Vanderbilt University Medical Center
Institutional Biosafety Committee (MC IBC) Minutes
January 27, 2026
Virtual Meeting

Attendance

Voting Members (Quorum = 7 voting members)

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

Non-Voting Members & Guests

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

Call to Order/Introductions/Announcements

The January meeting was held virtually by an internet-based meeting platform. The meeting was called to order at 12:01pm.

Dr. DiTullio presented the BSO report for this month. In the first incident, a researcher was feeding a macaque monkey grapes. The monkey reached through a small open door of its enclosure and scratched the researcher's hand when reaching for a grape. Also, the researcher should have been wearing two pairs of gloves and was only wearing one at the time. In future, the door will remain closed when not in active use, forceps or a similar tool will be used to place grapes in the cage and double gloves will be worn going forward. The researcher has been evaluated for possible Herpes B exposure. This was not NIH reportable.

In the second incident, a researcher cut their left hand while cutting a piece of lung tissue with a scalpel. The researcher was using a scalpel in each hand to manipulate the tissue. In future, the researcher will use forceps to hold the tissue in place while cutting it with the scalpel. The researcher is being medically evaluated. This was not NIH reportable.

Minutes Review/Approval

The Chair opened the floor for comments or proposed revisions of the minutes from the December 16th meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Cahill, Katherine – Medicine
TOPAZ Ref. # 100325 – Mechanisms of respiratory tract inflammation in Asthma (RENEWAL)

Lab Description (as stated by PI): Our lab studies mechanisms of airway inflammation in asthma and chronic rhinosinusitis. We analyze cells and mediators in human biological fluids and tissues with and without asthma and chronic rhinosinusitis. These tissues include whole blood, serum, plasma, peripheral blood cells, urine, nasal fluid and cells and sputum fluid and cells.

Committee review: The lab analyzes samples of blood, tissue and other body fluids for biomarkers of disease. They also culture primary cells from them.

-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.

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

NIHG activity category: N/A, HDM risk only

Haase, Volker – Medicine

TOPAZ Ref. # 100341 – HIF Oxygen Sensing Pathway (RENEWAL)

Lab Description (as stated by PI): The Haase laboratory studies the HIF oxygen sensing pathway and uses mouse genetics, as well as biochemical and functional genomics approaches to define the specific roles of the von Hippel-Lindau (VHL) tumor suppressor, the oxygen-sensitive transcription factors HIF-1 and HIF-2 and the HIF prolyl-hydroxylase enzymes PHD-1, -2 and-3 in liver metabolism, acute and chronic hypoxic injury of the kidneys, as well as erythropoiesis and iron metabolism.

As key mediators of cellular oxygen homeostasis, the transcription factors Hypoxia-Inducible-Factors 1 and 2 (HIF-1 and HIF-2) facilitate both oxygen delivery and adaptation to oxygen deprivation by regulating the expression of gene products that are involved in cellular energy metabolism and glucose transport, angiogenesis, erythropoiesis and iron metabolism, apoptosis and cell proliferation. When cells experience hypoxia, HIF is stabilized and executes a transcriptional hypoxia response, or it interacts with other non-HIF proteins, enabling convergence of HIF oxygen sensing with other signaling pathways.

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. The lab also breeds transgenic mice that are hypoxia models.

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

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

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

Hurley, Paula – Medicine
***TOPAZ Ref. # 100335 – Prostate Cancer Research Laboratory* (RE*NEWAL*)**

Lab Description (as stated by PI): Our research focuses on the understanding of genetic variations in both non-tumorigenic and tumorigenic human prostate cells. Cell lines are purchased from ATCC, cultured using ATCC guidelines, and may be genetically modified. Primary cells are derived from patients and may be genetically modified. Genetic modifications include: Adeno-associated Virus (AAV), CRISPR system, lentivirus, and commercially available overexpression vectors. In the future, we may order commercially available siRNA or shRNA overexpression vectors.

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, adeno-associated viral vectors, retroviral vectors and 3rd generation lentiviral vectors. In addition to culturing human cells, the lab obtains samples of patient blood, tissue and other body fluids for analysis.

In animal experiments, modified murine 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*. BSL-2 practices and containment are recommended for work with human-derived cells. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy.

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

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

Hwang, Tae Hyun – Surgical Research
TOPAZ Ref. # 100343 – Investigating Early Disease Mechanisms in Gastric Cancer and Intracellular Kinetics of HER2-Targeted Therapeutics (RENEWAL)

Lab Description (as stated by PI): ur research program focuses on understanding early disease mechanisms in gastric cancer and elucidating intracellular processes associated with antibodydrug conjugates (ADCs). First, we will be using formalin fixed paraffin embedded (FFPE) gastric tissues from approved protocols to investigate early molecular transitions in hereditary diffuse gastric cancer (HDGC). Using spatial transcriptomics, proteomics, high-resolution imaging, and single-cell profiling, we characterize cellular changes from normal mucosa to early T1a lesions and advanced diffuse-type disease. All human biospecimens undergo standard clinical disease screening, including testing for HIV, HBV, and HCV, and no modifications are made to these tissues prior to analysis. In parallel, we study the intracellular kinetics and functional behavior of Enhertu (trastuzumab deruxtecan), a HER2-targeted ADC, using commercially sourced gastric cancer cell lines. Through correlative 3D holotomography and multichannel fluorescence imaging, we examine ADC internalization, lysosomal trafficking, GGFG linker cleavage, and payload-mediated DNA damage. These complementary approaches aim to generate mechanistic insights into early gastric cancer pathogenesis and ADC mode-of-action, ultimately supporting the development of improved biomarkers and next-generation targeted therapeutics.

Committee review: The lab cultures human cells derived from gastric cancers to analyze how anti-cancer agents work.

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

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

NIHG activity category: N/A, HDM risk only

Karijolich, John – PMI
***TOPAZ Ref. # 100336 – Host-Virus Interactions and Nucleic Acid Biology* (RE*NEWAL*)**

Lab Description (as stated by PI): Research in my laboratory is interested in the molecular biology of viruses and the host's response to infection. Our approaches include cell culture based functional assays to identify roles of noncoding RNAs and proteins that regulate viral gene expression and replication, characterize protein-protein and protein-RNA interactions, and microscopy for determining where these events take place.

Committee review: The lab propagates many genes of interest in non-pathogenic *E. coli* and expresses them in murine, hamster and human-derived cells using expression plasmids, retroviral vectors and 3rd generation lentiviral vectors. The lab also genetically modifies Risk Group 2 viruses.

Risk Group 1 and 2 viruses are propagated in human and NHP cell culture.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli*. BSL-2 practices and containment are recommended for work with Risk Group 2 virus, NHP cells and human-derived cells. Personnel working with human-derived materials and lentiviral vectors should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy.

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

NIHG activity category: III-D-1-a, III-D-2-a, III-D-3, III-E-1, III-F-8/Appendix C-II

Paria, Bibhash – Neonatology
***TOPAZ Ref. # 100323 – Aspects of Blastocyst Implantation* (RE*NEWAL*)**

Lab Description (as stated by PI): The goal of my research studies is to identify genetic regulatory networks involved in blastocyst implantation (attachment of the blastocyst to the uterus, uterine stromal cell decidualization, and placentation surrounding the implanted blastocyst following blastocyst implantation). To study the impact of E. coli and LPS at an embryo implantation site, we will use a three-step approach involving 1) analyzing genes by expression studies; 2) cell-specific localization of genes, and 3) upregulation and downregulation of genes and proteins, specifically inflammatory cytokines, using quantitative RT-PCR and immunoassay, respectively. Quantitative RT -PCR will help to confirm upregulation and downregulation of genes. Lumit immunoassay will help to determine the upregulation and downregulation of cytokine proteins at the embryo implantation site. No RDNA will be used for these studies.

Committee review: The lab propagates a Risk Group 2 strain of *E. coli*. This strain will be administered to mice and tissues and samples from those mice will be analyzed in the lab. Transgenic mice will be maintained for these experiments. The lab also cultured human cells for co-culture experiments with the bacteria.

BSL-2 practices and containment are recommended for work with Risk Group 2 bacteria and human-derived materials. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. ABSL-2 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-F-8/Appendix C-VIII

Wilson, Matthew – Nephrology
***TOPAZ Ref. # 100333 – Transposon Modification and Administration for Cell and Gene Therapy* (RE*NEWAL*)**

Lab Description (as stated by PI): We use transposons for cell and gene therapy applications. Transposons are cut-and-paste DNA elements which work in mammalian and human cells and integrate DNA into the genomes of cells. Transposons are plasmid based and contain the transposase enzyme, inverted repeat DNA sequences (necessary for gene transfer) and recombinant DNA containing the gene(s) of interest. Transposons are treated in the lab just as regular plasmids. They may be administered as regular plasmids or packaged in adeno-associated viral vectors. These are then delivered to human cells in culture and in animals (mice) in vivo.

We have two main projects. The first involves using long-lived antigen-specific T cells as a cell therapy of Fabry's disease. We perform gene transfer of an inducible transgene into human T cells and test them in culture. These modified human T cells are not put back into patients; we are only performing ex vivo testing at this point. We also gene modify mouse T cells to then test their ability to correct Fabry's disease in a mouse model.

Our other project involves delivery of transposons to mouse kidney directly for correction of a mouse model of cystinuria. In these experiments we will deliver a cystine transporter into proximal tubular cells in culture and in mouse kidney in vivo. This is administered as regular plasmids or packaged in adeno-associated viral vectors. We also deliver luciferase transgene for in vivo imaging to monitor for long-term expression and determination of cell type transfected. Non-human primate work. Periodically, the laboratory receives fresh macaque kidney tissue from a collaborator at an institution outside of VUMC. DNA is isolated from the tissue. Additionally, sometimes the tissue is digested, and individual cell types are isolated. A Macaque-Derived Materials Biosafety Procedures Summary is included in this registration.

Committee review: The lab propagates many genes of interest in non-pathogenic *E. coli* and expresses them in murine and human-derived cells using adeno-associated viral vectors. In addition to culturing human cells, the lab obtains samples of patient blood, tissue and other body fluids for analysis.

The lab cultures a Risk Group 2 virus (Epstein Barr). It is used to immortalize immune cells isolated from patient samples for future study.

The lab receives samples of kidneys from macaque monkeys. These samples are processed for DNA and cell isolation.

In animal experiments, modified murine cells, unmodified human cells, expression plasmids or adeno-associated viral vectors will be administered to mice.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli*. BSL-2 practices and containment are recommended for work with Risk Group 2 virus, macaque tissue and human-derived cells. Personnel working with human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. Personnel working with macaque-derived materials should adhere to the practices of the VUMC MDM in Basic Research Policy. 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-3-a, III-D-3, III-D-4-a, III-E-1, III-F-8/Appendix C-I, C-II, VIII

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

Principal Investigator	VBMR#	Modification Summary
Chen, Jin	100249 V2	New animal protocols (V2500056, V2500058), Previously approved for similar materials and activities, personnel updates
Crowe, Jim	100309 V9	New animal protocols (M2500059), Previously approved for similar materials and activities
Georgiev, Ivelin	100340 V2	Addition of new materials similar to those already approved, personnel updates
Kim, Tae Kon	0459 R8	New animal protocol (M2600001) submission; previously approved for similar materials and activities
Knollmann, Bjorn	100173 V5	Personnel updates
Kropski, Jonathan	0533 R7	Personnel update
Weiss, Vivian	100235 V6	Personnel update

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

Adjournment

The meeting was adjourned at 12:45 pm.