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

September 23, 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		
Kyle Becker	Vanderbilt University	Biosafety Officer	Xes 🗌 No	
Chin Chiang	Vanderbilt University	Scientist,	🛛 Yes 🗌 No	
		Developmental		
		Biologist / RDNA		
		Delivery Expert		
Abigail Holloway	Metro Nashville	Non-Affiliated	🛛 Yes 🗌 No	
	Public Health	Community Member		
Ethan Lippmann	Vanderbilt University	Scientist, Engineer /	🛛 Yes 🗌 No	
		Drug Delivery and		
		Stem Cell Expert		
Ryan Mason	Tennessee	Non-Affiliated	🛛 Yes 🗌 No	
	Department of Health	Community Member		
Lisa McCawley	Vanderbilt University	Scientist, Biologist /	☐ Yes ☐ No	Communicated
		RDNA and Risk		review of materials
		Assessment Expert		ahead of meeting
Jenny Schafer	Vanderbilt University	Scientist,	🛛 Yes 🗌 No	
		Microscopist / Core		
		Representative		
Katherine Shuster	Vanderbilt University	Animal Containment	🛛 Yes 🗌 No	
	Medical Center	Expert		
	(VUMC)			
Benjamin Spiller	Vanderbilt University	Scientist, Structural	☐ Yes 🏻 No	Communicated
		Biologist /		review of materials
		Microbiology and		ahead of meeting
		Toxin Expert		
William Wan	Vanderbilt University	Scientist, Biochemist	🛛 Yes 🗌 No	
		/ Molecular Biology		
		and Virology Expert		
Jeanne Wallace	VUMC	Alternate Animal	🗌 Yes 🔀 No	
		Containment Expert		

Non-voting members in attendance:

Name	Affiliation	Title
Scott Bury	VUMC	Director of Office of Animal Welfare Assurance
Selene Colon	Vanderbilt University	Assistant Dean for Research, Dean's Office, School of
		Medicine Basic Sciences
Greta Messer	Vanderbilt University	Associate General Counsel, Office of the General Counsel
Katrina Ngo	Vanderbilt University	Safety Officer, Biosafety, EHSS
Venita White	VUMC	Infectious Disease Nursing Program Manager,
		Occupational Health Clinic

Quorum

Per the Vanderbilt University IBC Charter, at least five voting members of the Committee 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 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 10:47 am.

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 August 26, 2025 meeting. The Committee voted to approve the minutes as presented with no changes.

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

Biosafety Officer's Incident Report

There were no incidents to report.

Biomaterials Registration Reviews

VU- BMR	Review Type	PI	Department	Title
015	Renewal	Chazin, Walter	Biochemistry	Structural and Functional Investigation of Proteins

Research Description (as stated by PI): The research in the Chazin Lab focuses on understanding the structural basis for recognition, biochemical function, and biological specificity of proteins and of macromolecular complexes composed of proteins, DNA, and small molecule inhibitors. The lab applies an integrated structural biology approach to investigate the innate immune response to pathogenic organisms, activation of receptors mediating inflammation, calcium regulation of cardiac ion channels, and DNA replication, damage response, and repair.

Project Overview: This renewal registration involves the cloning and expression of genes involved in genome maintenance, inflammation, and immune response mechanisms in non-pathogenic *E. coli* to produce proteins for downstream structural, biochemical and microscopy experiments. Previously modified human immortalized cell lines will also be used in DNA damage and repair 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-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 Committee, 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 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: 9 Against: 0 Abstain: 0

VU- BMR	Review Type	PI	Department	Title
014	Renewal	Graham, Todd	Biological Sciences	Research in Membrane Biology and Protein Trafficking

Research Description (as stated by PI): The Graham Laboratory uses molecular genetic approaches to study protein trafficking and membrane biogenesis. Genes of interest are cloned into shuttle vectors that can be replicated and expressed in *E. coli* or expressed in either *S. cerevisiae* or mammalian cell culture. The lab typically performs site-directed mutagenesis of the genes of interest to test structure/function hypotheses for the proteins encoded by the cloned genes. PCR products expressing fluorescent proteins or epitope tags are integrated into specific sites in the yeast genome in order to study the trafficking of specific proteins.

Project Overview: This registration renewal involves the cloning and propagation of genes of interest (fluorescent markers and P4-ATPases) in non-pathogenic *E. coli* for expression in *E. coli*, *S. cerevisiae*, and murine or human cell lines. The cell lines are modified via transfection of an expression plasmid and used in downstream microscopy, imaging, and biochemical studies.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving RDNA in non-pathogenic strains of *E. coli, S. cerevisiae*, and cultured rodent cell lines. BSL-2 practices and containment were 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, a Committee member highlighted the switch from single-use razor blades to a reusable plastic slicer for excising bands in agarose gels. The BSO clarified to the Committee that a plastic slicer is a plastic device with a handle that can cut through agarose gels but does not penetrate the skin.

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

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

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: 9 Against: 0 Abstain: 0

VU- BMR	Review Type	PI	Department	Title
006	Renewal	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 organisms, the lab also heterologously express 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, mutant versions of biosynthetic genes are expressed in heterologous hosts. Selections are performed on these hosts to determine which gene clusters produce larger quantities of the desired product, or to select for more active natural products. The lab also investigates the antimicrobial properties of human milk oligosaccharides.

Project Overview: This renewal registration includes the manipulation of plasmids in non-pathogenic *E. coli* and *Saccharomyces cerevisiae* and the knockout and expression of genes of interest (genes involved in natural product regulation/production) in several non-pathogenic bacterial species including *Lactococcus lactis* and several *Streptomyces spp.* This renewal registration also includes the use of modified and unmodified Group B Streptococcus (*S. agalactiae*) and unmodified *Pseudomonas aeruginosa, Candida albicans*, and *Staphylococcus aureus* for growth inhibition assays.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving non-pathogenic *E. coli, S. cerevisiae, L. lactis* and *Streptomyces spp.* (i.e., *S. albus, S. exfoliatus, S. flavochromogenes, S. globisporus, S. bicolor,* and *S. baarensis*). BSL-2 practices and containment are recommended for experiments involving RDNA from potential RG2 agents in non-pathogenic *E. coli.* (The Committee may vote to lower containment for these experiments to BSL-1, per Section III-D-2-a of NIHG). BSL-2 practices and containment are also recommended for activities involving modification, culturing, and use of *S. agalactiae*, and the culturing and use of unmodified *P. aeruginosa, C. albicans,* and *S. aureus*.

A lab inspection was not required as the lab was inspected earlier this year as part of a biomaterials registration modification risk assessment. 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 *L. lactis* and *Streptomyces spp.* included 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 of BSL-1.

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 they are homologous throughout many species, both pathogenic and non-pathogenic. Therefore, the Committee was in agreement that this research can be conducted using BSL-1 practices. Additionally, the BSO clarified that the Walker Lab would be preparing plasmids in *E. coli* to use in conjunction with baculoviral vectors and insect cells to produce proteins. However, the baculoviral and insect cell work will be done by a collaborator who has IBC approval for these activities. 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-E, III-F-8 / Appendices C-II and C-III

Training: Biosafety 101: Standard Microbiological Practices (all personnel), Biosafety 201: BSL-2 Principles (infectious agent users only), Working Safely with Human-Derived Materials (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 registrationFor: 9Against: 0Abstain: 0				

VU- BMR	Review Type	PI	Department	Title
021	Renewal	Castiglione, Gianni	021	Effect of Genetic Mutations in Vision, Aging, and Cancer

Research Description (as stated by PI): Research in the Castiglione Lab will investigate the genetic basis of human blindness, aging, and cancer. This will be done using biochemistry, molecular biology, and microscopy. This involves production of recombinant DNA (including viral vectors); the study of mammalian and avian cell lines; and analysis of human, murine, avian, and equine cells and tissues.

Project Overview: This registration renewal involves the cloning and propagation of fluorescent markers and genes related to vision and oxygen signaling in non-pathogenic *E. coli* for expression in cultured murine, equine, avian, and human-derived cell lines. Cell lines are modified via chemical transfection, or viral vectors (adeno-associated viral vectors [AAVs] or 3rd generation lentiviral vectors) for use in microscopy, molecular biology and biochemical experiments. The lab will also use a modified strain of *Saccharomyces cerevisiae* for high-throughput screening. Additionally, 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 non-pathogenic strains of *E. coli*, and the modification of cultured murine, equine, and avian cell lines via expression plasmids or via AAVs. BSL-1 was also proposed for activities involving modified *S. cerevisiae*. BSL-2 practices and containment were proposed for activities involving human-derived materials, including the generation of and modification by AAVs and lentiviral vectors. BSL-2 was also proposed for the administration of AAVs to research animals. 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-1, III-F-8 / Appendices C-II and C-III

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: 9	Against: 0	Abstain: 0
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VU- BMR	Review Type	PI	Department	Title
009	Renewal	Chiang, Chin	Cell and Developmental Biology	Regulatory Mechanisms of Cerebellar Development and Disease

Research Description (as stated by PI): The Chiang Lab is interested in the regulatory mechanisms that govern cerebellar development and diseases. The research focuses on the proliferation and differentiation of various neural progenitors in the context of normal development and brain cancer, specifically medulloblastoma. The goal is to utilize efficient systems, such as electroporation and lentiviral transduction,

to introduce gRNA or genes of interest into both normal and tumor cells, and to evaluate the effects of gene knockdown or overexpression on cell proliferation and differentiation.

Project Overview: This registration renewal involves the cloning and propagation of genes related to cerebellar development and disease in non-pathogenic K-12 strains of *E. coli* for expression in both murine and human-derived cell culture using expression plasmids and 3rd generation lentiviral vectors created by the lab. The resultant cell lines are used in downstream experiments. Additionally, genetically modified or unmodified human-derived cancer cells, and plasmids containing genes of interest will be administered to research animals for downstream phenotypic studies.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving RDNA in non-pathogenic strains of *E. coli*, and for the modification of cultured murine cell lines via expression plasmids. BSL-2 practices and containment were proposed for activities involving human-derived materials, including the generation and use of lentiviral vectors. BSL-1 was proposed for the administration of plasmids to research animals. BSL-2 was also proposed for the administration of human immortalized cell lines to research animals. 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 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 Principal Investigators (PI only).

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

Conflict of interest: Chin Chiang declared a conflict of interest because this is his registration, so he was excused from the discussion and voting.

Motion to approve registration For: 8 Against: 0 Abstain: 0

VU- BMR	Review Type	PI	Department	Title
017	Renewal	Wright, Chris	Cell and	Embryonic Development and Organogenesis
			Developmental	
			Biology	

Research Description (as stated by PI): The Wright Laboratory studies secreted intercellular signaling molecules or transcription factors that dictate cell fates in different parts of the embryo. The lab's main model system is the mouse, which allows for genetic analysis of function. The long-term goal is to provide insight into the molecular mechanisms responsible for the coordinate development of complex organ systems, with deep relevance to human congenital birth defects.

Project Overview: This registration renewal involves the cloning and propagation of fluorescent markers and genes related to intercellular signaling molecules or transcription factors that dictate cell fates in non-pathogenic *E. coli* for downstream genetic and biochemical studies. The lab will also culture previously modified rodent immortalized cells and create transgenic rodents for use in downstream experiments.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RDNA in non-pathogenic *E. coli*, the use of previously modified rodent immortalized cell lines, and the creation of transgenic rodents.

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 upcoming roster changes (lab members planning to leave the lab by the end of the year) and whether the lab would continue to have lab members with the appropriate Biosafety training required to handle the lab's biomaterials. The BSO clarified that the PI has taken the required biosafety coursework although he does not currently handle biomaterials in the lab.

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

NIHG Activity Categories: III-E, III-E-3, III-F-8 / Appendices C-I and C-II

Training: Biosafety 101: Standard Microbiological Practices (all researchers), 2025 Biosafety Refresher for Vanderbilt Researchers (all researchers), 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
022	Renewal	Schneider, Claus	Pharmacology	Biotransformations of Small Molecules In Vitro and In Vivo

Research Description (as stated by PI): The Schneider Lab analyzes the formation and biological activity of novel eicosanoids in human cells. For that, they isolate human leukocytes from peripheral blood from normal healthy volunteers. Leukocytes are incubated and extracted followed by mass spectrometric (MS) analysis. Human-derived cultured cells are also used for analyzing biological activity of the novel eicosanoids. The lab also uses mouse tissue, plasma, and urine in these analyses. Additionally, the lab analyzes the metabolism of endogenous bioactive lipids in normal healthy volunteers by collecting blood and urine samples, followed by extraction and MS analysis. Finally, the lab analyzes metabolism and biological activity of a dietary supplement in human and mouse derived cells and in mice *in vivo*.

Project Overview: This registration renewal involves the expression of plasmids that have been amplified in non-pathogenic *E. coli* to overexpress proteins related to novel eicosanoids in murine and human-derived cells for downstream analysis. This renewal registration also involves the use of human blood and urine from healthy individuals for analysis via mass spectrometry.

Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving RDNA in non-pathogenic strains of *E. coli*, and for the modification of cultured murine cell lines via expression plasmids. BSL-2 practices and containment were 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.

The Committee discussed the recommendation that the lab switches from glass Pasteur pipettes to plastic aspirating pipettes for work involving human cell lines. The lab provided a justification regarding their continued use of glass Pasteur pipettes only for certain procedures in which the plastic aspirating pipettes are too large for use in conjunction with the 96-well plates used in the assay.

Following the discussion, the Committee voted to approve the registration 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 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 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
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Prior Business/Outstanding Actions

The BSO provided an update regarding the status of Xiaoguang Dong's new registration that was first discussed at the July IBC meeting. The Committee had decided to table this registration and requested supporting documentation regarding the infectious status of the explant lung tissue to be received for proposed experiments. The PI has acknowledged the need for additional supporting information before review by the Committee. As of this time, the PI is waiting on information pertaining to the infectious nature of these tissues from the collaborator and has indicated that the work is not imminent. Because the work is not imminent, the Committee decided that there is no need to consider the registration any further. Instead, the investigator must reengage the committee and provide the requisite information for evaluation prior to making any effort to procure the tissues and initiate the work.

The BSO also provided an update regarding the status of 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. Currently, VU Biosafety is working with the School of Medicine – Basic Sciences Dean's Office and the PI to determine potential solutions. Another update will be provided at the October IBC meeting.

Administrative Reviews

Principal Investigator	VU BMR#	Administrative Amendment Summary
Claxton, Derek	057 R4	Addition of RDNA inserts for use with previously approved activities, roster update.
Lee, Ethan	037 R5	Roster update.
Robinson, Rene	082 R1	Roster update.
Roy, Krishnendu	131 R1	Roster update.
Wan, William	067 R3	Roster update.

Following discussion of the items on the administrative review table, the Committee voted to approve the administrative reviews as specified above. William Wan 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: 8; Against: 0; Abstain: 0.

New Business

The BSO proposed a hybrid meeting format for the December 2025 meeting to allow for the Committee members to meet the incoming BSO in person. The Committee completed a poll to indicate interest and ability to attend in person. At the October meeting, the Biosafety team will update the Committee on the specifics of the December meeting.

Public Comments

There were no public comments.

Adjournment

The Chair adjourned the meeting at 11:28 am. The next meeting of the IBC will be held via Zoom on October 28, 2025, at 10:45 am.