INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

August 21, 2025, 1:00 PM

Name	IBC Office	Oct 17	Nov 21	Dec 12	Jan 16	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22	Aug 21
Dr. Michael Maceyka	Biosafety Officer, EHS	X	X	X	X	X	X	X	X	X	X	X
Dr. Michael McVoy	Chair, Scientist, Virologist	X	X	X	X	X	X	X	X	X	X	X
David J. Montefusco	Vice Chair, Scientist, Biochemistry	X	X	X	X	X	X	X	X	X	X	X
Michael Elliott	Non-Affiliated		X	X	X	X	X	X	X	X		X
Virginia Sykes	Asst. Biosafety Officer, EHS		X	X	X	X	X	X		X	X	X
Dr. Priscilla Hwang	Scientist, Biomedical Engineering	X		X	X		X	X	X			X
Dr. Devanand Sarkar	Scientist, Molecular Genetics	X			X		X	X		X	X	X
Nicky Rose	Non-Affiliated			X	X	X	X	X	X	X	X	X
Laurence Mendoza*	Lab Safety Officer, EHS	X	X	X	X	X	X	X	X	X	X	
Dr. Edward Crawford*	Scientist, Life Sciences	X	X	X	X		X	X	X		X	X
Charles Hall**	CAR-T specialist, Immunotherapy and Transplant	X	X	X	X		X	X	X	X	X	X
Peter Landsman^	IBC Coordinator	X	X	X	X	X	X	X	X	X	X	X
Rob Nelms	Animal Expert, DAR Operations	X			X	X	X		X	X	X	
Joe Yannie^	Laboratory Safety Specialist, EHS	X	X	X	X	X	X	X	X	X		
Sophie Makharita^	Biosafety Specialist, EHS	X		X	X	X	X	X	X			X
Lauren Wallace	Director of Clinical Research Regulatory Affairs, OVPRI	X	X		X	X	X		X			X

^{*} Alternate member, X attended meeting, ^ non-voting member, c cancelled meeting, r retired member, ** ad hoc member

- I. Introduction of Members and Guests: A quorum of nine full voting members was present, as was one alternate voting members for a total of ten voters. One full voting member, one alternate voting member, and one nonvoting member were absent. One full voting member had a partial scheduling conflict and voted on six of the ten protocols reviewed in this meeting. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.
- II. Review of Minutes from July 22, 2025, Meeting and Vote on Posting Redacted Minutes: The IBC reviewed and discussed a redacted version of the meeting minutes corresponding to the IBC's July 22, 2025, meeting. The IBC members determined that the redacted minutes were appropriate for public distribution and unanimously voted to approve the posting of the redacted minutes on the IBC's website. The IBC coordinator indicated that the approved minutes were likely to be posted and available on the IBC's website by close of business on August 22, 2025.

III.Ongoing Program Updates

A. Update on Previously Reviewed rDNA Protocol MUAs and BioRAFT Registrations:

- **1. Dr. Maggie Thomas Freeberg**: "*Lung fibrosis*" BioRAFT new registration. Conditionally approved 7/22/25. Approval conditions subsequently met and full approval granted.
- **2. Dr. Piyusha Pagare**: "(1) Characterization of small molecule modulators of opioid receptors; (2) Behavioral studies of novel compounds for neurological disorders" BioRAFT new registration. Fully approved 7/22/25.
- **3. Dr. Youngman Oh**: "(1) Anti-tumor effect of the IGFBP-3/IGFBP-3 receptor in human cancer; (2) IGFBP-3 and obesity-induced insulin resistance" BioRAFT 3-year renewal. Conditionally approved 7/22/25. Approval conditions subsequently met and full approval granted.
- **4. Dr. Huizhi Wang**: "SGK1 and the control of periodontal inflammation" BioRAFT 3-year renewal. Conditionally approved 7/22/25. Approval conditions subsequently met and full approval granted.

B. rDNA Protocols, New Reviews:

1. **Dr. Guang-Wei Zhang**: "Neural Circuit Mechanisms Underlying Social Behavior" BioRAFT new registration, [REDACTED]. A BSL-1/ABSL-1 study falling under

sections III-D and III-E of the NIH guidelines. The committee discussed the registration, and reviewed the Zhang laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Zhang laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the registration needed to be revised to indicate that all experiments would be performed at a biosafety level of BSL-2, the registration's Animal Source Materials Survey needed to be updated to reflect the laboratory's use of infectious agents, the registration's DURC/PEPP Survey needed to be updated to mention the potential for integration, the registration's Rooms and Spaces section needed to be updated to include the rooms being used for storage, and the registration's AAV Viral Vector Registration Form needed to be revised to clarify how the insert sequences being used are obtained and to add further details about the precautions being used by the laboratory. 9 of 9 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.

2. Dr. Aaron Barbour: "Memory activity in Alzheimer's disease mouse models" BioRAFT new registration, [REDACTED]. A BSL-1/ABSL-1 study falling under sections III-D, III-E, and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Barbour laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Barbour laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the registration needed to be revised to indicate that all experiments would be performed at a biosafety level of BSL-2, the laboratory needed to update its registration with details related to the biosafety cabinet being used and the laboratory's chemical inventory, the registration's Description of Experimental and Procedural Details section needed to be updated to contain more robust descriptions of the experiments being performed, the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to reflect the use of animals requiring containment at ABSL-1 or greater, and details provided throughout the registration needed to reflect the laboratory's use of viral vectors. 8 of 9 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above, and one IBC voter voted to grant the registration outright approval. As a result, the registration was granted conditional approval. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.

3. Dr. Swadesh Das: "(1) Molecular basis of cancer progression and metastasis; develop novel therapeutic approaches for advanced cancers, specific focus; (2) Evaluation of MDA-9/Syntenin PDZ1i in Metastasis; (3) Development and Characterization of Next Generation (NG) Therapeutic Cytokines; (4) PDZ1i (Small molecule inhibitor of the pro-metastatic protein MDA-9/Syntenin/SDCBP); (5) A Novel Treatment for Metastatic Cancers; (6) Novel Targeted Combinatorial Therapy for Hepatocellular Carcinoma" BioRAFT new registration, [REDACTED]. A BSL-2+/ABSL-2 group of studies falling under sections III-D, III-E, and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Das laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Das laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted the registration's Human Source Materials Survey needed to be updated to reflect the fact that the laboratory is not infecting human cells with wild type viruses, the registration needed to be revised to indicate that experiment #4 would be performed at an animal biosafety level of ABSL-2, the registration's Recombinant or Synthetic Nucleic Acid Molecules survey needed to be updated to reflect the introduction of greater than 2/3 of a eukaryotic viral genome into a non-human animal, the registration's source materials surveys needed to be updated to include all plasmids and bacteria being used, and the registration's adenovirus Viral Vector Registration Form needed to be updated to include further project details and clarification of the adenovirus' replication capabilities. 10 of 10 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.

C. Three-Year Renewals/Major Revisions:

1. **Dr. Edward Lesnefsky**: "The role of mitochondria in cardiac injury during heart attacks and reperfusion" BioRAFT 3-year renewal, [REDACTED]. A BSL-2+/ABSL-1 study falling under sections III-D, III-E, and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Lesnefsky laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Lesnefsky laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the registration needed to be revised to indicate that all experiments would be performed at an animal biosafety level of ABSL-2 and the registration needed to be expanded to

include information on whether the OPA1 gene being inserted has oncogene potential. 10 of 10 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.

- 2. Dr. Said Sebti: "Targeting mutant KRas for Cancer Therapy" BioRAFT 3-year renewal, [REDACTED]. A BSL-2+/ABSL-2 study falling under sections III-D and III-E of the NIH guidelines. The committee discussed the registration, and reviewed the Sebti laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Sebti laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the PI needed to complete three required training modules and the registration's Project Summary and Description of Experimental and Procedural Details sections needed a significant amount of editing to remove irrelevant details and clarify the exact procedures being used. 10 of 10 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.
- **3. Dr. Janina Lewis**: "(1) Virulence factors of anaerobic periodontopathogens; (2) Host-Pathogen interaction in oral cavity; (3) Effect of Targeted Antimicrobial Therapy for Oral Infectious Diseases; (4) Iron Therapy for Oral Cancer" BioRAFT 3-year renewal, [REDACTED]. A BSL-2/ABSL-2 group of studies falling under sections III-D and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Lewis laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Lewis laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the registration needed to be revised to indicate that experiment #4 would be performed at a biosafety level of BSL-2+, the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to reflect the housing of animals at ABSL-2, the registration's vaccinia Viral Vector Registration Form needed to be revised to include details of how the virus will be expanded, and references to a now-concluded study involving macaques needed to be removed from the registration. 10 of 10 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.

- 4. **Dr. Rebecca Martin**: "Flow Cytometry Shared Resource (FCSR)" BioRAFT 3-year renewal, [REDACTED]. A BSL-2+ core lab listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Martin laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee unanimously agreed that the documentation provided was sufficient to show that the registration was compliant with all applicable biosafety-related laws, regulations, and VCU policies. As a result, 9 of 9 IBC voters present voted to grant the registration full approval without required revisions.
- 5. **Dr. Soma Dhakal**: "(1) Multiplex Sensors (Single-Molecule High-Confidence Detection of miRNA Cancer Biomarkers); (2) DNAzyme discovery and optimization for high-yield DNA strand assembly" BioRAFT 3-year renewal, [REDACTED]. A BSL-1 group of studies falling under section III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Dhakal laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee unanimously agreed that the documentation provided was sufficient to show that the registration was compliant with all applicable biosafety-related laws, regulations, and VCU policies. As a result, 9 of 9 IBC voters present voted to grant the registration full approval without required revisions.
- **6. Dr. Peter Hamilton**: "Neuroepigenetic editing for causal mechanisms of addiction and depression" BioRAFT 3-year renewal, [REDACTED]. A BSL-2+/ABSL-2 study falling under sections III-D and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Hamilton laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Hamilton laboratory's registration complied with the majority of applicable laws, regulations, and VCU policies, but required some minor revisions in order to be fully approved. Specifically, the committee noted that the registration's equipment section needed to be updated to include the biosafety cabinet being used and its certification status, the registration's project summary needed to be expanded to include information relating to the use of ZFP189, and the registration's Viral Vector Registration Forms needed to be updated to indicate that bone wax would be used to seal burr holes created by stereotactic injections. 10 of 10 IBC voters present voted to grant the registration approval contingent upon the laboratory making the revisions specified above. The committee designated VCU's Biosafety Office as the body authorized to determine when the registration's approval conditions were met.
- **7. Dr. Nicholas Farrell**: "Antitumor and antiviral properties of metal complexes" BioRAFT 3-year renewal, [REDACTED]. A BSL-2 study falling under section III-F

of the NIH guidelines. The committee discussed the registration, and reviewed the Farrell laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee unanimously agreed that the documentation provided was sufficient to show that the registration was compliant with all applicable biosafety-related laws, regulations, and VCU policies. As a result, 10 of 10 IBC voters present voted to grant the registration full approval without required revisions.

D. Other rDNA Concerns/Administrative Approvals: N/A

IV. Old Business: N/A

V. New Business:

A. Pre-review Documentation: The Biosafety Officer educated the committee on the process the Biosafety Office uses when pre-reviewing registrations scheduled for full IBC review. The Biosafety Officer provided the committee a document containing some examples of typical communications the Biosafety Office has had with principal investigators immediately prior to their BioRAFT registrations being reviewed by the IBC. The Biosafety Officer also informed the committee of some updates of how comments work in BioRAFT, including a new optional ability to make IBC reviewer comments visible to principal investigators.

There being no further business before the committee, the meeting adjourned at approximately 3:01 PM. The next IBC meeting is scheduled for 1:00 PM, September 18, 2025.