INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

June 26, 2025, 1:00 PM

[REDACTED]

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. Two full voting members, an alternate voting member, and a nonvoting member were absent. Two full voting members had to leave the meeting early. One voted on five total protocols and one voted on seven. Both voted on the adoption of the Minutes Redaction and Posting Policy. Jimmy Spencer, Associate Director of VCU Environmental Health and Safety, attended as a guest.

II. **Review of minutes from May 15, 2025, meeting:** the minutes from the May 15, 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. Priyo Goswamee**: "*Functional Imaging and Circuit Analysis Using Viral Vectors and Behavioral Models in Mice*" New BioRAFT registration. Conditionally approved 5/15/25. Approval conditions subsequently met and full approval granted.

2. **Dr. Alexander Kenigsberg**: "*A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)*" New clinical trial MUA. Conditionally approved 5/15/25. Approval conditions subsequently met and full approval granted.

3. **Dr. Saul Karpen**: "*SSI Pre-clinical Lab: (1) Iron Overload Study, (2) Liver Fibrosis RESCA study, (3) Biliary Atresia study*" New BioRAFT registration. Conditionally approved 5/15/25. Approval conditions subsequently met and full approval granted.

4. **Dr. Victoria Findlay**: "*The Role of AGEs and MicroRNAs in Normal Development and Cancer Progression*" BioRAFT 3-year renewal. Fully approved 5/15/25.

5. **Dr. Senthil Radhakrishnan**: "*Understanding and targeting NRF-1 mediated proteasome recovery pathway in cancer*" BioRAFT 3-year renewal. Conditionally approved 5/15/25. Approval conditions subsequently met and full approval granted.

6. **Dr. David Turner**: "*The role of advanced glycation end products in cancer*" BioRAFT 3-year renewal. Conditionally approved 5/15/25. Approval conditions subsequently met and full approval granted.

7. **Dr. Jiong Li**: "*(1) BET bromodomain inhibition suppresses tumorigenesis and metastasis of HNSCC; (2) Establish head and neck PDX model; (3) Wnt induced oncogenesis*" BioRAFT 3-year renewal. Conditionally approved 5/15/25. Approval conditions not yet met as of 6/26/25, and as a result full approval not yet granted.

8. **Dr. Elvin Price**: "*(1) Medication Safety and Efficacy in Older People; (2) Translational Pharmacology and Pharmacogenomics*" BioRAFT 3-year renewal. Fully approved 5/15/25.

9. **Dr. Mazhar Kanak**: "*(1) Exosomal interaction between alpha and beta cells; (2) Role of exosome in islet transplantation*" BioRAFT 3-year renewal. Conditionally approved 5/15/25. Approval conditions not yet met as of 6/26/25, and as a result full approval not yet granted.

10. **Dr. Serge Nana-Sinkam**: "*(1) microRNA regulation of exosome release and lung cancer progression; (2) The development of a circulant biomarker for small cell lung cancer diagnosis; (3) Role of Cytoplasmic Capping in Lung Cancer drug resistance; (4) Evaluating for Genetic and Biologic Markers with Epidemiological Impact on the Susceptibility and Severity of Sarcoidosis*" BioRAFT 3-year renewal. Fully approved 5/15/25.

B. rDNA Protocols, New Reviews:

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, [REDACTED]. A BSL-2 clinical trial falling under sections III-C and III-F of the NIH guidelines. The committee discussed the clinical trial, and reviewed the trial's BioRAFT entry as well as additional documents provided by trial staff. The committee unanimously agreed that the documentation provided was sufficient to show that the trial 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 trial full approval without required revisions.

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, [REDACTED]. A BSL-2 expanded access program falling under section III-C of the NIH guidelines. The committee discussed the expanded access program, and reviewed the program's BioRAFT entry as well as additional documents provided by project staff. The committee unanimously agreed that the documentation provided was sufficient to show that the program 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 program full approval without required revisions.

C. Three-Year Renewals/Major Revisions:

1. **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, [REDACTED]. A BSL-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 Lemmon laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Lemmon 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 experimental details and storage locations for all three projects; the description of project #2 needed to be expanded to include a description of how the project would use CRISPR; the registration's equipment section needed to be updated to include documentation and certification details associated with the biosafety cabinet being used; the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to indicate that some of the registration's experiments involve the use of infectious DNA or RNA viruses in tissue culture; the registration's Tissues Table needed to be updated to include all tissues being used; and the registration's lentivirus Viral Vector Registration Form needed to be updated to include tropism details, details of how the lentivirus was being produced, and additional details on PPE to be used when cleaning up spills. 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. Erika Martin**: "*Identifying Hemostatic Assays that are Predictive of Clinical Efficacy in Blood from Hemophiliacs*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2 study listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Martin 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. Yana Cen**: "*(1) Small Molecule Activators of Class III sirtuins; (2) Allosteric Activation of SIRT6 by DNA strand breaks*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2 group of studies falling under sections III-E and III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Cen laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Cen 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 indicate all rooms and spaces being used for experiments and storage, the registration's Bacteria Table needed to be updated to reflect the use of Rosetta cells, several entries on the registration's Plasmids Table needed to be consolidated, and the registration's equipment section needed to be updated to include documentation and certification details associated with the biosafety cabinet being used. 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.

4. **Dr. Amy Lasek**: "*Roles of genes in behaviors related to alcohol addiction*" BioRAFT 3-year renewal, [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 Lasek laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Lasek 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 two laboratory members needed to complete required training modules and the registration's AAV Viral Vector Registration Form needed to be updated to include information on the potential carcinogenic effects of the genes being used and to indicate that proper disinfection

methods would be used in the case of spills such as autoclaving, application of 10% bleach solution, or application of iodine-based disinfectants among other options. 8 of 8 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.

5. **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, [REDACTED]. A BSL-2/ABSL-2 group of studies listed as exempt under the NIH guidelines. The committee discussed the registration, and reviewed the Xu laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Xu 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 one laboratory member needed to complete a required training module, the registration needed to be updated to indicate all rooms and spaces being used for experiments and storage, the registration's experimental details sections needed to be updated to indicate that all work involving pseudomonas aeruginosa would be performed in a biosafety cabinet, and the registration's equipment section needed to be updated to include documentation and certification details associated with the biosafety cabinet being used. 8 of 8 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.

6. **Dr. Jennifer Wolstenholme**: "*(1) Gene manipulation with viral vectors; (2) FMT on initiation of ethanol drinking*" BioRAFT 3-year renewal, [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 Wolstenholme laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Wolstenholme 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 use of infectious or defective

DNA or RNA viruses in tissue culture systems as well as the introduction of less than 2/3 of a eukaryotic viral genome into a non-human vertebrate; the registration's AAV Viral Vector Registration Form needed to be updated to indicate that proper disinfection methods would be used in the case of spills such as autoclaving, application of 10% bleach solution, or application of iodine-based disinfectants among other options; and the registration's experimental details sections needed to be updated to include specific details related to the laboratory's stereotactic brain injections and sealing and to indicate that such applications would only be performed using ABSL-2 precautions. 7 of 7 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.

7. **Dr. Shijun Zhang**: "*(1) Novel NLRP3 inflammasome inhibitors; (2) Development of novel compounds for AD*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2 group of studies falling under section III-E of the NIH guidelines. The committee discussed the registration, and reviewed the Zhang 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, 7 of 7 IBC voters present voted to grant the registration full approval without required revisions.

8. **Bone Engineering Science and Technology Lab (Dr. Henry Donahue)**: "*Determining the Mechanism Behind Bone Cell Transduction*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2+/ABSL-1 study falling under section III-D of the NIH guidelines. The committee discussed the registration, and reviewed the Donahue laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the Donahue 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 experimental details section needed to be updated to provide specific details on how lentiviral vectors would be used; the registration's Recombinant or Synthetic Nucleic Acid Molecules Survey needed to be updated to reflect the use of infectious or defective DNA or RNA viruses in tissue culture systems as well as the introduction of less than 2/3 of a eukaryotic viral genome into a non-human vertebrate; the registration's Plasmids Table needed to be updated to include all plasmids being used; and the registration's lentivirus Viral Vector Registration Form needed to be updated to include details on the vector's production, which genes the vector would be inserting, and what injection-related safety

precautions would be used. 7 of 7 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.

9. **Dr. Andrew George**: "*Characterization of amyloid-β:α7β2-nicotinic acetylcholine receptor interactions relevant to Alzheimer's disease*" BioRAFT 3-year renewal, [REDACTED]. A BSL-2/ABSL-1 study falling under sections III-D and III-E of the NIH guidelines. The committee discussed the registration, and reviewed the George laboratory's BioRAFT entry as well as additional documents provided by laboratory staff. The committee determined that the George 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 ChemTracker entry needed to be updated to include all qualifying chemicals being used, the registration's experimental details section needed to be updated to include the project's IACUC protocol number, the registration's Biological Toxins table needed to be updated with all biological toxins being used, and the safety section of the registration's AAV Viral Vector Registration Form needed to be updated to indicate that the project would not involve expression of oncogenes or toxin-producing genes and that proper disinfection methods would be used in the case of spills such as autoclaving, application of 10% bleach solution, or application of iodine-based disinfectants among other options. 7 of 7 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. In addition, the committee voted to refer the George laboratory's registration to the Institutional Review Entity for review due to its use of conopeptides that did not appear to qualify as select agents due to their molecular structure, but warranted further review to confirm.

10. **Dr. Karen Hendricks-Muñoz**: "*(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 access 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, [REDACTED]. A BSL-2/ABSL-1 group of studies falling under section III-F of the NIH guidelines. The committee discussed the registration, and reviewed the Hendricks-Muñoz 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, 7 of 7 IBC voters present voted to grant the registration full approval without required revisions.

D. Other rDNA Concerns/Administrative Approvals:

1. **Dr. Jonathan Berkman**: "*[HM20032424] CV-HNLC-001: A Phase I Dose-Finding Study to Evaluate Safety and Tolerability of CVHNLC plus Pembrolizumab in Patients with Squamous Non-Small-Cell Lung Cancer (sqNSCLC)*" Review of a novel pharmaceutical product. Administratively approved 5/15/25.

2. **Dr. Khalid Matin**: "*[HM20032325] LB1908-1001: A Phase 1, Open-Label, Dose Escalation and Expansion, Multicenter Study of Claudin 18.2-Targeted Chimeric Antigen Receptor T-cells in Subjects with Unresectable, Locally Advanced, or Metastatic Gastric, Gastroesophageal Junction (GEJ), Esophageal, or Pancreatic Adenocarcinoma*" Review of a novel pharmaceutical product. Administratively approved 5/22/25.

3. **Dr. Jonathan Berkman**: "*ResQ201A: Randomized, Open-Label, Phase 3 Clinical Trial of N-803 Plus Tislelizumab and Docetaxel Versus Docetaxel Monotherapy in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Acquired Resistance to Immune Checkpoint Inhibitor Therapy*" Review of a novel pharmaceutical product. Administratively approved 5/30/25.

4. **Dr. Renato Martins**: "*[HM20033098] BNT327-06: A Phase II/III, Multisite, Randomized Master Protocol for a Global Trial of BNT327 in Combination with Chemotherapy and Other Investigational Agents in First-line Non-small Cell Lung Cancer*" Review of a novel pharmaceutical product. Administratively approved 5/30/25.

5. **Dr. Jonathan Berkman**: "*[HM20032764] BNT327-03: A Phase III, Multisite, Double-blinded Randomized Trial of BNT327 in Combination with Chemotherapy (Etoposide/Carboplatin) Compared to Atezolizumab in Combination with Chemotherapy (Etoposide/Carboplatin) in Participants with First-line Extensive-stage Small-cell Lung Cancer*" Review of a novel pharmaceutical product. Administratively approved 5/30/25.

6. **Dr. Renato Martins**: "*[HM20032908] SMT112-3007: A Randomized, Double-blinded, Multiregional Phase 3 Study of Ivonescimab Versus Pembrolizumab for the First-line Treatment of Metastatic Non-small Cell Lung Cancer in Patients Whose Tumors Demonstrate High PD-L1 Expression (HARMONi-7)*" Review of a novel pharmaceutical product. Administratively approved 6/12/25.

IV. Old Business: N/A

V. New Business:

A. **Minutes Redaction and Posting Policy**: The IBC coordinator reminded the committee that in accordance with NIH notice NOT-OD-25-082, the IBC was expected to start posting minutes on its website for all IBC meetings occurring on or after June 1, 2025. The IBC coordinator indicated that NOT-OD-25-082 required minutes to be posted, "immediately after approval and once all appropriate and allowable redactions have been made." As a result, the IBC required a policy governing the redaction and public posting of its minutes. The committee reviewed and discussed a policy document prepared by VCU personnel containing details on how IBC meeting minutes would be generated, redacted, reviewed, approved, and posted. The committee voted unanimously to adopt the Minutes Redaction and Posting Policy, which took effect immediately following the vote.

There being no further business before the committee, the meeting adjourned at approximately 3:06 PM. The next IBC meeting is scheduled for 1:00 PM, July 22, 2025.