Vanderbilt University Medical Center
Institutional Biosafety Committee (MC IBC) Minutes
September 23, 2025
Virtual Meeting

Attendance

Voting Members (Quorum = 7 voting members)

- ☒ Mark Boothby
- ☒ Alexandra Elliott (BSO)
- ☒ Iuliia Gilchuk
- ☒ Izumi Kaji
- ☒ Rachelle Johnson
- ☒ Denis Mogilenko
- ☒ 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 September meeting was held virtually by an internet-based meeting platform. The meeting was called to order at 12:01pm.

The Chair announced that Dr. Mogilenko was stepping down as a Committee member due to his growing faculty commitments. The Committee thanked him for his service and Dr. Mogilenko stated that he hopes to rejoin the Committee in the future.

The BSO reported on three lab incidents. The first was a researcher that cut their hand on a broken coverslip left out by another lab member. The lab staff is being retrained in sharps disposal policies. The other two were animal bites sustained while trying to restrain animals. Both will undergo further training in animal restraint techniques before resuming work. None of the incidents were NIH reportable.

Minutes Review/Approval

The Chair opened the floor for comments or proposed revisions of the minutes from the August 26th meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Gamazon, Eric – Medicine
TOPAZ Ref. # 100292 – Functional characterization of disease-associated genetic variants (RENEWAL)

Lab Description (as stated by PI): Advanced computational analyses of large-omic datasets by our lab and others have yielded hundreds of new disease-associated genetic variants. Yet for many of these variants, little is known about their contributions to disease development and/or progression, hampering the ability to better predict individuals most at risk and develop more effective therapies. To address this issue, our lab will introduce disease-associated genetic variants into human or mouse cell lines using recombinant DNA-based methods. Mechanistic studies of these genetically modified mouse and human cells are expected to yield important insights into disease pathophysiology..

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them in murine and human-derived cells using expression plasmids, adeno-associated viral vectors, and 3rd generation lentiviral vectors to generate stable cell lines.

BSL-1 practices and containment are recommended for work with non-pathogenic *E. coli* and culturing murine cell lines. BSL-2 practices and containment are recommended for experiments with human-derived materials and lentiviral 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

Grueter, Brad – Anesthesiology

TOPAZ Ref. # 100271 – Investigation of neural circuits (RENEWAL)

Lab Description (as stated by PI): The Grueter lab utilizes viral mediated gene transfer in mice brains to study the neurocircuitry of reward. Tetrodotoxin is used in murine brain slices as a tool to investigate circuit function.

Committee review: The lab purchases ready-to-use adeno-associated viral vectors which are administered to mice. The lab also uses a toxin of biological origin (TTX) as part of electrophysiology experiments.

BSL-1 practices and containment are recommended for handling adeno-associated viral vectors. ABSL-1 practices and containment are recommended for the experimental animals. BSL-2 practices and containment are recommended for experiments with toxins of biological origin. Personnel working with lentiviral vectors and human-derived materials should adhere to the practices of the prepared Toxin Safety Plan.

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

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

Jan, Taha – Otolaryngology
***TOPAZ Ref. # 100309 – Inner Ear Development and Regeneration* (RE*NEWAL*)**

Lab Description (as stated by PI): We study the mammalian inner ear by answering fundamental questions of development and regeneration and performing translational research using mouse and in vitro disease models of hearing loss. Our research aims to transform the understanding of hearing loss and identify the mechanisms that can be targeted for diagnosis and treatment of patients suffering from hearing and balance impairment.

Committee review: The lab purchases adeno-associated viral vectors to express genes of interest in murine and human derived cells. The modified murine cells will be administered to mice.

In addition, the lab obtains samples of inner ear tissue from humans and macaques for analysis.

BSL-1 practices and containment are recommended for handling AAVs and culturing murine cells. BSL-2 practices and containment are recommended for experiments with human-derived materials and macaque-derived materials. 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 policies 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-I, III-F-8/Appendix C-I, C-VIII

Vickers, Kasey – Medicine

***TOPAZ Ref. # 100310 – Alternative Functions of Lipoproteins in Cardiometabolic Disease* (*RENEWAL*)**

Lab Description (as stated by PI): To investigate mechanisms and consequences of lipoprotein small RNA communication and systemic gene regulation. Short term goals include the characterization of small RNA regulatory modules controlling cholesterol, lipid homeostasis and cardiovascular inflammation. Moreover, we aim to determine i.) How small RNAs are selected and exported to lipoproteins, ii.) How small RNAs are transported on lipoproteins and altered in cardiometabolic disease, and iii.) How small RNAs are transferred to recipient cardiovascular disease related cells (e.g. macrophages, endothelial cells) and regulate genes related to cholesterol, lipid homeostasis and cardiovascular inflammation.
Some in vivo work will be done, using rodents injected with murine bone marrow and rodents injected with an adeno-associated viral vector (AAV).

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them in rodent, canine, human and insect cell culture using expression plasmids, adeno-associated viral vectors, adenoviral vectors, retroviral vectors and 3rd generation lentiviral vectors.

The lab obtains samples of serum from patients with active and suppressed HIV. Lipoproteins and small RNA are isolated from these samples for analysis. The lab performs similar analysis on samples of blood, plasma, urine, cerebrospinal fluid and synovial fluid from healthy patients.

In animal experiments, genetically modified murine cells, adeno-associated viral vectors or various antisense RNAs and miRNAs are administered to animals.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli*, rodent cells, canine cells and insect cells. BSL-2 practices and containment are recommended for experiments with adenoviral vectors, retroviral vectors, lentiviral vectors, patient samples containing HIV and other human-derived materials. Personnel working with HIV containing samples, lentiviral vectors and 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 animals receiving modified murine cells and RNA constructs.

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

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

Wanjalla, Celestine – Infectious Disease
TOPAZ Ref. # 100288 – The Role of Virus-Specific Immune Cells in Cardiovascular Disease Pathogenesis (RENEWAL)

Lab Description (as stated by PI): Persons with HIV (PWH/PLWH) on antiretroviral therapy have an increasing risk of mortality from cardiovascular disease that is likely multifactorial. Chronic inflammation due to co-infection with cytomegalovirus (CMV) alters the memory T cell repertoire and antibody responses and is likely important in the pathogenesis of cardiovascular disease. Our laboratory focuses on the role of CMV-specific immune cells in the progression of atherosclerotic disease in PWH/PLWH; to investigate newly discovered pathobiological mechanisms important to the onset of atherosclerotic cardiovascular disease and identify factors that account for differences in health among populations. Members of the lab will work with human samples from persons with HIV and controls. We will use a lab-adapted recombinant strain of CMV (strain 169 AD) and VSV-pseudotyped HIV. The CMV virus stocks will be cloned and harvested from fibroblast cell lines when we need to replenish used stocks. This work will be performed in Medical Center North A2116 BSL2+ space (CFAR). We will use a mouse model to understand the role of chemokine receptors in trafficking immune cells to the inflamed aorta. We plan to perform all the surgeries in the DAC facility, and will take human peripheral blood mononuclear cells and the aorta to the surgery room for surgical procedures.

Committee review: The lab propagates genes of interest, including those from Risk Group 2 and 3 agents, in non-pathogenic *E. coli* and expresses them in human-derived cells via 3rd generation lentiviral vectors.

The lab also propagates and genetically modifies Cytomegalovirus (CMV), a Risk Group 2 virus, and obtains samples of HIV from a collaborator.

The lab obtains blood samples from CMV positive patients and blood and tissue samples from HIV positive patients on viral suppression therapies. Most of these should be virus free but will be handled as though HIV is present.

The lab uses a toxin of biological origin (SEB) to induce cytokine productions in cells.

In animal experiments, human derived materials will be administered to recipient mice.

BSL-1 practices and containment are recommended for recombinant DNA work in non-pathogenic *E. coli*. BSL-2 practices and containment are recommended for cloning of genes from Risk Group 2 or 3 agents into non-pathogenic *E. coli*, experiments with Risk Group 2 agents, experiments with infected patient samples, experiments with lentiviral vectors and human-derived materials. Personnel working with HIV, lentiviral vectors and human-derived materials should adhere to the practices of the VUMC HDM/BBP in Basic Research Policy. BSL-2+ practices and containment are recommended for work with PBMCs from patients with HIV. ABSL-1 practices and containment are recommended for the experimental animals. Personnel working with toxins of biological origin should adhere to the practices of the Toxin Safety Plan.

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

NIHG activity category: III-D-2 III-D-3, III-D-4-a, III-E-1, III-E-3, III-F-8/ Appendix C-I, C-II, C-VIII

West, James – Medicine
TOPAZ Ref. # 100014 V4 – Pulmonary Vascular Biology (MODIFICATION)

Lab Description (as stated by PI): Our group studies the disease Pulmonary Arterial Hypertension. We use cell culture, mouse models, and patient samples. Our cell culture includes cells derived from patients and cells stably transfected with different reporters or mutations. Our mouse models are often newly created and incorporate recombinant DNA molecules designed to mimic patient mutations or report on activity of pathways of interest. However, the disease we study is not transmissible, and the mutations we are interested in are not tumorigenic.

Viral vectors (Adenoviral and Lentiviral) are used in cell culture to assess changes in metabolic activity and to aid in cell sorting, respectively.

Committee review: This modification adds the use of adenoviral and 3rd generation lentiviral vectors to express genes of interest in human-derived and rodent derived cells.

BSL-2 practices and containment are recommended for experiments with human-derived materials, adenoviral vectors and lentiviral 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

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

Principal Investigator	VBMR#	Modification Summary
Bratton, Benjamin	100166 V2	Personnel updates, addition of cell lines and RG2 agents; previously approved for similar materials and research activities
Choi, Eunyoung	100111 V2	Personnel updates
Crowe, James	100318 V3	Personnel updates
Freiberg, Jeffrey	100311 V3	Personnel updates
Georgiev, Ivelin	0292 R18	Personnel updates, addition of new lentiviral pseudovirus variants, previously approved for similar materials and research activities
Halasa, Natasha	100169 V4	Personnel updates and addition of CDC and USDA permits; previously approved for similar materials and research activities
Ikizler, Alp	100234 V6	Personnel updates
Kaji, Izumi	100323 V2	Personnel updates
Newcomb, Dawn	0308 R2	Addition of new animal cell line and two RG2 agents; previously approved for similar materials and research activities
Philip, Mary	100216 V3	Personnel Update
Rollins-Smith, Louise	100278 V2	Personnel Update
Weiss, Vivian	100235 V5	Personnel Update

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

Adjournment

The meeting was adjourned at 12:51 pm.