INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

October 16, 2025, 1:00 PM

Name	IBC Office	Dec 12	Jan 16	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22	Aug 21	Sep 18	Oct 16
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[r]	Former 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	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	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	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 eight full voting members was present, as was one alternate voting member for a total of nine voters. One full voting member was absent. Danny Muñoz, Director of VCU Environmental Health and Safety, and Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as guests. At the beginning of the meeting, Danny Muñoz addressed the committee and informed them that Dr. Michael Maceyka had resigned as VCU's biosafety officer. He wished Dr. Maceyka well in his future endeavors and informed the committee that Virginia Sykes would serve as VCU's biosafety officer moving forward.

II. **Review of Minutes from September 18, 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 September 18, 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 October 17, 2025.

III. **Ongoing Program Updates**

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

1. **Dr. Gordon Smith**: "*A Multicenter Phase 1 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. Fully approved 9/18/25.

2. **Dr. Carlos Castano Londono**: "*Growth of Cell Lines and Bacteria on Engineered Substrates*" BioRAFT new registration. Fully approved 9/18/25.

3. **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 3-year renewal. Conditionally approved 9/18/25. Approval conditions subsequently met and full approval granted.

B. **rDNA Protocols, New Reviews**:

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, [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 Battula laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee unanimously agreed that the laboratory's registration as presented to the committee 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. Specifically, the committee found that the registration's project summaries and descriptions of experimental details were either missing or overly truncated, the registration's source materials tables were incomplete, and the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey and Viral Vector Registration Forms contained numerous inaccuracies. As a result, 9 of 9 IBC voters present voted to temporarily table the IBC's review of the Battula lab's registration, and to reopen the review at a future IBC meeting when further details had been entered into the laboratory's BioRAFT registration.

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

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 APOL1-Mediated Kidney Disease (APPRECIATE)*" 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 Vinnikova 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. 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, [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 Landry laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Landry 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 plasmids table needed to be updated to include all genes associated with the plasmids being used, the Description of Experimental and Procedural Details section for project #1 needed to be updated to include details on the project's use of MXT- and MXT+ cells, the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to reflect the laboratory's use of transgenic mice and to indicate that a helper virus was not being used, and the registration needed to be supplemented to include specific details related to the use of bloodborne pathogens and pathogenic microorganisms listed in the registration's Usage Summary. 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. Richard Marconi**: "*Development of Vaccines and diagnostic tests for Leptospirosis, Spirochetal and other tick-borne pathogens*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2/ABSL-2 study falling under section III-D of the NIH guidelines. The committee discussed the registration, and reviewed the Marconi laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Marconi 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 reflect the laboratory's use of hamsters and its work with animals requiring containment at ABSL-2, the answers in the registration's Animal Source Materials (Non-Primate) Survey needed to be shortened to only include relevant details related to the laboratory's use of animals, the registration's bacteria table needed to be updated to indicate the risk groups for all bacteria being used, and the registration's Description of Experimental and Procedural Details section needed to updated to contain further details about the methods the laboratory

was using to genetically modify bacteria. 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.

D. Other rDNA Concerns/Administrative Approvals:

1. **Dr. Kelly Gwathmey**: "*IMVT-1402-3101: A Phase 3, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study to Assess the Efficacy and Safety of IMVT-1402 in Patients with Mild to Severe Generalized Myasthenia Gravis*" Review of a novel pharmaceutical product. Administratively approved 9/25/25.

IV. Old Business: **N/A**

V. New Business: **N/A**

There being no further business before the committee, the meeting adjourned at approximately 1:53 PM. The next IBC meeting is scheduled for 1:00 PM, November 20, 2025.