

# INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

July 22, 2025, 1:00 PM

Name	IBC Office	Sep 19	Oct 17	Nov 21	Dec 12	Jan 16	Feb 20	Mar 20	Apr 17	May 15	Jun 26	Jul 22
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	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	
Virginia Sykes	Asst. 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
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*	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
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	X	X	
Sophie Makharita^	Biosafety Specialist, EHS		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 seven full voting members was present, as were two alternate voting members for a total of nine voters. Three 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 June 26, 2025, meeting:** the minutes from the June 26, 2025, IBC meeting were accepted by the committee.

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

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

- 1. Dr. Renato Martins:** *“A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INterpath-009)”* New clinical trial MUA. Fully approved 6/26/25.
- 2. Dr. Andrew Poklepovic:** *“An Expanded Access Program – Real-world Data Collection for VO in Combination with Nivolumab in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 Containing Treatment Regimen”* New expanded access program MUA. Fully approved 6/26/25.
- 3. Dr. Christopher Lemmon:** *“(1) Mechanochemical Signaling Dynamics in Epithelial-Mesenchymal Transition; (2) Engineering a Kidney Organoid Model to Investigate Fibronectin-TGF-beta Signaling in Renal Fibrosis; (3) Engineering a Human Amniotic Membrane to Investigate Mechanisms of Rupture”* BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.
- 4. Dr. Erika Martin:** *“Identifying Hemostatic Assays that are Predictive of Clinical Efficacy in Blood from Hemophiliacs”* BioRAFT 3-year renewal. Fully approved 6/26/25.
- 5. Dr. Amy Lasek:** *“Roles of genes in behaviors related to alcohol addiction”* BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.
- 6. Dr. Qingguo Xu:** *“(1) Efficacy study of TMEM219 (IGFBP3 receptor) monoclonal antibodies and IGFBP-3 peptides at in vitro (retinal epithelium cell) and in vivo*

*AMD model; (2) Efficacy study of NLRP3 inflammasome inhibitors JC-124, JWF-33 and JWF-102 at in vitro (retinal endothelium cells) and in vivo models; (3) New mucus penetrating antibiotics loaded-dry powder aerosols for treating chronic pulmonary infections in rats*” BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.

**7. Dr. Jennifer Wolstenholme:** “(1) *Gene manipulation with viral vectors; (2) FMT on initiation of ethanol drinking*” BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions not yet met as of 7/22/25, and as a result full approval not yet granted.

**8. Dr. Yana Cen:** “(1) *Small Molecule Activators of Class III sirtuins; (2) Allosteric Activation of SIRT6 by DNA strand breaks*” BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.

**9. Dr. Shijun Zhang:** “(1) *Novel NLRP3 inflammasome inhibitors; (2) Development of novel compounds for AD*” BioRAFT 3-year renewal. Fully approved 6/26/25.

**10. Bone Engineering Science and Technology Lab (Dr. Henry Donahue):** “*Determining the Mechanism Behind Bone Cell Transduction*” BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.

**11. Dr. Andrew George:** “*Characterization of amyloid- $\beta$ : $\alpha$ 7 $\beta$ 2-nicotinic acetylcholine receptor interactions relevant to Alzheimer's disease*” BioRAFT 3-year renewal. Conditionally approved 6/26/25. Approval conditions subsequently met and full approval granted.

**12. Dr. Karen Hendricks-Munoz:** “(1) *Effect of Kangaroo Mother Care on Microbiome of the Preterm Infant; (2) Birth Vitamin C and impact on infection and infant outcome; (3) Pilot Study to determine Biomarkers to assess risk for neonatal abstinence syndrome; (4) Effect of diesel exhaust pollution on developing microbiome and later lung and brain development; (5) Coronavirus Pandemic: Impact on Maternal and Infant Immunity; (6) The influence of dietary donor human milk components on gut microbiota and postnatal growth failure in the premature infant*” BioRAFT 3-year renewal. Fully approved 6/26/25.

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

1. **Dr. Maggie Thomas Freeberg:** “*Lung fibrosis*” BioRAFT new registration, [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 Thomas Freeberg laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Thomas Freeberg 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 Usage Summary needed to be updated to reflect the presence of bloodborne pathogens, one laboratory member needed to complete three required training modules, the registration needed to be updated to include a Viral Vector Registration Form for the lentivirus being used, the answers to several questions in the registration’s Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be changed to reflect the use of lentivirus, and the registration’s plasmids table needed to be updated to include plasmids being used with any lentivirus being produced by the lab. 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. Piyusha Pagare:** “(1) *Characterization of small molecule modulators of opioid receptors*; (2) *Behavioral studies of novel compounds for neurological disorders*” BioRAFT new registration, [REDACTED]. A BSL-2/ABSL-2 group of studies falling under section III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Pagare 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. Youngman Oh:** “(1) *Anti-tumor effect of the IGFBP-3/IGFBP-3 receptor in human cancer*; (2) *IGFBP-3 and obesity-induced insulin resistance*” BioRAFT new registration, [REDACTED]. A BSL-2+/ABSL-2 group of studies falling under sections III-D and III-E of the NIH guidelines. The committee discussed the registration, and reviewed the Oh laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Oh 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 project 1 should be listed as being performed under BSL-2 precautions and project 2 should be listed as being performed under BSL-2+ precautions, question 7-F-I of the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be changed to reflect the lab's experiments with transgenic rodents, the registration's adenovirus Viral Vector Registration Form needed to be updated to include information on the oncogenic potential of the IGFBP-3 mutant being produced, and the registration's lentivirus Viral Vector Registration Form needed to be revised to reflect changes being made to the natural host range or tropism. 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. Huizhi Wang:** “*SGK1 and the control of periodontal inflammation*” BioRAFT 3-year renewal, [REDACTED]. A BSL-2/ABSL-1 study falling under section III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Wang laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Wang 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 lab needed to attach all relevant biological registration documents to the registration, the registration's project should be revised to be listed as being performed under ABSL-2 precautions, the registration's source materials surveys and project description needed to be updated to clarify if and how the lab is producing replication deficient virus and how that virus will be used, and the registration's bacteria table needed to be updated to include all relevant data points related to the lab's use of *P. gingivalis*, *Streptococcus*, and *F. nucleatum*. 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. Jaclyn Wall:** “*GOG-3103: A Phase 3, Randomized, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of Sacituzumab Tirumotecan Maintenance Treatment With or Without Bevacizumab Versus Standard of Care After Second-line Platinum-based Doublet Chemotherapy in Participants With Platinum-sensitive Recurrent Ovarian Cancer*” Review of a novel pharmaceutical product. Administratively approved 6/20/25.

2. **Dr. Thuy Ho:** “[HM20030185] D7405C00001: A Phase 1/2 Study to Evaluate the Safety and Efficacy of AZD0486 in Adolescent and Adult Participants with Relapsed or Refractory B-Cell Acute Lymphoblastic Leukaemia” Review of a PI change. Administratively approved 7/2/25.
3. **Dr. Andrew Poklepovic:** “[HM20033272] MK-3120-002: A Phase 1/2 Open-label Study to Evaluate the Safety and Efficacy of MK-3120 in Participants with Advanced Solid Tumors” Review of a novel pharmaceutical product. Administratively approved 7/16/25.

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

#### **V. New Business:**

- A. **Approval of Posting of Redacted Minutes from June 26, 2025, IBC Meeting:** The IBC reviewed and discussed a redacted version of the meeting minutes corresponding to the IBC’s June 26, 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 July 24, 2025.

There being no further business before the committee, the meeting adjourned at approximately 1:48 PM. The next IBC meeting is scheduled for 1:00 PM, August 21, 2025.