

Institutional Biosafety Committee
University of Arizona
September 16, 2026
Zoom
10:00AM – 11:00AM
Meeting Minutes

Members' Present: Dr. Michael Riehle, Dr. David Besselsen, Ceasar Ramirez, Dr. Kathryn O'Connell, Hien Trinh, Patricia Gundy, Jennifer Uhrlaub,

Non-members' Present: None.

Members Absent: Lauren Melcher, Dr. Jonathan Sexton, Dr. Lynn Stone, Dr. Anita Koshy, Dr. Mrinalini Kala, Marcy Milbrandt, Dr. Judith Brown

The meeting was called to order at 10:01 AM

1. Review of the previous meeting minutes: August 19, 2026
2. Biosafety Level 1 (Non-Exempt-rNucleic Acid) Application
 - a. Xia Xiao, PhD, CoM-PHX- Basic Medical Sciences, Approval No. 11123
Protocol Title: Use AAV to treat fibrosis
Agents: Recombinant Adeno-Associated Virus (replication deficient), Tissue (mouse)

This protocol falls under NIH Guidelines Section III-D-4-a.

The Committee provisionally approved this protocol but is requesting the following revisions to protocol:

- Revise Section 5 to ensure consistency with animal facility protocols regarding hazardous bagging and solid waste and PPE disposal.
- Ceasar will also edit the use of centrifuges and biosafety cabinets in Section 3 of protocol application.

Please email your responses to Ceasar Ramirez at cramirez82@arizona.edu.

3. Biosafety Level 2 (Non-Exempt-rNucleic Acid) Application
 - a. Jing-Ping Lin, PhD, Physiology, Approval No. 12516
Protocol Title: Molecular and Cellular Analysis of Demyelination and Remyelination in Experimental Models of Multiple Sclerosis
Agents: Marmoset/mouse brain tissue, organs, Cell lines (marmoset/mouse), Cell lines (Human), AAV vectors (replication deficient)

This protocol falls under NIH Guidelines Section III-D-1-a

The Committee approved this protocol.

4. Human Subjects

- a. Igor Kozak, MD, PhD, University of Arizona, Ophthalmology and Vision Science

Protocol Title: A Randomized, Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age-Related Macular Degeneration (nAMD)

Product: ABBV-RGX-314 (AAV8 vector)

Biosafety Level: 1

The Committee approved this protocol.

- b. Cori Daines, MD, Asthma and Airway Disease Research Center

Protocol Title: An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis - 4D-710-C001"

Product: 4D-710 (AAV capsid variant)

*This is an amendment (see amendment summary). IBC must review since there is a dose change found on page 5 of amendment summary.

The Committee approved the amendment to this protocol.

5. Advisements

- a. Melville Wohlgemuth, PhD, Neuroscience, Approval No. 12410

Protocol Title: Modeling Natural Processes of Sensing and Action Through Studies of the Echolocating Bat

Agents: Cholera Toxin Subunit B (<https://www.thermofisher.com/order/catalog/product/C34777>)

The Committee approved of the adding of this agent but wants Dr. Wohlgemuth to update the explanation to state that it is non-hazardous because this subunit is inactive rather than being non-toxic.

6. Compliance Review Issues

- a. The audit report for August- September 2026
b. Incident(s): None.

7. Old Business

- a. Dr. Song's response- see updated protocol with edits requested

- Dr. Song still needs to update his protocol to take out "when applicable."

- b. Mouth pipetting- already approved for CoM-Phoenix lab, need to approve for GEMM Core. Dr. Georgieva is the PI.

- The Committee approved this request; therefore, approving mouth pipetting for embryo transfer.

- c. Dr. Maldonado's response

- PI responded after agenda was sent out but BSO notified the Committee that she agreed to the edits to her protocol request by the IBC at August's meeting.

- d. Dr. Chen's MERS protocol

- BSO stated that he is working with the CAF facility to meet CDC's recommendations for the import permit by the deadline of October 8.

8. New Business

a. NIH update

- BSO provided a columned explanation showing the changes that may need to be implemented if the NIH policies are finalized and accepted. BSO mentioned that the real new burden for the IBC for the implementation will be the reviewing and renewing of protocols every 3 years, past and present. BSO mentioned that the NIH will be providing templates for IBC minutes and incident reporting.

b. Gain of Function update

- BSO explained that the new policy will require all pre-submitted and post-awarded protocols of “life sciences” to be reviewed by an IRE committee and signed off by an ICDGOF before federal funding can be submitted, with implementation required by January 2027.

The next meeting is scheduled for October 21, 2026, for via Zoom.

The meeting was adjourned at 10:43AM.

Prepared by: Ceasar Ramirez

Reviewed by:

A handwritten signature in blue ink, appearing to read "Michael Riehle".

Michael Riehle, PhD
Chair, Institutional Biosafety Committee