

Vanderbilt University Medical Center
Institutional Biosafety Committee (MC IBC) Minutes
June 23, 2026
Virtual Meeting

Attendance

Voting Members (Quorum = 7 voting members)

- | | |
|---|---|
| ☐ Mark Boothby | ☐ Danyvid Olivares-Villagomez |
| ☒ Alexandra Elliott (BSO) | ☒ Ana Nobis |
| ☒ Iuliia Gilchuk | ☒ Jonathan Schmitz, Chair |
| ☐ Rachelle Johnson | ☒ Kate Shuster |
| ☒ Izumi Kaji | ☒ Cara Sutcliffe |
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| ☐ Julie Viruez | ☒ April Weissmiller |
| ☒ Paula Spitzler | |

Non-Voting Members & Guests

- | | | |
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| ☒ Rich DiTullio | ☒ Chris Svitek | ☒ Scott Bury |
| ☐ Maria Garner | ☒ Bettye Ridley | |
| ☒ Kevin Warren | | |

Call to Order/Introductions/Announcements

The May meeting was held virtually by an internet-based meeting platform. The meeting was called to order at 12:04pm.

Minutes Review/Approval

The Chair opened the floor for comments or proposed revisions of the minutes from the May 2026 meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Alexander, Matthew – Cardiovascular Medicine

TOPAZ Ref. # 100372 – Role of immune cells in the pathogenesis of hypertension (RENEWAL)

Lab Description (as stated by PI): We study the role of immune cells in hypertension, using cultured human and rodent cells, mouse models, and human immune cells. This enables a basic/translational approach to determine changes in immune cell function in hypertension that can potentially be targeted as new therapies for this condition.

Committee review: The lab purchases plasmids expressing genes of interest and expresses those genes in human-derived cell lines. The vectors are made in the lab. In addition to human cells, the lab obtains patient samples of blood for analysis.

In animal experiments, genetically modified murine cells harvested from transgenic mice will be administered to wild type mice.

BSL-2 practices and containment are recommended for rDNA work in human-derived cells including modification with plasmids. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-1 practices and containment are recommended for the experimental mice.

The Committee voted to approve the registration at the biosafety levels recommended with the condition that the registration is amended as directed by the reviewer.

NIHG activity category: III-D-4-a, III-E-1, III-F-8/Appendix C-VIII

Gohar, Eman – Nephrology

TOPAZ Ref. # 100231 V2 – Sex Differences in Renal Sodium Handling (MODIFICATION)

Lab Description (as stated by PI): The new biological material changes are intended for studies aimed at discovering an antibody therapeutic targeting G-protein coupled estrogen receptor 1 (GPER1). The added new biological materials to our protocol will be used in immunization studies in female GPER1 KO and WT mice aged 6-8 weeks old.

GPER1 mRNA-lipid nanoparticles (LNP) biological material for use in mice studies. The GPER1 mRNA-lipid nanoparticles peptide immunization will be conducted following the same timeline as the three KLH-conjugated GPER1 peptide antigens. On day 1, 10 ug (total) mRNA-LNP will be injected intramuscularly in 2 sites (5 ug in a volume of 50 ul per site). On day 21, the mice will be boosted with 10 ug (total) mRNA-LNP intramuscularly in 2 sites (5 ug in a volume of 50 ul per site). On day 42, the mice will be given a second booster using 10 ug (total) mRNA-LNP intramuscularly in 2 sites (5 ug in a volume of 50 ul per site). Test bleed (0.2 per mouse) will be collected from all mice for isolation of test sera on day 52. A final booster injection will be given intramuscularly on day 66. The final boost will be using 5 ug (total) of mRNA-LNP split as 2.5 ug in a volume of 50 ul per site. Three days post final booster injection, on day 69, all mice will be sacrificed, and spleens will be harvested for splenocytes isolation and subsequent antigen-specific B cell sorting using LIBRA-seq. If no sufficient antibodies are present based on ELISA with the test sera, a third booster will be given on day 55 with similar dosing and volume to the first and second booster injections.

Committee review: mRNAs in lipid nanoparticles will be administered to mice.

BSL-1 practices and containment are recommended for handling mRNA. ABSL-1 practices and containment are recommended for the experimental animals.

The Committee voted to approve the registration at the biosafety levels recommended

NIHG activity category: III-D-4-a

Kang, Jingqiong – Neurology

TOPAZ Ref. # 100369 – Towards Understanding the Pathophysiological Mechanisms and Developing Better Treatments for Epilepsy Associated with GABAA Receptor Mutations (RENEWAL)

Lab Description (as stated by PI): The Kang lab studies genetic epileptic epilepsies and epileptic encephalopathies (EE) involving GABAR gene and GAT-1 mutations. Some of the mutant genes have been shown to underlie genetic generalized epilepsies and to contribute to the causes of EE. We transfect human cDNAs of wild type and mutant GABAR subunits or GAT-1 into cell lines and into neurons dissociated from mouse brain. The functions of wild type and mutant receptors have been examined using confocal microscopy, western blot and biotinylation, electrophysiology, and flow cytometry. With collaborators at the University of Connecticut, we have made mouse models carrying GABAR and GAT-1 genetic mutations associated with epilepsy in patients. Our long goal is to seek possible treatments for patients by developing novel treatments in animal models.

Committee review: The lab propagates genes of interest in non-pathogenic E. coli and expresses them in murine and human derived cell culture via expression plasmids and adeno-associated viral vectors.

The lab used a toxin of biological origin as part of electrophysiology experiments. A Toxin Safety Plan has been submitted and reviewed.

In animal experiments, AAVs will be administered to mice.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic E. coli and handling AAVs. BSL-2 practice and containment are recommended for work with human-derived materials and toxins of biological origin. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. Personnel working with toxins should adhere to the practices of the Toxin Safety Plan. ABSL-1 practices and containment are recommended for the experimental animals.

The Committee voted to approve the registration at the recommended biosafety levels.

NIHG activity category: III-D-4-a, III-E-1, III-E-3, III-F-8/Appendix C-II, C-VIII

Levine, Edward – Vanderbilt Eye Institute

TOPAZ Ref. # 100368 – Retinal Development and Regeneration (RENEWAL)

Lab Description (as stated by PI): We use recombinant DNA to express gene products such as fluorescent reporter proteins, transcription factors, growth factor receptors, intracellular signaling molecules to understand the molecular, genetic, and cellular properties that underlie retinal development, regeneration, and disease. We also use genetically

modified mice that are commercially available.

Committee review: The lab propagates many genes of interest in non-pathogenic *E. coli* and expresses them in murine-derived cells using expression plasmids. The lab also breeds transgenic animals that are models of retinal disorders.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli* and murine cells.

The Committee voted to approve the registration at the biosafety levels recommended.

NIHG activity category: III-E-1, III-F-8/Appendix C-II, C-VIII

Linton, MacRae – Cardiovascular Medicine

TOPAZ Ref. # 100382 - Mechanisms of HDL Action on Lipoprotein Receptors and Effects on Atherosclerosis in Mice (RENEWAL)

Lab Description (as stated by PI): The study of macrophage contribution to atherosclerosis, as well as the underlying mechanisms of reverse cholesterol transport, atherosclerotic lesion formation, and cholesterol homeostasis.

Committee review: The lab purchases plasmids containing many genes of interest and expresses them in murine, and human-derived cells using expression plasmids. In addition to human cell culture, the lab obtains patient samples of blood and urine for analysis.

In animal experiments, modified murine cells will be administered to mice.

BSL-1 practices and containment are recommended for rDNA work in murine cells. BSL-2 practices and containment are recommended for work with human-derived materials. Personnel working with human-derived materials and lentiviral vectors should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-1 practices and containment are recommended for all experimental animals.

The Committee voted to approve the registration at the biosafety levels recommended.

NIHG activity category: III-D-4-a, III-E-3, III-E-1, III-F-8/Appendix C-I, C-VIII

Miller, Francis – Cardiovascular Medicine

TOPAZ Ref. # 100370 – Redox Biology of Cardiovascular Disease (RENEWAL)

Lab Description (as stated by PI): Studies examine the molecular mechanisms and potential therapies of cardiovascular diseases, focusing on the role of NADPH oxidases, redox-mediated signaling and circulating histone proteins. Experiments are performed in cultured cells and animal models of disease, including transgenic and KO mice from Jackson Labs.

Committee review: The lab uses purchased RNA aptamers and AAVs to modify human-derived cells.

In animal experiments, RNA aptamers or AAVs will be administered to mice, rats and pigs.

BSL-1 practices and containment are recommended for handling the RNA aptamers and AAVs. BSL-2 practices and containment are recommended for work with human-derived materials. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-1 practices and containment are recommended for all experimental animals.

The Committee voted to approve the registration at the biosafety levels recommended.

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

Rhoades, Julie – Heme/Onc

TOPAZ Ref. # 100378 – Investigating Mechanisms of Bone Disease (NEW)

Lab Description (as stated by PI): Our research goal is to find mechanisms of decreasing bone destruction and increasing bone formation in a variety of bone diseases. This research focuses on mechanisms to inhibit tumor growth in the bone and the vicious cycle of bone destruction, increase bone mass, reduce fractures, and reduce healing time when fractures occur. Our research utilizes cell lines (human and mouse) and primary stem cells in culture, mouse models of bone disease, and pharmacological inhibitors of signaling pathways important in bone disease.

Committee review: The lab propagates many genes of interest in non-pathogenic *E. coli* and expresses them in murine and human-derived cells using expression plasmids. In addition to cultured human cells, the lab obtains patient samples of tumor tissue extracted from bone.

In animal experiments, modified murine cells, modified human cells, or unmodified human cells will be administered to mice.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic E. coli and murine cells. BSL-2 practices and containment are recommended for work with human-derived materials. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-1 practices and containment are recommended for all experimental animals.

The Committee voted to approve the registration at the biosafety levels recommended.

NIHG activity category: III-D-4-a, III-E-3, III-E-1, III-F-1, III-F-8/Appendix C-II, C-VIII

Santisteban, Calvo, Monica – Clinical Pharmacology

TOPAZ Ref. # 100366 – Mechanisms of Hypertension Induced Cognitive Impairment (RENEWAL)

Lab Description (as stated by PI): Our research aims to investigate the mechanisms underlying hypertension induced cognitive impairment, focusing on cerebrovascular contributions. Genetically modified mice are used to investigate the molecular mechanisms underlying neurovascular dysfunction and cognitive decline, to specifically knockdown various genes in a cell-specific manner. To achieve cell-specific gene knockdown, mouse strains are purchased from Jax that carry either tamoxifen inducible Cre driven by cell specific promoters or floxed target genes. These mice are crossed to achieve floxflox Cre⁺ mice to achieve cell-specific gene deletion. No exogenous or viral vectors are utilized for this approach.

Human derived samples from the Vanderbilt Memory and Alzheimer's Center are processed in the lab depending on the space/scheduled availability of the VMAC project manager.

Committee review: The lab processes patient samples of blood and cerebrospinal fluid.

In animal experiments, transgenic mice are bred to create disease models.

BSL-2 practices and containment are recommended for work with human-derived materials. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-1 practices and containment are recommended for all experimental animals.

The Committee voted to approve the registration at the biosafety levels recommended.

NIHG activity category: III-F-8/Appendix C-II

Administrative Reviews / IBC Notification: The Chair opened the floor for comments on the administrative reviews. These reviews included:

Principal Investigator	VBMR#	Modification Summary
Barricarte, Ruben	100044 V2	Personnel updates; addition of human cells and lentiviral vectors like those already approved
Crowe, James	100309 V13	Personnel updates
Doran, Amanda	100303 V2	Personnel updates
Haake, Scott	100040 V3	Personnel updates and lab relocation; new lab space inspected on 6/11/2026
Holowatyj, Andreana	100276 V4	Personnel updates and lab relocation; new lab space inspected on 6/11/2026
Hurley, Paula	100352 V3	Personnel updates
Karagoz, Huseyin	100218 V3	IBC registration transferred from Wesley Thayer; Personnel updates
Kim, Tae Kon	100366 V2	Personnel update
Lacy, D. Borden	100371 V2	Personnel addition (ABSL-2)
Pua, Heather	100075 V2	Addition of RDNA in vitro and in vivo; previously approved for similar activities and materials.
Schoenecker, Jonathan	100237 V3	Additional of a new type of human derived material; previously approved for similar activities and materials.
Yan, Fang	100315 V3	Personnel update

The Committee approved the administrative updates as presented. Dr. Gilchuk declared a conflict of interest and was not present for the pre-vote discussion or vote.

The BSO announced that next month all IBC registered PIs will be entered in our online registration system. From this point forward, only the TOPAZ system will be used for IBC registration and processing.

Adjournment

The meeting was adjourned at 12:45 pm.