Vanderbilt University Medical Center
Institutional Biosafety Committee (MC IBC) Minutes
April 28, 2026
Virtual Meeting

Attendance

Voting Members (Quorum = 7 voting members)

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

Non-Voting Members & Guests

- ☒ Rich DiTullio
- ☒ Maria Garner
- ☒ Kevin Warren
- ☒ Chris Svitek
- ☒ Bettye Ridley
- ☒ Venita White

Call to Order/Introductions/Announcements

The April 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 March 2026 meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Chen, Limin – Radiology
TOPAZ Ref. # 100311 – Chemogenetics and optogenetics for ultrasound and MR imaging in nonhuman primates and rodents (RENEWAL)

Lab Description (as stated by PI): Commercially available viral vectors will be purchased or acquired from grant co-investigators or commercial resources for expression of designer receptors (for chemogenetics) and, in separate experiments, light-sensitive channels (for optogenetics) in the brain of nonhuman primates or rats. The viral vectors will not be altered and will be injected into the central nervous system of animals in the approved surgical room. Collection of blood, urine and tissue may occur, and samples may be analyzed outside the lab of the PI.

Committee review: The lab obtains commercially prepared adeno-associated viral vectors (AAVs) and administers them to non-human primates (NHPs), including macaques.

BSL-1 practices and containment are recommended for handling of AAVs. 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 biosafety levels recommended.

NIHG activity category: III-D-4-a, III-E-1

Collins, Shiela – Cardiovascular Medicine

TOPAZ Ref. # 100337 – Signaling mechanisms regulating adipocyte metabolism and gene expression (RENEWAL)

Lab Description (as stated by PI): The lab is interested in the biochemical mechanisms that regulate body weight and insulin sensitivity. Activation of the adrenaline receptors, specifically the members of the beta-adrenergic receptor (beta-AR) family, provides the major stimulus for the hydrolysis and release of stored lipids. They are also key drivers of a process called 'nonshivering thermogenesis' in brown fat. Brown fat cells are specialized cells rich in mitochondria and largely defined by their ability to express the mitochondrial uncoupling protein UCP1, which allows the dissipation of the proton gradient in the inner mitochondrial membrane to yield heat at the expense of ATP production. In addition to the beta-ARs, the cardiac natriuretic peptides also activate these same mechanisms through a parallel pathway in fat cells. By understanding their signal transduction properties and how they are regulated, Dr. Collins hopes to be able to find a way to increase energy expenditure in fat in the fight against obesity and the devastating diseases that accompany it, such as diabetes, cardiovascular disease, and hypertension. The experiments performed to understand this physiology involve cultured cell lines of mouse or human origin and we also introduce genes to be expressed in these cells to measure the promoter regulatory regions of specific proteins of interest.

Committee review: Genes of interest are propagated in non-pathogenic *E. coli* and expressed in murine and human cell culture using 3rd generation lentivral vectors. The lab produces these vectors.

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 materials and lentivral vectors. 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 biosafety levels recommended

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

Crowe, James – Vaccine Center
***TOPAZ Ref. # 100309 V11 – Human Immune Responses to Pathogenic Microorganisms and Their Products* (MODIFICATION)**

Amendment Description (as stated by PI): IBC amendment changes explanation for March 2026:
(1) Addition of Infectious Agents to Section 4.2.1.4.1.1
The following infectious agents will be added to section 4.2.1.4.1.1 for approved use in the BSL-3 laboratory:

(a) Andes Virus (ANDV), strain Chile-9717869
Research activities with ANDV will include:
-Growth in cell culture to produce workable virus stocks
-Virus titration using plaque assays and focus-forming assays
-Antibody neutralization assays, quantified via real-time cellular analysis and focus reduction
-Future studies may involve antibody discovery campaigns performed in the BSL-3 laboratory. This work will build on and expand data previously derived from experiments utilizing pseudotyped, non-authentic virus in the BSL-2 laboratory.

(b) Hantaan Virus (HTNV), strain 76-118
Research activities with HTNV will include:
-Growth in cell culture to produce workable virus stocks
-Virus titration using plaque assays and focus-forming assays
-Antibody neutralization assays, quantified via real-time cellular analysis and focus reduction
-Similar to ANDV, future work with HTNV may include antibody discovery campaigns conducted at BSL-3. These efforts will support and enhance data generated from pseudotyped virus experiments conducted at BSL-2.
(c) Sin Nombre Virus (SNV), strain SN 77734

Research activities with SNV will include:
-Growth in cell culture to produce workable virus stocks
-Virus titration using plaque assays and focus-forming assays
-Antibody neutralization assays, quantified via real-time cellular analysis and focus reduction
-As with ANDV and HTNV, future work with SNV may involve antibody discovery campaigns performed in the BSL-3 laboratory. This research will complement and expand findings from studies using pseudotyped, non-authentic virus at BSL-2.

(d) Administration of Binjari virus chimeras previously added to mice.

(2) Personnel Updates to Section 8.1

The following infectious agent will be added to section 4.2.1.4.1.1 for approved use in the BSL-3 laboratory:
The Boon lab at WUSTL will use β-Propiolactone (BPL) to inactivate Heartland virus. This compound is widely used as a viral inactivating agent.

Inactivation of pathogens by BPL is based on an irreversible alkylation of nucleic acids but also on acetylation and cross-linking between proteins, DNA or RNA. The Boon lab has shown this method to be effective for inactivation of bunyaviruses, including Heartland. Once they perfrom inactivation, data to validate the efficacy of inactivation will be sent to VUMC for review prior to authorixation to ship. These inactivated viral particles will be used to screen antibodies tageteing the Heartland virus.

-BSL-3 research capabilities will be assigned to select personnel as part of their updated training and clearance.

(3) Facility Updates to Section 8.3
A newly designated BSL-3 space will be added to the registry to reflect recent infrastructure enhancements.
This amendment supports our ongoing research efforts by enabling the use of authentic infectious agents in the BSL-3 laboratory and pseudotyped constructs in the BSL-2 laboratory, ensuring alignment with biosafety protocols, and expanding our research capacity in support of future scientific discoveries.

Committee review: This amendment adds the use of three Risk Group 3 hantavirus and the BSL-3 space where these viruses will be worked with. The BSL-3 space has been recertified, standard SOPs have been reviewed by OCRS, and the personnel that will work in the space have completed the first stage of BSL-3 training. The BSL-3 manager has years of experience working in this BSL-3 and no work with Risk Group 3 material will start until he certifies them for independent work.

In addition to that, the lab is adding animal experiments where previously approved chimeras of Binjari virus will be administered to mice.

The Committee discussed if there was enough risk of recombination between hantavirus variants to recommend procedures to prevent different viruses from being incubated together or worked with simultaneously. It was confirmed the lab tries to separate work with each virus to prevent cross contamination and that they have enough incubators to dedicate one to each virus.

BSL-3 practices and containment are recommended for the work with BSL-3 agents. ABSL-2 practices and containment are recommended for the experimental animals receiving the Binjari virus chimeras.

The Committee voted to approve the registration at the recommended biosafety levels. Dr. Gilchuk declared a Conflict of Interest and was not present for the pre-vote discussion or vote.

NIHG activity category: III-D-4-a

Kim, Tae Kon – Heme/Onc
TOPAZ Ref. # 100361 – Identifying the Mechanism of Immune Evasion in Cancers Including Leukemia (RENEWAL)

Lab Description (as stated by PI): Our lab studies the function of co-inhibitory molecules on leukemia cells. In order to carry out this research aim, we will engineer murine and human leukemia cell lines to overexpress or knock down co-inhibitory molecules using shRNA or CRISPR-Cas9 technologies and develop mouse leukemia models using retroviral transduction into mouse hematopoietic progenitors.

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, retroviral vectors, and 3rd generation lentiviral vectors. In addition to culturing human cells, the lab obtains samples of patient tissue and blood for analysis.

The lab uses a toxin of biological toxin as a tissue culture additive. Amounts used are below the amount that requires Select Agent registration.

In animal experiments, plasmids, modified murine cells, modified human cells or unmodified murine cells will be administered to mice. Some of these mice are humanized mouse 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 retroviral vectors, lentiviral vectors and 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. Personnel working with toxins of biological origin should adhere to the practices of the Toxin Safety Plan. ABSL-1 practices and containment are recommended for the experimental mice.

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

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

Mallal, Simon – Infectious Disease
TOPAZ Ref. # 100363 – Immunological Consequences of Self and Non-Self Recognition (RENEWAL)

Lab Description (as stated by PI): The rapidly changing clinical challenges presented by adverse drug reactions, infectious and autoimmune diseases have been the key drivers of the groups focus on translational aspects of personalized medicine. Our research group will apply a systems biology approach to conduct clinically relevant collaborative research involving large, diverse cohorts of patients with high burden diseases/infections and application of large-scale genetic sequencing and analysis, (including host HLA typing and SNP typing where relevant), genome-wide viral sequencing and RNA transcriptomics (example:10x genomics), immunological and cellular assays (example: Elispot assays). Using automated liquid handlers (Biomeks) and Laboratory Information Management systems (REDBRICKs), large-scale experiments will be performed to elucidate the functional characteristics of host-specific immunity directed against self and non-self-antigens.

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, retroviral vectors, and 2nd generation lentiviral vectors. In addition to culturing human cells, the lab obtains samples of patient tissue and blood for analysis.

The lab processes human samples containing Risk Group 2 and Risk Group 3 infectious agents. In addition the lab propagates a Risk Group 2 and Risk Group 3 virus in human or NHP tissue culture.

The lab uses a toxin of biological toxin as a tissue culture additive. Amounts used are below the amount that requires Select Agent registration.

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 agents, retroviral vectors, lentiviral vectors, non-human primate materials and 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. Personnel working with toxins of biological origin should adhere to the practices of the Toxin Safety Plan. BSL-2 practices with enhanced biosafety practices are recommended for work with select Risk Group 2 agents and the Risk Group 3 agents listed in the protocol.

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

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

Pozzi, Ambra – Nephrology
TOPAZ Ref. # 100358 – Analysis of Receptor Tyrosine Kinases in Kidney Disease (MODIFICATION)

Lab Description (as stated by PI): The goal of our research is to use animal and cell culture systems to define how receptor tyrosine kinases control fibrotic processes. To do this, we will use several techniques (e.g. ELISA, Western Blots, PCR, cloning, mutagenesis) to identify the signaling activated by receptor tyrosine kinases in eukaryotic cells. To do this we will use human and mouse eukaryotic cells, non-pathogen E. Coli for protein expression and plasmid amplifications, so that we can express and/or downregulate wild type and/or mutated receptors as well as their downstream signaling molecules. In addition, we will use mouse tissues, mouse plasma, mouse urine to identify biomarkers linked to a particular disease we study. Finally, we will use paraffin sections of human tissues from donors or subjects with disease to validate the findings obtained with cells and/or mouse systems.

NOTE for this Amendment: We intend to inject into nude mice human papillary renal cell carcinoma cells (pRCC) and follow their primary and metastatic growth over time. These cells (approved in this protocol) are UOK-112; UOK-274 and UOK-342. They will be injected either 'unmodified' or after they have been stably transfected with some of the plasmids approved in this protocol. The goal is to analyze their in vivo growth after proteins of interest have been either downregulated or upregulated using tools approved in this protocol.

Committee review: This amendment adds administration of genetically modified and unmodified human cells into mice.

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 the experimental mice.

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

NIHG activity category: III-D-4-a

Stein, C. Michael – Clinical Pharmacology
TOPAZ Ref. # 100350 – Handling of Human and Murine Biospecimens, Cells and Cell Lines (MODIFICATION)

Lab Description (as stated by PI): The overall research objective for the lab is to investigate mechanisms behind excess inflammation and accelerated cardiovascular disease in patients with rheumatoid arthritis and systemic lupus erythematosus. We use human plasma/ serum and isolate cells for isolation of DNA, RNA, proteins, and lipoproteins. We also use cell lines and primary human cells to test effects of various treatments, including treatment with synthetic small RNAs, purified bacterial extracellular vesicles and high-density lipoproteins. We also process and store human urine for measurement of biomarkers. Human microbiome specimens including stool, saliva and dental plaque are processed in the lab.

NOTE for this Amendment: We also conduct murine studies. These studies consist of testing the effect of small RNAs, purified bacterial extracellular vesicles, and dietary emulsifiers on a mouse model of rheumatoid arthritis. Live mice will not be in the laboratory space, but euthanized mice will. The protocols use recombinant DNA in that they use synthetic RNA oligonucleotides for mouse experiments, and synthetic RNA oligonucleotides and plasmid expression systems for in vitro experiments. The purified bacterial extracellular vesicles will be purified from human plasma or from culture of non-genetically modified bacteria (either grown in the lab or purchased commercially).
From Section 1.2.2.1 of Topaz: We are now including use of mice. This will include administering mice with synthetic oligonucleotides as well as bacterial extracellular vesicles purified from bacteria (not genetically modified) or from the blood of humans.

Committee review: This amendment adds the culturing of non-pathogenic *E. coli* and the obtaining of human blood samples for analysis.

In animal experiments, small synthetic RNAs 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 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 the experimental mice.

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

NIHG activity category: III-D-4-a, III-F-1

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

Principal Investigator	VBMR#	Modification Summary
Hadjifrangiskou, Maria	100317 V2	Addition of a previously approved RG2 agent to the PI's previously approved animal protocol (IACUC# M1800101-02)
Halasa, Natasha	100169 V6	Update to a lab room's research activities
Kaji, Izumi	100323 V5	Personnel updates
Kirschner, Austin	100113 V2	Addition of a RG2 agent and genetically modified murine cells to previously approved animal protocols (IACUC# M1700134-92 and M19000-02); previously approved for similar materials and research activities
Rosenthal, Eban	100290 V4	Personnel update
Schmitz, Jonathan	100116 V6	Personnel update
Watson, Robert	100232 V5	Personnel update
Weiss, Vivian	100235 V8	Addition of new IACUC protocol (M2600021) for human cells in animals and genetically modified murine cells in animals. Personnel updates. Previously approved for similar materials and activities.

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

Adjournment

The meeting was adjourned at 12:46 pm.