

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

November 11, 2025
10:45am to 11:55am
Virtual Meeting

Voting Members Present:

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

Non-voting members in attendance:

| Name | Affiliation | Title |
|------------------|-------------|--|
| Andrea George | VU | Assistant Vice Chancellor, Environmental Health, Safety, and Sustainability (EHSS) |
| Kendra Hoffsmith | VU | Safety Officer, Biosafety, EHSS |
| Matt Loch | VU | Safety Officer, Biosafety, EHSS |
| Ryan McAllister | VU | Associate Director of Biosafety, EHSS |

| | | |
|--------------|------|---|
| Selene Colon | VU | Assistant Dean for Research, Dean's Office, School of Medicine Basic Sciences |
| Greta Messer | VU | Associate General Counsel, Office of the General Counsel |
| Scott Bury | VUMC | Director of Office of Animal Welfare Assurance |
| Venita White | VUMC | Infectious Disease Nursing Program Manager, OHC |

Quorum

Per the VU IBC Charter, at least five voting members of the IBC must be present to conduct business. Eight 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.

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 10:48 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.

Minutes Review / Approval

The BSO informed the IBC of a clerical error from the August 2025 IBC meeting that resulted in the August 2025 IBC minutes reporting the incorrect IACUC protocol number for an administrative amendment. Following this explanation, the IBC voted to approve a correction of the August 2025 IBC minutes such that it includes the following statement: "A clerical error in the administrative update table originally listed IACUC protocol number: M2200070 instead of IACUC protocol number: M2200051. In the November 2025 IBC meeting, the IBC voted to amend the August 2025 IBC minutes to reflect the correct IACUC protocol number: M2200051 "

Motion to approve the August 2025 IBC minutes correction: For: 8 ; Against: 0; Abstain: 0.

The IBC Chair opened the floor for comments and proposed revisions to the minutes of the October 28, 2025 meeting. The IBC voted to approve the minutes as presented with no changes.

Motion to approve the October 2025 IBC minutes: For: 8; 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 |
|---|-------------|-----------------|---------------------------------------|--|
| 146 | Renewal | Guelcher, Scott | Chemical and Biomolecular Engineering | <i>Investigations in the Use of Polyurethane-Derived Biomaterial Grafts for the Aid of Bone and Soft Tissue Remodeling Processes</i> |
| <p>Research Description (as stated by PI): Novel polyurethane-derived biomaterials are being designed to heal bone and soft tissue defects, as well as investigate healthy and diseased states of bone tissue, bone marrow, and soft tissue sites. The cellular responses to these materials, including cytotoxicity, proliferation, and differentiation, are being investigated in 2D and 3D cell culture experiments and <i>in vivo</i> grafting experiments in rodent models.</p> | | | | |
| <p>Project Overview: This renewal registration includes the administration of murine cells modified to express fluorescent markers to mouse models of bone remodeling. The migration and proliferation of the administered cells are monitored via <i>in vivo</i> imaging and <i>ex vivo</i> sectioning. Unmodified human-derived cells will be used in downstream differentiation / proliferation and microscopy experiments.</p> | | | | |
| <p>Risk Assessment and Discussion: BSL-1 practices and containment were proposed for activities involving the culturing and use of modified murine cells, including administration to animal models. ABSL-1 containment was proposed for subsequent animal maintenance. BSL-2 practices and containment were proposed for activities involving human-derived materials.</p> <p>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.</p> <p>No questions or concerns were raised by the IBC, and the registration was approved at the biosafety levels proposed.</p> | | | | |
| <p>NIHG Activity Categories: III-D-4-a, III-F-8 / Appendix C-I</p> | | | | |
| <p>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).</p> <p>All required trainings are complete for all lab staff listed in the registration.</p> | | | | |
| <p>COI: No IBC members declared a conflict of interest.</p> | | | | |
| Motion to approve registration | | | For: 8 | Against: 0 Abstain: 0 |

| VU-BMR | Review Type | PI | Department | Title |
|---|--------------|-----------------|---------------------------------------|---|
| 105 R2 | Modification | Lippmann, Ethan | Chemical and Biomolecular Engineering | <i>Engineering and Regenerative Medicine Strategies to Model, Understand, and Treat Disease</i> |
| <p>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. These models are probed using recombinant DNA technology via techniques such as cloning, viral transduction, and CRISPR. We perform validation work in mouse brain slice cultures and in living mice using viral transduction. We also complement these validations using primary human tissue samples.</p> | | | | |
| <p>Project Overview: This registration modification involves two discrete projects:</p> | | | | |

1) Extracellular vesicles (EVs) will be isolated from human and mouse cell lines that were previously modified to express genes of interest (neuron differentiation genes or fluorescent markers) for administration to research animals for downstream phenotypic experiments.

2) The receipt of recombinant human alpha-synuclein pre-formed fibrils (a-syn PFFs) from an extramural collaborator outside of VU for the development of an *in vitro* neuronal cell-based assay.

Risk Assessment and Discussion: Assessment of project #1: BSL-1 practices and containment were proposed for activities involving the administration of EVs derived from modified murine cells to research animals. BSL-2 practices and containment were proposed for the administration of EVs derived from modified human cells to research animals. ABSL-1 containment was proposed for subsequent animal maintenance.

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 IBC verified that the facilities, 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 related to the proposed EV work, and that modification was approved at the biosafety levels proposed.

Assessment for project #2: BSL-2 containment was proposed for activities involving a-syn PFFs. During the presentation to the IBC, the BSO introduced a biosafety practices document related to the use of a-syn PFFs to the IBC with the request that the IBC provide feedback for the work requirements at a future IBC meeting. Additional discussion on this subject was tabled until a future IBC meeting to allow the PI to incorporate suggestions made by the IBC. Therefore, the IBC proceeded to entertain a motion on project #1 only.

NIHG Activity Categories: III-D-4-a

Training: Biosafety 101: Standard Microbiological Practices (all researchers), Biosafety 201: BSL-2 Principles (a-syn PFFs and HDM users only), Working Safely with Human-Derived Materials (a-syn PFFs and 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: Ethan Lippmann declared a conflict of interest because this is his registration, so he was excused from the discussion and voting.

Motion to approve Project 1: the modification to administer EVs to animal models

For: 7

Against: 0

Abstain: 0

| VU-BMR | Review Type | PI | Department | Title |
|---|--------------|---------------|------------------------|---|
| 089 | Modification | Locke, Andrea | Biomedical Engineering | <i>Locke Lab Optical Biosensing of Biospecimens</i> |
| <p>Research Description (as stated by PI): The Locke biosensing lab uses light to characterize and detect biomolecules such as bacteria, nucleic acid, proteins, lipids, carbohydrates, and other metabolites in human-derived biofluids and tissue specimens. The lab's overarching goal is to understand and design point-of-care tools to address current clinical challenges.</p> | | | | |
| <p>Project Overview: This registration modification involves the receipt, culture, and use of double/triple auxotrophic (ΔpanCD, ΔleuCD, and ΔmetA), drug-resistant (rifampin and/or isoniazid) strains of <i>Mycobacterium tuberculosis</i> (Mtb) (mc²6206, mc²8242, mc²8243, and mc²8251) (parent strain H37Rv) to assess the ability of the lab's detection platform to detect drug-resistant pathogens. Strains will be provided to the lab from an external collaborator.</p> | | | | |
| <p>Risk Assessment and Discussion: Per the NIH Guidelines BSL-3 practices and containment are recommended for experiments involving Mtb (parent strain H37Rv).. The strains the lab is proposing to work with are double auxotrophic for leucine and pantothenate (vitamin B5), or triple auxotrophic for leucine, pantothenate, and methionine. The collaborating lab that created these strains has published peer reviewed articles demonstrating that these strains lack the infectious ability of wild-type Mtb, specifically of the parental H37Rv strain.</p> <ul style="list-style-type: none"> Jain, P., Hsu, T., Arai, M., Biermann, K., Thaler, D. S., Nguyen, A., González, P. A., Tufariello, J. M., Kriakov, J., Chen, B., Larsen, M. H., Jacobs, W. R. (2014). Specialized transduction designed for precise high-throughput unmarked deletions in mycobacterium tuberculosis. <i>mBio</i>, 5(3). https://doi.org/10.1128/mbio.01245-14 Sambandamurthy, V. K., Wang, X., Chen, B., Russell, R. G., Derrick, S., Collins, F. M., Morris, S. L., Jacobs, W. R. (2002). A pantothenate auxotroph of mycobacterium tuberculosis is highly attenuated and protects mice against tuberculosis. <i>Nature Medicine</i>, 8(10), 1171–1174. https://doi.org/10.1038/nm765 Vilchèze, C., Copeland, J., Keiser, T. L., Weisbrod, T., Washington, J., Jain, P., Malek, A., Weinrick, B., Jacobs, W. R. (2018). Rational design of Biosafety Level 2-approved, multidrug-resistant strains of mycobacterium tuberculosis through nutrient auxotrophy. <i>mBio</i>, 9(3). https://doi.org/10.1128/mbio.00938-18 <p>Based on scientific literature and a risk assessment conducted alongside VU biosafety, the Locke Lab is proposing to work with these strains using BSL-2 practices and containment. This necessitates a request to be submitted to the NIH Office of Science Policy (OSP) for permission to lower containment from BSL-3 to BSL-2. The IBC may vote to approve lowering the containment from BSL-3 to BSL-2 based on the response from the NIH OSP at a future IBC meeting.</p> <p>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.</p> <p>During the discussion, an IBC member raised a concern that there could be false positive medical surveillance if a laboratory exposure occurred and a Mtb skin test is used. A second IBC member familiar with the OHC procedure for veterinary staff indicated that the more sensitive interferon-gamma release assay has replaced the Mtb skin test, which would not yield false positive medical surveillance for Mtb. After the IBC meeting a member of OHC confirmed that the interferon-gamma release assay is the standard test for researchers working with Mtb.</p> <p>Following the discussion, the IBC voted to endorse outreach to the NIH OSP to lower containment from BSL-3 to BSL-2 for these strains and work.</p> | | | | |
| <p>NIH Activity Categories: III-D-1-b</p> | | | | |
| <p>Training: Biosafety 101: Standard Microbiological Practices (all researchers), Biosafety 201: BSL-2 Principles (Infectious Agent users only), Working Safely with Human-Derived Materials (Infectious Agent users only),</p> | | | | |

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 endorse the containment lowering request from BSL-3 to BSL-2 for work involving the auxotrophic drug-resistant strains of <i>Mycobacterium tuberculosis</i> (parent strain H37Rv) | For: 8 | Against: 0 | Abstain: 0 |
|--|--------|------------|------------|

| VU-BMR | Review Type | PI | Department | Title |
|--------|-------------|---------------|--------------|--|
| 135 | New | Meers, Chance | Biochemistry | <i>Molecular Mechanisms of Mobile Genetic Elements</i> |

Research Description (as stated by PI): The Meers Lab focuses on mobile genetic elements, which are naturally occurring pieces of DNA that can move within genomes, including their biological roles and evolutionary impact. The lab studies the molecular mechanisms that determine when and where these elements move, as well as their long-term influence on genome evolution. Because many key cellular processes such as adaptive immunity, telomere maintenance, and splicing originated from mobile elements, future work will explore other host pathways shaped by them.

Project Overview: This new biomaterials registration includes the cloning and expression of genes of interest (transposases, nucleases, and helicases) in non-pathogenic *E. coli* and *S. cerevisiae* for use in downstream genetic, biochemical, and structural studies.

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

Representatives from the VU biosafety team consulted with the lab as part of the risk assessment and lab set up process and found that the procedures, practices, and expertise of personnel involved in this research were sufficient for the scope of work. VU biosafety will return to the lab within one year post-approval to review the lab spaces.

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 / Appendices C-II, C-III

Training: Biosafety 101: Standard Microbiological Practices (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: 8 | Against: 0 | Abstain: 0 |
|---------------------------------------|--------|------------|------------|

| VU-BMR | Review Type | PI | Department | Title |
|--------|-------------|----------------|-------------------------------------|--|
| 029 | Renewal | Neuert, Gregor | Molecular Physiology and Biophysics | <i>Signal Transduction and Gene Regulation in Eukaryotic Cells</i> |

Research Description (as stated by PI): Yeast strains are employed in the study of fundamental biological processes, particularly in signal transduction and gene regulation within single cells. These strains elucidate how cells perceive and respond to their environments over time, as well as how protein complexes regulate

| | | | |
|---|--------|------------|------------|
| various stages of gene expression. Mutant strains facilitate the linking of signaling pathways, gene expression, and viability phenotypes to specific proteins. In contrast, mammalian cells are utilized to investigate analogous questions and lncRNAs within these cells. <i>E. coli</i> strains serve as repositories and replicators of modified DNA sequences, which can subsequently be introduced into yeast strains. | | | |
| Project Overview: This registration renewal includes the cloning and expression of genes involved in signal transduction and gene regulation in non-pathogenic <i>E. coli</i> and <i>S. cerevisiae</i> for use in downstream genetic, biochemical, and structural studies. This registration renewal also includes the use of unmodified human cell lines for downstream gene expression experiments. | | | |
| Risk Assessment and Discussion: BSL-1 practices and containment were proposed for experiments involving RDNA in non-pathogenic <i>E. coli</i> and <i>S. cerevisiae</i> . 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 IBC, and the registration was approved at the biosafety levels proposed. | | | |
| NIHG Activity Categories: III-F-8 / Appendices C-II, 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 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: 8 | 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 of the NIH IBC registration roster update that designates him as the institutional BSO. The website to submit this change is currently unavailable, and hence, Kyle Becker remains as the official BSO for this meeting. The VU biosafety team will submit the NIH IBC registration roster update once the website becomes available.

Administrative Reviews

| Principal Investigator | VU BMR# | Administrative Amendment Summary |
|------------------------|---------|---|
| Barbara Fingleton | 167 R1 | Space and roster update. |
| Andrea Page-McCaw | 120 R1 | Roster update. |
| Fiona Yull | 177 R3 | Space and roster update; lab confirmed activities associated with IACUC three-year review (M2200070). |

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: 8; Against: 0; Abstain: 0.

New Business

The BSO reminded IBC members that the December IBC meeting will be a hybrid meeting and provided a location for those who are planning to attend in person.

The BSO discussed the dates for the 2026 IBC meetings so that Committee members could plan for the upcoming year.

Dr. McAllister proposed adjustments to the IBC Agenda. These adjustments include an approach for discussing non-NIH related topics and moving the “Prior business/Outstanding actions” section to after the “Administrative updates” section.

Public Comments

There were no public comments.

Adjournment

The Chair adjourned the meeting at 11:19am. The next meeting of the IBC will be held in person and via an internet-based video meeting platform on December 9, 2025, at 10:45 am.

List of Abbreviations

| | |
|----------------------|---|
| ABSL | Animal Biosafety Level |
| a-syn PFFs | alpha-synuclein pre-formed fibrils |
| BSL | Biosafety Level |
| BSO | Biosafety Officer |
| COI | Conflict of Interest |
| <i>E. coli</i> | <i>Escherichia coli</i> |
| EHSS | Environmental Health, Safety, and Sustainability |
| EV | Extracellular Vesicles |
| HDM | Human-Derived Materials |
| IACUC | Institutional Animal Care and Use Committee |
| IBC | Institutional Biosafety Committee |
| Mtb | <i>Mycobacterium tuberculosis</i> |
| 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 |
| RDNA | Recombinant DNA |
| RG | Risk Group |
| <i>S. cerevisiae</i> | <i>Saccharomyces cerevisiae</i> |
| VU | Vanderbilt University |
| VUMC | Vanderbilt University Medical Center |