

Institutional Biosafety Committee

910 Madison Avenue, Suite 650 Memphis, TN 38163 Phone: (901) 448-2164 Fax: (901) 448-5222

The University of Tennessee Health Science Center Institutional Biosafety Committee Meeting Minutes Friday, July 11, 2025

I. CALL TO ORDER

IBC Chair Dr. Mark Miller called the regular meeting of the Institutional Biosafety Committee to order at 3:03pm on Friday, July 11, 2025. The meeting was held via a remote Zoom video conference.

II. IBC MEMBERS IN ATTENDANCE

Dr. Mark Miller, Mr. Tim Barton, Dr. Vickie Baselski, Dr. David Hamilton, Ms. Jeannie Johnson, Dr. Kui Li, Dr. Kaushik Parthasarathi, Dr. Brandt Pence, Dr. Lawrence Pfeffer, Dr. Marko Radic, Dr. Jennifer Tate, Dr. Thirumalini Vaithianathan, and Ms. Evelyn Wright-Lewis.

Absent: Dr. Radhakrishna Rao, Dr. Zheng Fan, Dr. Glen Palmer, Dr. Ramesh Ray, and Dr. Bayly Wheeler.

III. OTHERS PRESENT

IV. APPROVAL OF THE MINUTES

The minutes of the June 6, 2025 meeting were unanimously approved with one correction.

V. ANNOUNCEMENTS

VI. REVIEW OF PROTOCOLS:

Renewal Protocol 25-1156: entitled: Engineered Exosomes with scaRNA20 for Hypertrophic Cardiomyopathy. The committee determined that the PI had identified each of the potential hazards associated with the work and had supplied appropriate mitigation protocols to minimize those risks. The committee voted unanimously to approve the protocol pending changes that will be overseen administratively by the IBC chair.

Approved Biosafety Level and Classifications:

BSL-2: for *in vitro* culture and handling of primate-derived cells until the material has been subjected to a decontaminating procedure, and then **BSL-1** thereafter **BSL-1-III-F-4:** for *in vitro* work with tissues collected from mice previously treated

with scRNA20-transfected human-derived exosomes, until the material has been subjected to a decontaminating procedure

ABSL-2: for *in vivo* work involving introduction of exosomes derived from humans that have been transfected with scaRNA into research mice

Renewal Protocol 25-1158: entitled: Transplant Research Institute IBC (recombinant DNA and virus). The committee determined that the PI had not sufficiently described the experimental plan, making it impossible for a complete risk assessment to be performed. The committee voted unanimously not to approve the protocol and to require that the PI make significant changes to the protocol and resubmit for full committee review at an upcoming meeting.

Renewal Protocol 25-1159: entitled: Pathogenesis of mycobacteria and therapeutic development for tuberculosis. The committee determined that the PI had identified each of the potential hazards associated with the work and had supplied appropriate mitigation protocols to minimize those risks. The committee voted unanimously to approve the protocol pending changes that will be overseen by the IBC chair.

Approved Biosafety Level and Classifications:

BSL-1: for *in vitro* handling of cells derived from non-primates

BSL-2: for *in vitro* culture and handling of primate-derived cells and for culture and handling of non-tuberculosis strains of *Mycobacterium, Staphylococcus aureus*, and *Psuedomonas spp.* until the material has been subjected to a decontaminating procedure, and the **BSL-1** thereafter

BSL-3: for *in vitro* culture and handling of primate-derived cells and for culture and handling of non-*tuberculosis* strains of *Mycobacterium*, until the material has been subjected to a decontaminating procedure, and the **BSL-1** thereafter

BSL-1/III-D-2-a: for *in vitro* work involving the use of lab-adapted E. coli, recombinant plasmid DNA, and/or synthetic nucleic acids for expression/manipulation of non-hazardous transgenes

BSL-1/III-D-2-a: for *in vitro* work involving transfection of cells derived from non-primates with expression plasmids engineered to express non-hazardous transgenes

BSL-2/III-D-2-a: for *in vitro* work involving the use of expression plasmids to express non-hazardous transgenes in eukaryotic cells that will then be infected with non-tuberculosis strains of *Mycobacterium*

BSL-3/III-D-2-a: for *in vitro* work involving the use of expression plasmids to express transgenes in eukaryotic cells that will then be infected with various strains of *Mycobacterium tuberculosis*

ABSL-3/III-D-4b: for *in vivo* work involving infection of research mice with *Mycobacterium tuberculosis*

Renewal Protocol 25-1160: entitled: Mechanism of MYB in fetal hemoglobin induction. The committee determined that the PI had identified each of the potential hazards associated with the work and had supplied appropriate mitigation protocols to minimize those risks. The committee voted unanimously to approve the protocol pending changes that will be overseen administratively by the IBC chair.

Approved Biosafety Level and Classifications:

BSL-2: for *in vitro* culture and handling of primate-derived cells, until the material has been subjected to a decontaminating procedure, and the **BSL-1** thereafter

BSL-1/III-D-2-a: for *in vitro* work involving the use of lab-adapted E. coli, recombinant plasmid DNA, and/or synthetic nucleic acids for expression/manipulation of non-hazardous transgenes

BSL-2/III-D-2-a: for *in vitro* work involving the use of lab-adapted E. coli, recombinant plasmid DNA, and/or synthetic nucleic acids for expression/manipulation of hazardous transgenes

BSL-2/III-D-3-a: for *in vitro* work involving propagation of recombinant AAV, adenoviral or lentiviral vectors using primate-derived cells and for transduction of primate-derived cells with these recombinant vectors until the material has been subjected to a decontaminating procedure, and then **BSL-1/III-D-3-a** thereafter

ABSL-1/III-D-4b: for *in vivo* work involving introduction of recombinant AAV vectors engineered to express non-hazardous transgenes into research animals

ABSL-2/III-D-4b: for *in vivo* work involving introduction of recombinant AAV vectors engineered to express hazardous transgenes into research animals

Renewal Protocol 25-1161: entitled: Studies on MicroRNAs and human cancer cells. The committee determined that the PI had identified each of the potential hazards associated with the work and had supplied appropriate mitigation protocols to minimize those risks. The committee voted unanimously to approve the protocol pending changes that will be overseen administratively by the IBC chair.

Approved Biosafety Level and Classifications:

BSL-2: for *in vitro* culture and handling of primate-derived cells, until the material has been subjected to a decontaminating procedure, and the **BSL-1** thereafter **BSL-2-III-F-4:** for *in vitro* work involving samples collected from in study mice that have received human-derived tumor cells and miRNA treatments, until the material has been subjected to a decontaminating procedure, and the **BSL-1-III-F-4** thereafter

ABSL-2: for *in vivo* work involving introduction of cells derived from primates and miRNA into research mice

- VII. IBO REPORT
- VIII. OLD BUSINESS
 - IX. NEW BUSINESS
 - X. MISCELLANEOUS
 - XI. ADJOURNMENT

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Dr. Miller adjourned the meeting at 4:19pm.

XII. NEXT MEETING

The next meeting is tentatively scheduled for Friday, August 1, 2025 at 3:00 PM via a Zoom video conference call.

Minutes Prepared by: John M. Denton Minutes Reviewed by: Dr. Mark Miller