



Institutional Biosafety Committee
University of Arizona
September 17, 2025
Zoom
10:00AM – 11:00AM
Meeting Minutes

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

Non-members’ Present: Marcy Milbrandt

Members Absent: Rhonda Evans, Dr. Samuel Campos, Dr. Jonathan Sexton. Dr. Lynn Stone, Dr. Anita Koshy, Dr. Mrinalini Kala, Lauren Melcher

The meeting was called to order at 10:00 AM

1. Review of the previous meeting minutes: August 20, 2025
 - Edited Marcy Milbrandt’s name to reflect correct spelling
 - Added “replication deficient” to Pseudorabies virus (PRV) per Dr. Besselsen’s request
2. Human Subjects
 - a. David Sherman, MD, Neurology
Protocol Title: A Phase II, Multicentre, Randomised, Double-blind, Parallel-Group, Placebo-controlled Study to Evaluate the Efficacy and Safety of IPN10200 as a Treatment for Cervical Dystonia in Adult Participants
Product: IPN10200

Recommended biosafety level: BSL1

The Committee granted full approval.
 - b. Geoffrey Block, MD, Thomas D. Boyer Liver Institute
Protocol Title: A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of efruxifermin in subjects with non-cirrhotic nonalcoholic steatohepatitis (nash)/metabolic dysfunction-associated steatohepatitis (mash) and fibrosis.
Product: Efruxifermin (EFX)

Recommended biosafety level: BSL1

The Committee granted full approval.

3. Compliance Review Issues

- a. The audit report for August- September 2025
- b. Incident(s): None

4. Human Subjects

- b. Geoffrey Block, MD, Thomas D. Boyer Liver Institute
Protocol Title: a phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of efruxifermin in subjects with compensated cirrhosis due to nonalcoholic steatohepatitis (nash)/metabolic dysfunction-associated steatohepatitis (mash)
Product: Efruxifermin (EFX)

Recommended BSL: 1

The Committee granted full approval.

5. Old Business

- a. Dr. Kim's response- see attached email
 - Committee members were satisfied with the response provided by Dr. Kim.
- b. Dr. Huntoon's response- see attached email
 - Committee members were satisfied with the response provided by Dr. Huntoon.
- c. Dr. Hu's update- see attached email, Ceasar meeting with Dr. Hu.
 - Committee members were satisfied with the update provided by Dr. Hu.
 - BSO also provided information about the laboratory walkthrough with Dr. Hu in September.
 - Dr. Brown provided information on the laboratory meeting with Dr. Hu and his workers, which was completed on September 4th, 2025.
 - The Committee is requiring Dr. Hu and his workers to attend the 6th month meeting with Dr. Brown's group, and any subsequent meeting(s) would be voluntary.

6. New Business

- a. NIH Initiative
 - BSO provided the latest report on the NIH Initiative, with further information to come as released by the NIH.
- b. BSL3/CDC Import Permit
 - The Committee was given information about the recent issues with the CDC Import Permit for MERS by the BSO. Jennifer Uhrlaub shared with the Committee that the other BSL3 facility can be used for MERS but that the PI would have to update the CDC Import Permit.

The next meeting is scheduled for October 15, 2025, via Zoom.

The meeting was adjourned at 10:25AM.

Prepared by: Ceasar Ramirez

Reviewed by:

A handwritten signature in blue ink, appearing to read "Michael Riehle". The signature is fluid and cursive, with the first name "Michael" and last name "Riehle" clearly distinguishable.

Michael Riehle, PhD
Chair, Institutional Biosafety Committee