

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 11, 2025, 1:00 PM

Name	IBC Office	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22	Aug 21	Sep 18	Oct 16	Nov 20	Dec 11
Virginia Sykes	Biosafety Officer, EHS	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
Dr. Michael Maceyka [*]	Former Biosafety Officer, EHS	X	X	X	X	X	X	X	X			
Dr. Priscilla Hwang	Scientist, Biomedical Engineering		X	X	X			X	X		X	
Dr. Devanand Sarkar	Scientist, Molecular Genetics		X	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		
Charles Hall ^{**}	CAR-T specialist, Immunotherapy and Transplant		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		
Sophie Makharita [^]	Biosafety Specialist, EHS	X	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 five full voting members was present, as was one alternate voting member for a total of six voters. Four full voting members and two nonvoting members were absent. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.

II. Review of Minutes from November 20, 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 November 20, 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 December 17, 2025.

III. Ongoing Program Updates

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

- 1. Dr. Amanda Hale:** “(1) *Transformative research in forensic anthropology*; (2) *Forensic Anthropology Instruction*” BioRAFT new registration. Conditionally approved 11/20/25. Approval conditions subsequently met and full approval granted.
- 2. Dr. Jia-Ray Yu:** “*Regulation of canonical and non-canonical substrates of histone lysine methyltransferases*” BioRAFT new registration. Conditionally approved 11/20/25. Approval conditions subsequently met and full approval granted.
- 3. Dr. Renato Martins:** “[HM300000492] *An Interventional Open-Label Phase 1B/2 Study to Evaluate the Safety, Pharmacokinetics, and Preliminary Efficacy of PF-08634404 in Combination with Different Anticancer Agents in Participants with Advanced Solid Tumors*” New clinical trial MUA. Fully approved 11/20/25.
- 4. Dr. Robert Winn:** “*The investigation of novel biomarkers and targeted gene therapy in lung tumorigenesis*” BioRAFT major revision. Fully approved 11/20/25.
- 5. Dr. MaryPeace McRae:** “*Understanding the effects of HIV-1 Tat, EcoHIV and drug abuse on the integrity of the brain*” BioRAFT 3-year renewal. Conditionally approved 11/20/25. Approval conditions subsequently met and full approval granted.
- 6. Dr. Andrew Crowther:** “*Neural mechanisms underlying chronic pain*” BioRAFT 3-year renewal. Fully approved 11/20/25.

7. **Dr. Venkata Lokesh Battula:** “(1) Targeting Ganglioside GD2 to Overcome Chemotherapy-resistance in Triple-negative Breast Cancer; (2) Arming NK Cells to Target B7-H3+ AML Cells” BioRAFT new registration. Registration previously reviewed and tabled on 10/16/25 and temporarily approved by IBC subcommittee on 10/31/25. Fully approved 11/20/25.

B. rDNA Protocols, New Reviews: N/A

C. Three-Year Renewals/Major Revisions:

1. **Dr. Swati Deb:** “(1) Identification of novel p53 pathway-related therapeutic approaches for cancer treatment; (2) The investigation of novel biomarkers and targeted gene therapy in lung tumorigenesis” BioRAFT major revision, [REDACTED]. A BSL-2+/ABSL-2 study falling under sections III-D, III-E, and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Deb laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Deb 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 human and animal source material surveys needed to be updated to remove references to recombinant viruses, the registration’s Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to indicate to reflect the use of infectious DNA or RNA viruses in tissue culture without the use of a helper system, the registration’s transgenic animal table needed to be updated with information on how the animals involved in the laboratory’s experiments are obtained, the registration’s source materials tables needed to be updated to more accurately reflect what viral vectors were being used, the viral vector form for the registration’s adenovirus needed to be expanded to include additional risk information and to require the use of N95 masks when work is performed outside of a biosafety cabinet, and the viral vector forms for all lentiviruses being used needed to be updated to ensure that stocks are filtered to remove packaging cells. 6 of 6 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: N/A

IV. Old Business: N/A

V. New Business:

- A. IBC Member Training:** The Biosafety Officer administered a training session to the IBC members regarding laboratory safety and implementation of the NIH Guidelines. Topics discussed included the required composition and duties of IBCs, an overview of different biosafety levels and when they apply, best practices applicable to biological risk assessments, and the general responsibilities of everyone involved in the performance and review of biological experiments involving recombinant DNA.

There being no further business before the committee, the meeting adjourned at approximately 1:53 PM. The next IBC meeting is scheduled for 1:00 PM, January 15, 2026.