

# INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

*April 30, 2026, 1:00 PM*

Member Name	IBC Office	Jun 26	Jul 22	Aug 21	Sep 18	Oct 16	Nov 20	Dec 11	Jan 15	Feb 19	Mar 19	Apr 30
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
David J. Montefusco	Vice Chair, Scientist, Biochemistry	X	X	X	X	X	X	X	X			X
Michael Elliott	Non-Affiliated	X		X		X	X	X	X	X	X	X
Dr. Priscilla Hwang	Scientist, Biomedical Engineering			X	X		X		X	X		
Dr. Devanand Sarkar	Scientist, Molecular Genetics	X	X	X	X	X		X	X	X	X	X
Nicky Rose	Non-Affiliated	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 <sup>r</sup>	Scientist, Life Sciences		X	X	X	X						
Charles Hall**	CAR-T specialist, Immunotherapy and Transplant	X	X	X	X	X			X			
Peter Landsman <sup>^</sup>	IBC Coordinator	X	X	X	X	X	X	X	X	X		X
Rob Nelms	Animal Expert, DAR Operations	X	X			X	X		X	X		
Joe Yannie <sup>^</sup>	Laboratory Safety Specialist, EHS	X			X	X			X	X	X	X
Sophie Makharita <sup>^</sup>	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
Rodney Dyer	Scientist, Life Sciences											X
Jimmy Spencer*	Associate Director, EHS											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 seven full voting members was present, as were two alternate voting members for a total of nine voters. Three full voting members and one nonvoting member were absent. The IBC Coordinator introduced two new IBC members to the committee: Dr. Rodney Dyer and Jimmy Spencer. Dr. Dyer, a scientist and professor of life sciences at VCU, joined the IBC as a full voting member and Jimmy Spencer, the Associate Director of VCU's Environmental Health & Safety, joined the IBC as an alternate voting member.

**II. Review of Minutes from March 19, 2026, Meeting and Vote on Posting Redacted Minutes:** The IBC reviewed and discussed a redacted version of the meeting minutes corresponding to the IBC's March 19, 2026, 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 May 1, 2026.

### **III. Ongoing Program Updates**

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

- 1. Dr. Inan Olmez:** *“Developing therapeutic strategies against primary and metastatic brain tumors”* BioRAFT new registration. Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.
- 2. Dr. William Clark:** *“[HM300000862] LYL314-102: A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (Pinnacle-H2H)”* Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.
- 3. Dr. Emily Kinsey:** *“[HM300000748] VNX-202-01: A Phase 1/2, First-in-Human of VNX-202 Gene Therapy in Patients with HER2-Positive Cancer (SENTRY-HER2)”* New clinical trial MUA. Fully approved 3/19/26.
- 4. Dr. Javier-Gonzalez-Maeso:** *“Mouse models of schizophrenia signaling and epigenetics”* BioRAFT 3-year renewal. Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.

5. **Dr. Rebecca Heise:** “(1) Surfactant depletion and replacement therapy; (2) Ventilator Induced Lung Injury; (3) Role of Cell Stretch in Lung Diseases; (4) ECM hybrid gels; (5) Airway hyperresponsiveness/allergen model” BioRAFT 3-year renewal. Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.
6. **Dr. Xiang-Yang (Shawn) Wang:** “Immune modulation in diseases and therapies” BioRAFT 3-year renewal. Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.
7. **Dr. Tomasz Kordula:** “Mechanisms of glioma invasion” BioRAFT 3-year renewal. Conditionally approved 3/19/26. Approval conditions subsequently met and full approval granted.

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

1. **Dr. Jason Kidd:** “[HM300000644] D8313C00001: Phase 1b/2 Study of AZD0120, a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects with Refractory Systemic Lupus Erythematosus (SLE)” New clinical trial review, [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 Kidd 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. Richard Marconi:** “Development of Vaccines and diagnostic tests for Leptospirosis, Spirochetal and other tick-borne pathogens” BioRAFT Major Revision, [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 needed to be updated to include additional details related to the gene modifications the laboratory intends to make; the registration’s bacteria table

needed to be updated to include risk groups of the bacteria being used; the registration's Borreliella Pathogen Registration Form needed to be updated to include information on applicable handling precautions and animal containment and to correct typos; the registration's Authorizations and Permits section needed to be updated with the latest applicable authorizations and permits; the registration's Human Source Materials Survey needed to be updated to reflect the pathogen-free nature of the human samples being used; the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be revised to indicate that genes encoding proteins expressed by bacterial pathogens would be cloned and manipulated and that animals would be infected with bacterial pathogens that have mutations engineered in specific genes; and the registration's plasmids table needed to be updated to properly indicate that the plasmids were not being used for virus particle production. 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 entity authorized to determine when the registration's approval conditions were met.

#### **D. Other rDNA Concerns/Administrative Approvals:**

- 1. Dr. Renato Martins:** “[HM300000488] CA2440010: IZABRIGHT-Lung01: A Randomized, Open-label, Phase 2/3 Study of Izalontamab Brengitecan (BMS-986507) versus Platinum-based Chemotherapy in Patients with EGFR-mutated Non-small Cell Lung Cancer and Disease Progression on EGFR Tyrosine Kinase Inhibitor Therapy” Review of a novel pharmaceutical product. Administratively approved 3/16/26.
- 2. Dr. Apostolos Perelas:** “[HM300000533] M25-268: A Phase 2a Multicenter Platform Study of Investigational Products for the Treatment of Adult Subjects with Idiopathic Pulmonary Fibrosis” Review of a novel pharmaceutical product. Administratively approved 4/2/26.
- 3. Dr. Jonathan Berkman:** “M23-384: A Phase 3 Randomized, Open Label, Multicenter Study to Evaluate the Safety and Efficacy of ABBV-706 versus Standard of Care in Subjects with Relapsed/Refractory Small Cell Lung Cancer (SCLC)” Review of a novel pharmaceutical product. Administratively approved 4/8/26.
- 4. Dr. Jose Trevino:** “[HM300001022] A Phase 2b/3, Randomized, Double-Blind Study to Investigate the Efficacy, Safety, and Tolerability of Ponsegramab (PF-06946860) Compared with Placebo Both with Background First-Line Chemotherapy in Adult Participants with Cachexia and Metastatic Pancreatic Ductal Adenocarcinoma” Review of a novel pharmaceutical product. Administratively approved 4/29/26.

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

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

There being no further business before the committee, the meeting adjourned at approximately 1:41 PM. The next IBC meeting is scheduled for 1:00 PM, May 21, 2026.