

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

November 20, 2025, 1:00 PM

Name	IBC Office	Jan 16	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22	Aug 21	Sep 18	Oct 16	Nov 20
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	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	X	
Nicky Rose	Non-Affiliated	X	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	
Charles Hall ^{**}	CAR-T specialist, Immunotherapy and Transplant	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	X
Joe Yannie [^]	Laboratory Safety Specialist, EHS	X	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	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 eight full voting members was present, as was one alternate voting member for a total of nine voters. One full voting member was absent. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.

II. Review of Minutes from October 16, 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 October 16, 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 November 21, 2025.

III. Ongoing Program Updates

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

- 1. 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. Tabled and later reviewed and temporarily approved by an IBC subcommittee. See Section IV below for further details.
- 2. Dr. Nicholas Johnson:** *“DYNE101-DM1-201: A Randomized, Placebo-Controlled, Multiple Ascending Dose Study Assessing Safety, Tolerability, Pharmacodynamics, Efficacy, and Pharmacokinetics of DYNE-101 Administered to Participants with Myotonic Dystrophy Type 1”* New clinical trial MUA. Fully approved 10/16/25.
- 3. Dr. Anna Vinnikova:** *“Phase 2b Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Dose-Ranging Study to Assess the Efficacy, Safety, and Tolerability of AZD2373 in Participants with APOLI-Mediated Kidney Disease (APPRECIATE)”* New clinical trial MUA. Fully approved 10/16/25.
- 4. Dr. Joseph Landry:** *“(1) Investigations into chromatin remodeling as a regulator of cancer biology; (2) Investigating Drug Combinations to Improve Lung Cancer Treatment; (3) Ascites production; (4) Creation of Induced Pluripotent Stem Cells from Tumor Fibroblasts”* BioRAFT major revision. Conditionally approved 10/16/25. Approval conditions subsequently met and full approval granted.

5. **Dr. Richard Marconi:** “*Development of Vaccines and diagnostic tests for Leptospirosis, Spirochetal and other tick-borne pathogens*” BioRAFT 3-year renewal. Conditionally approved 10/16/25. Approval conditions subsequently met and full approval granted.

B. rDNA Protocols, New Reviews:

1. **Dr. Amanda Hale:** “(1) *Transformative research in forensic anthropology*; (2) *Forensic Anthropology Instruction*” BioRAFT new registration, [REDACTED]. A BSL-1 group of studies listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Hale laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Hale 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 laboratory needed to provide additional details related to the nature of the human materials being used in its projects, needed to provide accurate building and room numbers for where the laboratory’s projects would be taking place, and needed to provide a set of SOPs documenting the lab’s handling of human materials, including SOPs related to hand hygiene, PPE, decontamination, and biological waste management. 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. Jia-Ray Yu:** “*Regulation of canonical and non-canonical substrates of histone lysine methyltransferases*” BioRAFT new registration, [REDACTED]. A BSL-2+ study falling under sections III-D, III-E, and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Yu laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Yu 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 Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to indicate that no helper virus would be used, the safety sections of the registration’s Viral Vector Registration Forms needed to be updated to address the oncogenic properties of the viral-encoded proteins being expressed, references to helper viruses needed to be removed, and the laboratory’s use of baculovirus needed to be reclassified as the use of a virus rather than a viral vector. 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.

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, [REDACTED]. A BSL-2 clinical trial falling under section III-C of the NIH guidelines. The committee discussed the registration, and reviewed the Martins 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.

C. Three-Year Renewals/Major Revisions:

1. **Dr. Robert Winn:** “*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 and III-E of the NIH guidelines. The committee discussed the registration, and reviewed the Winn 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.
2. **Dr. MaryPeace McRae:** “*Understanding the effects of HIV-1 Tat, EcoHIV and drug abuse on the integrity of the brain*” BioRAFT 3-year renewal, [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 McRae laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the McRae 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 biosafety level applicable to the registration's project needed to be raised from BSL-2 to BSL-2+ due to the use of samples from HIV positive subjects, the registration's cell lines table needed to be updated to include all cell lines mentioned in the registration's Human Source Materials Survey, the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to

reflect the laboratory's exposure of whole animals to recombinant microbial agents, the registration's Usage Summary needed to be revised to remove references to viral vectors, and the Pathogen Registration Form corresponding to the registration's use of HIV needed to be updated to include details of how mice are being inoculated with HIV and to include information in its safety section regarding the potential risks of accidental exposure to EcoHIV. 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 and the IBC Chair as the bodies authorized to determine when the registration's approval conditions were met.

3. **Dr. Andrew Crowther:** "*Neural mechanisms underlying chronic pain*" 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 Crowther 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.

D. Other rDNA Concerns/Administrative Approvals:

1. **Dr. Shraddha Mainali:** "[HM300000206] *Strategy for Improving Stroke Treatment Response (SISTER) Trial*" Review of a novel pharmaceutical product. Administratively approved 10/16/25.
2. **Dr. Chelsea Salyer:** "[HM300000295] *GOG-3110: A Phase III, Randomized, Open-Label, Multicenter, Global Study of Puxitatus Samrofecan (AZD8205) Monotherapy Versus Physician's Choice of Chemotherapy in Participants with B7-H4-Selected Advanced/Metastatic Endometrial Cancer Who Progressed on or After Platinum-Based Chemotherapy and Anti-PD-I/Anti-PD-L1 Therapy*" Review of a novel pharmaceutical product. Administratively approved 10/30/25.

IV. Old Business:

- A. **IBC Subcommittee Approval and Full Committee Review of 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*." A BSL-2+/ABSL-2 group of studies falling under sections III-D and III-F of the NIH guidelines. In the October 16, 2025, IBC meeting, the IBC voted to table the Battula

registration, indicating that the registration was incomplete, and contained insufficient details to allow for a determination as to whether the registration was compliant with all applicable biosafety-related laws, regulations, and VCU policies. Subsequent to that meeting, several members of the IBC including the Chair, Vice Chair, Biosafety Officer, and others met with members of the Battula laboratory to discuss the registration. Based on that meeting, the Battula laboratory revised its registration and requested that the IBC review the registration again before the regularly scheduled IBC meeting on November 20, 2025. Laboratory staff provided compelling evidence that its projects would be negatively impacted by the delay. As a result, a subcommittee of the IBC convened on October 31, 2025, to review the revised Battula registration. The subcommittee consisted of the Chair, the Vice Chair, the Biosafety Officer, the Coordinator, Larry Mendoza, Sophie Makharita, and Joe Yannie. Upon review of the updated Battula registration, the subcommittee unanimously voted that the documentation in the revised registration was sufficient to show that the registration was compliant with all applicable biosafety-related laws, regulations, and VCU policies, without required revisions. The subcommittee allowed the Battula laboratory to temporarily begin operations, with a vote by the full IBC at the November 20, 2025, meeting serving as a full-time review of the laboratory. At the November 20, 2025, meeting, the full committee reviewed the revised registration and 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.

V. New Business:

- A. IBC Plant Expert:** The IBC Coordinator indicated that Dr. Ed Crawford, the IBC's plant expert, had been selected to lead a large-scale ecology project and as a result had to resign from the IBC. The Coordinator expressed his gratitude for Dr. Crawford's contributions to the IBC, and informed the committee that per NIH regulations, the IBC needed to replace Dr. Crawford with a new plant expert. Sophie Makharita indicated that Dr. Crawford had been in contact with the Biosafety Office and indicated that he might be able to provide the name of a suitable replacement. The Committee unanimously agreed to await Dr. Crawford's suggestion and make a subsequent determination as to whether the suggested individual would be an appropriate replacement.
- B. December 11th IBC Meeting:** The IBC Coordinator informed the committee that the next IBC meeting was scheduled for December 11th, and would be a hybrid in-person meeting. For those interested, the meeting would be held in person and lunch would be served. For those that preferred to attend via Zoom, that option would also still be available.

There being no further business before the committee, the meeting adjourned at approximately 2:24 PM. The next IBC meeting is scheduled for 1:00 PM, December 11, 2025.