and toxin users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all researchers), 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: 11	Against: 0	Abstain: 0

VU-BMR	Review Type	PI	Department	Title
019	Renewal	Iverson, Tina	Pharmacology	*Biological Information Transfer*

Research Description (as stated by PI): Each cell in the body can respond to its local environment. Through this, individual cells can work together to appropriately respond to hormones or sensory stimuli. There are many ways that cells process information, which is often carried through proteins. At a more technical level, the methods of information transfer include (but are not limited to) processes called cellular signaling, transcriptional activation, glycobiology, chemotaxis, and enzyme catalysis. The Iverson Lab studies this information transfer. A common way that information is transferred by proteins is by having the protein change shape, with a specific shape associated with different types of information. The laboratory seeks to identify how the different shapes promote different cellular outcomes. The Iverson Lab uses structural techniques such as cryoEM, NMR, and X-ray crystallography to reveal the shapes of these proteins under different conditions, allowing them to infer how the information is coded.

Project Overview: This registration renewal includes the cloning and expression of genes involved in cell signaling and the transfer of biological information (which may originate from RG1 or RG2 organisms) in non-

pathogenic *E. coli* for use in downstream experiments, including expression in immortalized human cell lines for downstream analysis.

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 organisms in non-pathogenic *E. coli*. (The IBC may vote to lower containment for these experiments to BSL-1, per Section III-D-2-a of NIHG; see below for discussion). BSL-2 practices were also proposed for experiments involving 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.

During the discussion regarding experiments involving RG2 RDNA in non-pathogenic *E. coli*, the IBC determined that the genes of interest are highly unlikely to affect virulence or pathogenicity because the genes of interest are not virulence factors, are biologically incompatible with *E. coli*, and are not expressed as whole complexes. The BSO clarified with the IBC that this determination included the expression of the spike protein from SARS-CoV-2 and the IBC agreed that it did. The IBC was in agreement that this research can be conducted using BSL-1 practices. The IBC Chair inquired whether the lab would need to reach out to the IBC again if they express RG2 genes in human cells and the BSO clarified that they would not because they are already approved for similar BSL-2 activities.

Following the discussion, the IBC 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-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 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: 11	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 use of tissue samples from human patients and animal disease models for microscopy experiments. This modification also includes the use of bandages from patient wounds for analysis using fluorescence intensity staining. This registration modification does not include the use of RDNA.

Risk Assessment and Discussion: BSL-2 practices and containment were proposed for activities involving 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.

During the discussion, an IBC member noted that this work was similar to work previously approved for the lab. The BSO confirmed that the work is similar to previous approvals, but work with bandages from patient wounds poses an infectious agent risk that warranted bringing this modification to the IBC for review. Another IBC member inquired whether the samples from animal models were strictly from mice; the BSO confirmed that the animal samples used by the lab were only from mice.

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

NIHG Activity Categories: N/A

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 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: 11	Against: 0	Abstain: 0

VU-BMR	Review Type	PI	Department	Title
020	Renewal	Spiller, Benjamin	Pharmacology	*Antibody and Nanobody Discovery and Structure Determination*

Research Description (as stated by PI): The overall goal of the Spiller Lab is to use structural biology to understand immunology using recombinant DNA to express and purify proteins. These proteins are expressed in *E. coli* BL21, expiCHO, or expi293 cells strains and purified by chromatography. Purified proteins are studied with biochemical tools. The primary goal is structural studies by crystallography. There are two areas of current focus. The first is how does immune recognition of bacterial toxins and non-toxin antigens contribute to toxin neutralization and bacterial clearance, and how can this be used in vaccine design. The second is how do human IgE molecules cause allergy and alpha gal syndrome. For the second goal, the lab is focused on peanut allergens and alpha gal.

Project Overview: This renewal registration includes the cloning and expression of RG1 and RG2 genes of interest (antibodies and nanobodies) in non-pathogenic *E. coli* and mammalian, including human, cell lines for the expression and purification of proteins. The resultant proteins are used for downstream biochemical experiments. This renewal registration also includes the expression of four toxins from *C. difficile* and *C. perfringens* in strains of non-pathogenic *E. coli* and *Bacillus megaterium* for purification. These toxins are then transferred to a collaborating lab in VUMC for downstream analysis and experiments.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RG1 RDNA in non-pathogenic *E. coli* and rodent cell lines. BSL-2 practices and containment were recommended for experiments involving RDNA from RG2 organisms in non-pathogenic *E. coli*. (The IBC may vote to lower containment for these experiments to BSL-1, per Section III-D-2-a of NIHG; see below for

discussion). BSL-2 was also proposed for experiments involving the expression of toxins from RG2 agents in strains of non-pathogenic *E. coli* and *Bacillus megaterium*, and for experiments involving 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. During the discussion regarding experiments involving non-toxigenic RG2 RDNA in non-pathogenic *E. coli*, the IBC determined that the genes of interest are highly unlikely to affect virulence or pathogenicity because the genes of interest are not virulence factors and are biologically incompatible with *E. coli.* Therefore, the IBC was in agreement that this research can be conducted using BSL-1 practices. Following the discussion, the IBC voted to approve the registration at the biosafety levels proposed, including the lowering of containment to BSL-1 for activities involving the expression of non-toxigenic genes of interest from RG2 agents in non-pathogenic *E. coli*.			
NIHG Activity Categories: III-B, III-D-2-a / Appendix F-I, III-E, III-F-8 / Appendix C-II			
Training: Biosafety 101: Standard Microbiological Practices (all researchers), Biosafety 201: BSL-2 Principles (HDM and infectious agent users only), Working Safely with Human-Derived Materials (HDM and infectious agent users only), 2025 Biosafety Refresher for Vanderbilt Researchers (all researchers), 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: Benjamin Spiller declared a conflict of interest because this is his registration, so he was excused from the discussion and voting.			
Motion to approve registration	For: 10	Against: 0	Abstain: 0

Prior Business/Outstanding Actions

The BSO provided an update regarding the status of Dr. Vivian Gama's registration renewal, which was approved at the August IBC meeting with the condition that food and drink be stored and consumed outside of the laboratory. Dr. Gama has acknowledged the conditional approval, and all food/drink storage was removed from the lab space. Additionally, a door will be installed to physically separate a break area from the rest of the lab; installation is anticipated in November.

Administrative Reviews

Principal Investigator	VU BMR#	Administrative Amendment Summary
Burnette, Dylan	134 R1	Roster update; lab confirmed no changes associated with IACUC three-year review (M2100073).
Chen, Wenbiao	051 R2	Addition of transgenic rodents to IACUC protocol M2500047; roster update.
Constantinidis, Christos	086 R1	Roster update.
Lippmann, Ethan	105 R1	Roster update.
Locke, Andrea	089 R2	Addition of RG1 and RG2 bacterial agents similar to agents currently in use with previously approved protocols / activities (no RDNA); roster update.
O'Brien, Richard	194 R1	Addition of transgenic rodents to IACUC protocol M1600247.
Wikswo, John	034 R2	Space addition; roster update, including addition of Lisa McCawley as Co-PI.

Following discussion of the items on the administrative review table, the IBC voted to approve the administrative reviews as specified above. Ethan Lippmann and Lisa McCawley declared a conflict of interest because their registration, or the registration of a close collaborator, was in the table. As such, they did not vote.

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

New Business

Dr. McAllister updated the IBC on the NIH initiative to modernize biosafety. Dr. McAllister summarized 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 that of RDNA, decrease oversight for widely used low risk activities, and strengthen partnerships between the IBC and other institutional oversight bodies. The timeline for this initiative was also discussed including the listening sessions that are ongoing and the goal for the new guidelines to be implemented by fall 2026. Dr. McAllister and Dr. George shared their experience attending the first virtual listening session and summarized the main talking points of the public comments, which primarily included thoughts on expanding the scope of the NIH guidelines and increasing coordination and congruency with other regulatory agencies. Dr. George noted that VU Biosafety would notify the IBC when the date of the listening session for the Southeast region (region 2) is known.

Public Comments

There were no public comments.

Adjournment

The Chair adjourned the meeting at 11:43am. The next meeting of the IBC will be held via Zoom on November 11, 2025, at 10:45 am.