

# INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

March 19, 2026, 1:00 PM

Name	IBC Office	May 15	Jun 26	Jul 22	Aug 21	Sep 18	Oct 16	Nov 20	Dec 11	Jan 15	Feb 19	Mar 19
Virginia Sykes	Interim Biosafety Officer, EHS		X	X	X	X	X	X	X		X	X
Dr. Michael McVoy	Chair, Scientist, Virologist	X	X	X	X		X	X	X	X	X	
Dr. 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. Michael Maceyka <sup>r</sup>	Former Biosafety Officer, EHS	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	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 <sup>r</sup>	Scientist, Life Sciences	X		X	X	X	X					
Charles Hall**	CAR-T specialist, Immunotherapy and Transplant	X	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	X	
Joe Yannie <sup>^</sup>	Biosafety 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

\* 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 including the IBC Chair and Vice Chair. As a result, Dr. Devanand Sarkar acted as Chair Pro tem for this meeting. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.

**II. Review of Minutes from February 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 February 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.

**III. Ongoing Program Updates**

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

- 1. Dr. Gregory Buck:** “(1) *High Throughput Sequencing and Microarraying*; (2) *Molecular Biology and Pathogenesis of Parasitic Protozoa*; (3) *Epidemiology and Evolution of SARS-CoV-2 / COVID-19 and the Human Microbiome*; (4) *Pathogen Genomics Center of Excellence*; (5) *A Citizen Science Strategy for Monitoring the Appearance of Avian Flu in Virginia*; (6) *Host Response to Bacterial Vaginosis-Associated Taxa*” BioRAFT major revision. Completion of approval conditions pending as of 3/19/26.
- 2. Dr. Maria Garcia Bonilla:** “(1) *Cerebrospinal fluid profiling in preterm infants with hydrocephalus: defining a novel pathway to disability*; (2) *Gene therapy in experimental hydrocephalus*” BioRAFT major revision. Approval conditions subsequently met and full approval granted.
- 3. Dr. Thomas Thatcher:** “(1) *Lung inflammation and Fibrosis*; (2) *Fatal COVID-19 from an Italian hospital*; (3) *Deficient Resolution of Inflammation is Linked to post-COVID-19 Pulmonary Fibrosis*; (4) *Post-TB lung disease*” BioRAFT 3-year renewal. Approval conditions subsequently met and full approval granted.

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

- 1. Dr. Inan Olmez:** “Developing therapeutic strategies against primary and metastatic brain tumors” BioRAFT new registration, [REDACTED]. A BSL-2+ study falling under sections III-D-4 and III-D-4-b of the NIH Guidelines. The committee determined that the Olmez 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 all rooms and storage spaces being used, the viral vector form needed genes added to it that are mentioned in the summary/project review, there needed to be more details added to the shRNA particle form, one plasmid had not been included on the plasmid list, and more information was needed on one form about both BSC use and needle use. 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 entity authorized to determine when the registration's approval conditions were met.

**2. Dr. William Clark:** MUA-LYL314102-CT07188558-LYL314-CarT “*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 (PINACLE-H2H)*” New clinical trial MUA, [REDACTED]. A BSL-2+ study. The committee discussed the registration and reviewed the Clark laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Clark 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 revised so that some entries previously labeled as BSL-2 were changed to BSL-2+. 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 entity authorized to determine when the registration's approval conditions were met.

**3. Dr. Emily Kinsey:** MUA-VNX20201-VNX202-CT07192432-AAV “Phase 1/2, First-in-Human of VNX-202 Gene Therapy in Patients with HER2-Positive Cancer” New clinical trial MUA, [REDACTED]. A new BSL-2 Clinical trial. The committee discussed the registration and reviewed the Kinsey 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, 6 of 6 IBC voters present voted to grant the registration full approval without required revisions.

### C. Three-Year Renewals/Major Revisions:

- 1. Dr. Javier Gonzalez-Maeso:** “Mouse models of schizophrenia signaling and epigenetics“ BioRAFT 3-year renewal, [REDACTED]. A BSL-2+ study falling under sections III-D-4, III- D-4-a, III-D-4-b, III-D-4-c-(2), III-E-3, and III-F-8 of the NIH Guidelines. The committee discussed the registration, and reviewed the Maeso laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Maeso 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 information in regard to an injection listed. Also, an update to two answers in regard to the natural host range/tropism and gene drive are needed. Lastly, the Maeso lab needs to update an answer in regard to the recombinant or synthetic nucleic acid molecules survey. 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 entity authorized to determine when the registration’s approval conditions were met.
- 2. 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, [REDACTED]. A BSI-2+ study falling under the sections, F-Appendix C-VII, III-D-4, III-D-4-c-(2), III-F-1, and III-F-2 of the NIH Guidelines. The committee discussed the registration, and reviewed the Heise laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Heise 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 some safety training of lab members needed to be completed, the registration needed to be updated to include all rooms and storage spaces being used, the registration’s cell lines table needed to be updated with all cell lines being used, more information is needed in regard to vectors used in the lab and a SOP for the procedure should be uploaded to the ‘Documents’ section, the PI indicated that one project will not move forward, it should be archived, a correction to a fungus used in the lab is needed, edits to the tropism are needed on the viral vector form for pInducer HuSH-20, and on the recombinant or synthetic nucleic acid molecules survey, the registration needs to indicate that they use packaging cells to generate viral particles for transduction. 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 entity authorized to determine when the registration’s approval conditions were met.

- 3. Dr. Xiang-Yang (Shawn) Wang:** “Immune modulation in diseases and therapies” BioRAFT 3-year renewal, [REDACTED]. A BSL-2+ study falling under sections III-D-3, III-D-4-a, III-E-1, and III-F-1 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 registration needed to be updated to include all rooms and storage spaces being used, one project lacks an explanation of experimental details, the Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to reflect the registration’s inclusion of animal models, the plasmid list (under Source Materials) should indicate that two listed are of SARS\_CoV-2 viral origin, the viral vector form for AAV8-TBG-iCre: needs more information about the host range/tropism, updating to indicate animal use, and confirmation that vector/cells transduced by vector will not be injected into live animals, on the viral vector form for Adeno-X Adenoviral Expression System confirmation is needed that the adenovirus injections into tumors will be done in a BSC, on the viral vector form for pLenti-CMVpuro-dest/Lenti sgRNA(MS2)\_zeo/pLKO confirmation is needed in regard to the host range, and on the Viral Vector Registration Form-pLenti-CMVpuro-dest/Lenti sgRNA(MS2)\_zeo/pLKO, indicate if it is a 2nd or 3rd generation system. 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 entity authorized to determine when the registration’s approval conditions were met.
- 4. Dr. Tomasz Kordula:** “Mechanisms of glioma invasion” BioRAFT 3-year renewal, [REDACTED]. A BSL-2+ study falling under sections III-D-4, III-D-4-a, III-D-4-b, III-E, III-F-1, and III-F-2 of the NIH Guidelines. The committee discussed the registration, and reviewed the Kordula laboratory’s BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Kordula 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 the registrations AAV Viral Vector forms could be condensed to cover many of the similar types of AAVs used and the registration needs to be updated to include the genes which will be targeted by sgRNA on the viral vector registration form for CRISPR Cas9 lentivirus. 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 entity authorized to determine when the registration’s approval conditions were met.

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

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

There being no further business before the committee, the meeting adjourned at approximately 2:22 PM. The next IBC meeting is scheduled for 1:00 PM, April 16, 2026.