

LBRI Institutional Biosafety Committee Meeting Minutes
2425 Ridgecrest Drive SE, Albuquerque, NM 87108
Conducted via Zoom
November 11, 2025

Members in Attendance:

David Revelli (Chair)
Dale Mack (Vice Chair)
Debra Sharpe (BSO/RO)
Adriana Kajon
Nancy Davis
Carin Kelley
Richard Conn
Ted Sanders
Rene Matison
Annette Breer

Members Absent:

Rhonda Peyton (ARO)

Call to Order:

The meeting was called to order by the Chair Dr. David Revelli at 11:07 a.m.

I. Review of the August 12, 2025 Meeting Minutes will be reviewed during the October regularly scheduled meeting.

Aug 12, 2025 minutes were provided in advance. Motion to approve as written (Mack/Davis) Conn abstains minutes pass with a few pointed corrections

Only a special September meeting was conducted, minutes were provided in advance. Motion to approve as written (Revelli/Kajon)

No October meeting

II. Old Business

None at this time.

III. New Business

FY25-152 AAV9-MMAB: GLP Three to Six Month Toxicity Study with Biodistribution Following a Single Intravenous Injection in mice, the study director gave a brief explanation of the protocol; Isolated methylmalonic acidemia (MMA) is a group of heterogenous metabolic disorders caused by complete or partial deficiency of the mitochondrial enzyme methylmalonyl-CoA mutase (MMUT); a defect in the transport or synthesis of its cofactor, 5'-deoxyadenosylcobalamin; or deficiency of the enzyme methylmalonyl-CoA epimerase. These mitochondrial matrix enzymes are responsible for the metabolism of methylmalonyl-CoA to succinyl-CoA, and mutations in the genes that encode for the respective enzymes can lead to elevations of methylmalonic acid in the blood and urine. Patients with the cobalamin B type of MMA experience severe symptoms, which can appear in early infancy or the first year of life, of acid-base imbalance, high levels of ammonia, lethargy, vomiting, dehydration, hypotonia and delayed development. Long-term complications can include kidney disease, pancreatitis, cytopenias and neurological damage from metabolic strokes of the basal ganglia. The current treatment for MMAB MMA is dietary restriction of protein, vitamin B12 given as an injection, carnitine and intermittent antibiotics. There is no cure for the cobalamin B type of MMA. Despite medical and dietary management, patients with MMAB MMA can experience significant medical complications, underscoring the need for new therapies. Preclinical AAV gene therapy has been used successfully to treat mouse models of MMA caused by mutations in a related gene (MMUT) and, by extension, is predicted to be equally effective for the treatment of the cobalamin B type of MMA. The sponsor has been developing a new AAV9 gene therapy that replaces the deficit in MMAB. The proposed study is designed to evaluate the safety and biodistribution of the AAV9-MMAB gene therapy. To do this, mice will be administered the test article by intravenous injection and observed for up to 180 days for clinical pathology, biodistribution, mortality, clinical signs, body weight and have a functional observational battery testing conducted to inform on potential toxicity. Q&A with discussions ensued, suggestions for some changes were made. Motion to pass with corrections (Mack/Revelli) pass with the minor changes suggested.

IV. Standing Reports

a. Security Reports

None to report

b. Laboratory Incidents

None to report

c. ABSL-3 Facility Inspection

None to report

d. Agents and Toxins Inventory

None to report

V. Other Business

None to report

Adjourn

There being no further business to conduct at this time, meeting adjourned at 11:37 a.m.

Next Meeting

The next regularly scheduled meeting of the LBRI Institutional Biosafety Committee is scheduled to occur on Tuesday, December 9, 2025 at 11:00 a.m.

Respectfully submitted,

David Revelli, Ph.D.
Chairman, IBC Committee

Date

Annette Breer
Recording Secretary

Date