Vanderbilt University Medical Center Institutional Biosafety Committee (MC IBC) Minutes June 24, 2025 Virtual Meeting

Attendance

oting Members (Quorum = 7 voting mer	mbers)	
☐ Mark Boothby	☐ Danyvid Olivares-Villagomez	
⊠ Alexandra Elliott (BSO)	☑ Ana Nobis	
☐ Iuliia Gilchuk	☑ Jonathan Schmitz, Chair	
☐ Izumi Kaji		
⊠ Rachelle Johnson	⊠ Cara Sutcliffe	
☐ Denis Mogilenko		
☐ Rolinda Bailey		
☐ Paula Spitzler		
Non-Voting Members & Guests		
⊠ Rich DiTullio	☐ Venita White	
	Scott Bury	
⊠ Kevin Warren		
Call to Order/Introductions/Anne	ouncements	
The June meeting was held virtually b 12:01pm.	y an internet-based meeting platform. The meeting was called to order at	
The BSO informed the Committee of tune 2025 minutes.	the new NIH directive to publish minutes on a public website starting with the	

Minutes Review/Approval

The Chair opened the floor for comments or proposed revisions of the minutes from the May 27th meeting. The Committee voted to approve the minutes as presented.

Protocol Reviews

Gonzalez-Hunt, Claudia- Genetic Medicine

TOPAZ Ref. # 100291 - The role of genome integrity in disease pathogenesis (NEW)

Lab Description (as stated by PI): The Gonzalez-Hunt laboratory investigates how loss of genome integrity contributes to disease pathogenesis. We primarily work in neurodegenerative diseases such as Parkinson's disease, where our work has found that there is a dysregulation of the DNA damage response and accumulation of DNA damage in monogenic models of disease. We aim to understand how disease-associated proteins regulate the DNA damage response and lead to DNA damage, and how this loss of genome integrity contributes to neurodegeneration. Additionally, we investigate how mutations in proteins associated with neurodegenerative disease (such as LRRK2) may also contribute to DNA damage and mutagenesis in cancer. Our laboratory is also interested in understanding how DNA repair in post-mitotic neurons differs from DNA repair in cycling cells, and how these differences contribute to selective neuronal cell death as observed in neurodegenerative diseases.

Committee review: The lab cultures human-derived cells and genetically modifies them using expression plasmids to generate stable cell lines. The lab also breeds transgenic animals that are disease models.

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. ABSL-1 containment is recommended for the transgenic animals.

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

NIHG activity category: III-E-1, III-E-3, III-F-8/Appendix VIII

Hadjifrangiskou, Maria - PMI

TOPAZ Ref. # 100263 – Pathogenesis of Urinary Tract Infections and Bacterial Adherence/Multicellular Behavior (RENEWAL)

Lab Description (as stated by PI): The research in the Hadjifrangiskou laboratory focuses on understanding regulatory mechanisms that underlie multicellular behavior and virulence in bacteria that cause urinary tract infections (UTI). The bacterial uropathogen we focus on the most is uropathogenic E. coli (UPEC), which accounts for the majority of community- and hospital-acquired UTIs worldwide. We are interested in infection dynamics of UPEC in the context of community-acquired infections as well as in specialized populations, such as catheterized individuals and diabetics. We study how E. coli intercept and transduce nutrient and other signals during biofilm formation and infection. Along these studies we investigate the properties of adhesive fibers on biotic and abiotic surfaces and investigate their contribution of biofilm infrastructure. Our approaches include bacterial mutagenesis, in vitro functional assays (to study bacterial signaling network interactions and adherence), microscopy and murine models of acute, chronic and catheter-associated UTI. Other uropathogens we study are Klebsiella pneumoniae, Pseudomonas aeruginosa, as well as members of the urinary microbiome, Lactobacillus and Actinotiqnum schaalii.

Committee review: The lab propagates genes of interest, including genes from Risk Group 2 agents, in non-pathogenic *E. coli* and expresses them in Risk Group 1 bacteria (*Lactobacillus* sp.) and Risk Group 2 bacteria (*Actinotignum schaalii, Klebsiella pneumoniae, P. aeruginosa, UPEC and EHEC*). The lab also cultures other species of Risk Group 2 bacteria (*H. pylori and S. typhimurium*). The lab also cultures human-derived cells for co-culture experiments with the bacteria.

The lab obtains patient samples of human urine to analyze the microorganisms present in the sample.

In animal experiments, modified or unmodified Risk Group 2 bacteria (*UPEC, P. aeruginosa*) 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 experiments with human-derived materials and Risk Group 2 bacteria including genetic modification of the bacteria with expression plasmids. 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 animals receiving Risk Group 2 agents.

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

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

Lannigan, Deborah - PMI

TOPAZ Ref. # 100274 - Identification of Novel Therapeutic Targets (RENEWAL)

Lab Description (as stated by PI): The focus of our research is on identifying novel therapeutic opportunities using the RSK1/2 inhibitor that we are developing. We use techniques encompassing modern molecular biology, biochemistry and cell biology in appropriate model systems to achieve our aims.

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses them in insect cells using baculoviral vectors and in human and murine cell culture using expression plasmids and 2nd and 3rd generation lentiviral vectors. The lentiviral vectors are made in the lab. In addition, the lab obtains samples of patient breast tissue to isolate cells for primary cell culture.

In animal experiments, modified human and murine cells or unmodified human breast tissue will be administered to animals as part of a cancer model.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli* and insect cells. 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. 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-3-b, III-D-4-a, III-E-1, III-F-8/Appendix C-I, C-II

Peck, Sun – Clinical Pharmacology

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TOPAZ Ref. # 100284 – Cell Signaling in Mesenchymal Stem Cell Differentiation in Musculoskeletal Tissue Formation (RENEWAL)

Lab Description (as stated by PI): We study the effects of cell signaling induced by growth factors and other small molecules on the differentiation of mesenchymal stem cells, which are the progenitor cells for many musculoskeletal tissues. We treat human mesenchymal stem cells under various differentiation culture conditions (adipogenic, chondrogenic, and osteogenic), with and without the addition of proteins and drugs and investigate changes to cell differentiation using gene expression measurements, protein expression measurements, histology, and immunohistochemistry.

Committee review: The lab cultures human-derived cells for biomarker analysis and microscopy.

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

Peek. Richard - GI Medicine

TOPAZ Ref. # 100282 – Helicobacter pylori and Gastric Diseases (RENEWAL)

Lab Description (as stated by PI): Gastric adenocarcinoma is the leading infection-associated cancer and third most common cause of global cancer mortality. Helicobacter pylori is the agent associated with gastric carcinogenesis and, therefore, we use clinical and laboratory isolates of H. pylori for in vitro and in vivo to study this association.

Committee review: The lab propagates genes of interest in non-pathogenic *E. coli* and expresses those genes in human-derived cell culture using expression plasmids or 3rd generation lentiviral vectors or in *H. pylori* (Risk Group 2) using expression plasmids. The lentiviral vectors are purchased from a vendor. In addition to cultured human cells, the lab obtains samples of human serum and stomach tissue from healthy and *H. pylori* infected patients for analysis.

The lab cultures Risk Group 2 bacteria: H. pylori, H. felis, C. acnes, S. epidermidis, S. salivarius.

In animal experiments, wild-type or genetically modified *H. pylori* will be administered to transgenic mice or gerbils.

BSL-1 practices and containment are recommended for rDNA work in non-pathogenic *E. coli*. BSL-2 practices and containment are recommended for experiments with Risk Group 2 agents, 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. ABSL-2 practices and containment are recommended for the experimental and transgenic animals.

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

NIHG activity category: III-D-1-a, III-D-2-a, III-D-3, III-D-4-a, III-E-3, III-F-8/ Appendix 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 V3	Personnel update; addition of new virus similar to those previously approved
Freiberg, Jeffery	100311 V2	Personnel update
Halasa, Natasha	100169 V3	Addition of new RG2 viruses, previously approved for similar materials
Knollmann, Bjorn	100173 V2	Addition of new lab space and personnel updates
Osteen, Kevin	100285 V2	Addition of new animal protocol (M2500031), previously approved for similar materials and research activities, and personnel updates
Park, Ben	100313 V2	Update information on description of work; previously approved for this work.
Patel, Mayur	100257 V7	Personnel update, including new person for shipping, addition of new BSC, change in infex agent Risk Group designation.
Peterson, Todd	100305 V2	Update information on description of work; previously approved for this work.

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Zhu, Wenhan	0471 R5 (should	Personnel update, including ABSL2 work. Addition of two agents,
	be V6)	including RDNA modification of one. Previously approved for similar
	·	materials and activities.

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

Adjournment

The meeting was adjourned at 12:40 pm.

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