

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

September 18, 2025, 1:00 PM

Name	IBC Office	Nov 21	Dec 12	Jan 16	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22	Aug 21	Sep 18
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	
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	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		
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 six full voting members was present, as was one alternate voting member for a total of seven voters. Four full voting members were absent including the IBC Chair. As a result, the IBC Vice Chair acted as the Chair for this meeting. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.

II. Review of Minutes from August 21, 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 August 21, 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 September 19, 2025.

III. Ongoing Program Updates

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

1. **Dr. Guang-Wei Zhang:** "*Neural Circuit Mechanisms Underlying Social Behavior*" BioRAFT new registration. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
2. **Dr. Aaron Barbour:** "*Memory activity in Alzheimer's disease mouse models*" BioRAFT new registration. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
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. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
4. **Dr. Edward Lesnefsky:** "*The role of mitochondria in cardiac injury during heart attacks and reperfusion*" BioRAFT 3-year renewal. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.

5. **Dr. Said Sebti:** “*Targeting mutant KRas for Cancer Therapy*” BioRAFT 3-year renewal. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
6. **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. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
7. **Dr. Rebecca Martin:** “*Flow Cytometry Shared Resource (FCSR)*” BioRAFT 3-year renewal. Fully approved 8/21/25.
8. **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. Fully approved 8/21/25.
9. **Dr. Peter Hamilton:** “*Neuroepigenetic editing for causal mechanisms of addiction and depression*” BioRAFT 3-year renewal. Conditionally approved 8/21/25. Approval conditions subsequently met and full approval granted.
10. **Dr. Nicholas Farrell:** “*Antitumor and antiviral properties of metal complexes*” BioRAFT 3-year renewal. Fully approved 8/21/25.

B. rDNA Protocols, New Reviews:

1. **Dr. Gordon Smith:** “*A Multicenter Phase I Double-blind, Randomized, Sham-controlled Dose Escalation Study to Determine Safety and Tolerability of Single Dose Intrathecal ST-503 Gene Therapy for Refractory Pain Due to Idiopathic Small Fiber Neuropathy (iSFN)*” New clinical trial MUA, [REDACTED]. A BSL-2 clinical trial falling under sections III-C and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Smith 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, 7 of 7 IBC voters present voted to grant the registration full approval without required revisions.

2. **Dr. Carlos Castano Londono:** “*Growth of Cell Lines and Bacteria on Engineered Substrates*” BioRAFT new registration, [REDACTED]. A BSL-2 study listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Castano Londono 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, 7 of 7 IBC voters present voted to grant the registration full approval without required revisions.

C. Three-Year Renewals/Major Revisions:

1. **Dr. Dana Selley:** “(1) *Opioid drug discovery screening*; (2) *Central Virginia Center for Drug Abuse Research, Neuropharmacology Core*; (3) *Targeting Sphingosine-1-phosphate receptors in pain states*” BioRAFT new registration, [REDACTED]. A BSL-2 group of studies listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Selley laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Selley 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 cell lines table needed to be updated to include all cell lines being used and the registration’s project description sections needed to be expanded with details of the transfection technique being used with HEK-293 cells. 7 of 7 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.

D. Other rDNA Concerns/Administrative Approvals:

1. **Dr. Kelly Gwathmey:** “[HM20032219] NECT 24-03: *An Open Label Study of STR04 in Participants with Amyotrophic Lateral Sclerosis*” Review of a novel pharmaceutical product. Administratively approved 9/10/25.

IV. Old Business: N/A

V. New Business: N/A

There being no further business before the committee, the meeting adjourned at approximately 1:43 PM. The next IBC meeting is scheduled for 1:00 PM, October 16, 2025.