Meeting Minutes

Institution:	Tribe Clinical Research at Parkside Pediatrics, Harrison Bridge Road
Meeting Date:	March 19, 2026
Meeting Time	12:30 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Campbell, Mark / Yes / Core Member: Biosafety Expert/HGT Expert Gansauer, Lucy J / Yes / Local Unaffiliated Member Hauke, Caitlyn A. / Yes / Chair: Biosafety Expert/HGT Expert Kirkland, Cindy / No / Site Contact - Rostered Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Weathers, Jo / Yes / Local Unaffiliated Member
Invited Members Not in Attendance:	None
Guests:	Cablay, Alyssa Oppatt, Jenna Mercer, Carole
Staff:	Mahrt, Elena Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 12:32 PM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: None

New Business:

PI:	Mercer, Carole MD
Sponsor:	Blue Lake Biotechnology Inc.
Protocol:	BLB-201-002: A Phase 1/2a Trial of the Safety, Tolerability, and Immunogenicity of PIV5-vectored RSV Vaccine (BLB-201) in RSV Seronegative and Seropositive Infants and Children
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: BLB-201-002 is a Phase I/IIa, randomized, placebo-controlled trial sponsored by Blue Lake Biotechnology Inc. and designed to evaluate the safety, tolerability, and immunogenicity of CPI-RSV-F (BLB-201) as a Respiratory Syncytial Virus (RSV) vaccine in seropositive and seronegative infants (8 to 24 months of age) and children (18 to 59 months of age). CPI-RSV-F is a live recombinant parainfluenza virus 5 (PIV5) expressing the fusion protein from RSV. The investigational product (IP) is administered by intranasal administration.

Biosafety Containment Level (BSL): The study agent CPI-RSV-F consists of a recombinant version of a parainfluenza virus type 5 containing more than 2/3 of the native genome. To date, PIV5 has not been associated with human disease and therefore reasonably meets the definition of a Risk Group 1 organism for which Biosafety Level 1 may potentially be considered. However, due to the communicability of the agent to both humans and a wide range of animals, potential pathogenicity of the agent in canine populations, and special considerations for restricting access to animals where the study agent is handled, Biosafety Level 2 containment may also be considered. This agent is administered in a clinical setting requiring compliance with OSHA Bloodborne Pathogen Standard.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills, splashes, or aerosols of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Site confirmed that the IP Room is a separate room from the TCR Office. The Committee had no concerns.
  - The Site confirmed that the ultra-low freezer has not yet been received from the sponsor. The Committee stipulated that once installed, a photo of the ultra-low freezer labeled with a biohazard sticker be provided.
  - The Committee discussed the sink with plumbed eyewash in the 1st Floor Lab and noted that it appeared cluttered with extraneous materials that could inhibit access to the eyewash. The Site confirmed that some of the extraneous materials can be removed. The Committee also recommended regular disinfection practices be put in place to decontaminate the sink. The Committee stipulated that an updated photo of the 1st Floor Lab sink with extraneous materials removed be provided.
  - The Committee discussed the split A/C units in the 2nd Floor, IP Room and recommended that the units be cleaned and maintained regularly to reduce potential for room contamination. The Committee had no further concerns.
  - The Site confirmed that there is carpeting in the clinical hub area outside the 1st Floor Lab area, but all agent handling activities take place in rooms without carpeting. The Committee had no further concerns.
  - The Site confirmed that the bathrooms with sinks that will be used for handwashing outside the 2nd Floor IP Prep room are restricted to staff access only. The Committee had no concerns.
  - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. At the specific request of the Site, the Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - The Committee stipulated that once installed, a photo of the ultra-low freezer labeled with a biohazard sticker be provided by 4/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that an updated photo of the 1st Floor Lab sink with extraneous materials removed be provided by 4/19/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 1:11 PM

Post-Meeting Pre-Approval Note: None