Vanderbilt University Medical Center
Institutional Biosafety Committee (MC IBC) Minutes
August 26, 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
- ☒ 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
- ☒ Scott Bury
- ☒ Rolinda Bailey
- ☒ Venita White

Call to Order/Introductions/Announcements

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

The Chair announced that Rolinda Bailey was stepping down as community member to enjoy her retirement. The Committee thanked her for her service and wished her well in her future endeavors. The Chair then introduced our new community member Dr. Julie Viruez. Dr. Viruez is a Safety Officer at the TN Department of Health with many years of bacteriology and public health experience. The Committee thanked her for joining the Committee and looks forward to working with her.

The BSO reported on a lab injury where a researcher was bit my a mouse while trying to administer a Risk Group 1 bacteria via oral gavage. The researcher will retrain in oral gavage techniques before resuming this work. The incident was not NIH reportable.

Minutes Review/Approval

The Chair opened the floor for comments or proposed revisions of the minutes from the July 22nd meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Hudson, Billy – Medicine
TOPAZ Ref. # 100302 – Biology and Pathology of Glomerular Basement Membrane (RENEWAL)

Lab Description (as stated by PI): We use tissue-derived and recombinant collagen IV to investigate its role in Alport syndrome (a genetic disease leading to kidney failure), Goodpasture's disease (a rare autoimmune disease affecting kidneys and lungs), and diabetic nephropathy. We produce and use recombinant antibodies for studying autoimmune responses. We use urine-derived and recombinant uromodulin to investigate its role in genetic inherited kidney diseases. We use recombinant collagen fragments and collagen-binding proteins for diagnostics and therapeutic studies. The studies are focused on deciphering mechanisms of kidney diseases and development of novel diagnostics and therapies.

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them in hamster and human-derived cells using expression plasmids to generate stable cell lines. In addition to human cells, the lab obtains patient samples of blood and tissue for analysis.

BSL-1 practices and containment are recommended for work with non-pathogenic *E. coli* and culturing hamster cell lines. BSL-2 practices and containment are recommended for experiments with human-derived materials including genetic modification with plasmids. 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-I,C-II

Roden, Dan – Clinical Pharmacology

TOPAZ Ref. # 100301 – Functional Genomics of Cardiac Ion Channels (RENEWAL)

Lab Description (as stated by PI): Our research is directed at elucidating mechanisms underlying abnormalities of cardiac rhythm and mechanisms underlying variable responses to antiarrhythmic drug treatments. To accomplish our aims, we will be using cells transfected with plasmids and cardiomyocytes derived from pluripotent stem cells to look at differences in ion channel expression and function in the presence or absence of specific drugs and small molecules. Westerns, RNA seq, real time assays, immunoprecipitation, immunostaining, and electrophysiology experiments will be used to profile the variability in protein and gene expression of ion channels.

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them human-derived and hamster-derived cell lines using 2nd generation lentiviral vectors. The viral vectors are made in the lab. In addition to culturing human cells, the lab obtains patient samples of blood for analysis

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli* and hamster cells. BSL-2 practices and containment are recommended for experiments with human-derived materials and lentiviral vectors. Personnel working with lentiviral vectors and 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.

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

Stier, Matthew – Allergy, Pulmonary and Critical Care Medicine
***TOPAZ Ref. # 100306 – Immunologic and Metabolic Dysfunction in Human Sepsis and Critical Illness* (*NEW*)**

Lab Description (as stated by PI): Our research program focuses on understanding immunologic and metabolic dysfunction in human sepsis and critical illness. We use primary human biospecimens—including blood-derived components such as peripheral blood mononuclear cells, plasma, and serum—from critically ill patients and healthy controls. We also work with established human cell lines, including endothelial cells, to model immunometabolic and host-pathogen interactions. Experimental work includes functional, molecular, and metabolic assays performed under standard biosafety level 2 (BSL-2) conditions. Select studies may involve the use of lentiviral vectors for genetic manipulation of human primary cells or cell lines; these procedures involve recombinant nucleic acid technology and are conducted in accordance with NIH Guidelines. All human samples are de-identified and collected under IRB-approved protocols. The overarching goal of our work is to define the mechanisms of immune and metabolic dysregulation in sepsis and to identify new therapeutic strategies to improve outcomes in critical illness.

Committee review: The lab purchases 3rd generation lentiviral vectors to express genes of interest in human derived cells. In addition, the lab obtains samples of blood from septic patients. The blood is assumed to contain infectious agents common to sepsis patients and will be handled accordingly.

BSL-2 practices and containment are recommended for experiments with specimens from sepsis patients, 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-b, III-F-8/Appendix C-I

Van Kaer, Luc – Pathology, Microbiology & Immunology

***TOPAZ Ref. # 100303 – Innate and Innate-like Lymphocytes in Health and Disease* (*RENEWAL*)**

Lab Description (as stated by PI): Our research focuses on the functions of a subset of white blood cells that regulate immune responses. These cell types, referred to as innate and innate-like lymphocytes, have substantial potential for therapeutic targeting in a variety of diseases. Our studies are aimed at investigating the roles of these cells in mouse models of disease, including infections and autoimmune diseases. Some of our studies involve mouse or human cell lines, genetically engineered mice, disease models that involve non-select agent biological toxins, and we are also planning some experiments with de-identified human-derived samples.

Committee review: The lab expresses genes of interest in murine cell culture using 3rd generation lentiviral vectors. The lab also cultures human-derived cells and obtains patient samples of blood and cardiac tissue for analysis.

The lab cultures a Risk Group 2 strain of influenza virus using canine cell culture. This virus is administered to animals and samples from those animals are analyzed to determine the immune response.

In other animal experiments, genetically modified murine cells are administered to animals.

BSL-1 practices and containment are recommended for culturing murine cells. BSL-2 practices and containment are recommended for experiments with Risk Group 2 agents, lentiviral vectors, and human-derived materials. Personnel working with 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. ABSL-2 practices and containment are recommended for the animals receiving virus.

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

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

Ward, Nicole – Dermatology
***TOPAZ Ref. # 100300 – Understanding the Pathogenesis of Chronic Inflammatory Skin Disease and Systemic Co-Morbidities.* (*RENEWAL*)**

Lab Description (as stated by PI): Our lab utilizes a mouse molecular genetics approach to test hypotheses about the cause and effect of different genes to inflammatory skin phenotypes and how the skin-contained inflammation leads to systemic inflammation that damages distant organs. We engineer and use transgenic and knockout mice to study these scientific hypotheses. Skin cells interacts with skin-resident and circulating immune cells to elicit sustained inflammatory responses. To study these interactions, we mate different genetically modified mice with each other and transplant transgenic cells (isolated from syngeneic knockout or transgenic mice) into our inflammatory skin diseased mice to better understand the interactions that occur between skin-derived factors and circulating immune cells that are responsible for the inflammatory phenotypes. We also use topically applied siRNA to selectively deplete genes of interest in our models. Additionally, we create lentiviral constructs to overexpress and knock out three genes of interest in human skin cells and mouse fibroblasts. This work is only conducted in vitro, using mouse and human cell lines. Finally, we receive human patient samples and work with human cell lines.

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them in murine and human-derived cells via expression plasmids, retroviral vectors and 3rd generation lentiviral vectors. In addition to human cells, the lab obtains samples patient blood and tissues for analysis.

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

BSL-1 practices and containment are recommended for culturing murine cells and recombinant DNA work in non-pathogenic *E. coli*. BSL-2 practices and containment are recommended for experiments with retroviral vectors, lentiviral vectors and human-derived materials. Personnel working with 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 experimental animals.

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

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

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

Principal Investigator	VBMR#	Modification Summary
Crowe, James	100309 V5	Addition of new agents similar to those already approved.
Haas, David	100275 V6	New CDC import permit
Holowatyj, Andreana	100276 V3	Personnel update
Kim, Tae Kon	0459 R7	New animal protocol (IACUC# M250040) submission; previously approved for similar materials and activities
Kirabo, Annet	100136 V8	Personnel update and new animal protocol (IACUC# M1800059), previously approved for similar materials and activities
Knollmann, Bjorn	100173 V3	Personnel updates
Lacy, D. Borden	0021 R7	Personnel updates, including ABSL2 work and UGIAPP form submission; previously approved for similar materials and activities
Patel, Mayur	100257 V8	Personnel Update
Philip, Mary	100216 V2	Personnel Update
Schoenecker, Jonathan	100237 V2	Personnel Update
Skaar, Eric	0294 R18	New routes of administration in an animal model (M2300091); Previously approved for similar materials and activities on this protocol. Personnel updates, including ABSL2 work.
Thayer, Wesley	100171 V2	New animal infection model with a RG1 agent; Personnel update.
Zhu, Wenhan	0471 R7	Addition of new RG2 Agent to M2300019; Previously approved for similar materials and activities on this protocol.

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.

Other Business

Updates on previous reviews requiring PI action

At the July meeting the Committee voted that the mouse experiments using a colonoscope should be performed under ABSL-2 and that the approval was contingent on their personnel getting trained for ABSL-2 work. Dr. Coffey reported that those experiments are no longer being done and will be removed from the registration. The Committee agreed that the approval could go forward once the registration is updated.

High Risk Agent Policy Document: Vote

Prior to this meeting a draft update of the IBC High Risk Agent Policy Document was sent to the Committee for review. The update simplified our procedures for labs wanting to obtain inactivated samples of high risk organisms and detailed the information about the inactivation and validation processes that needed to be sent to OCRS Biosafety for review prior to receipt of these samples. Biosafety would inform the IBC about these requests and bring any that required further discussion to meeting for review. The Committee voted to approve the updated policy.

Adjournment

The meeting was adjourned at 12:55 pm.