Meeting Minutes

Meeting Date:	June 27, 2025 1:00 PM Mountain Time
Meeting Place:	Teleconference (Remote) Meeting Open to Public
Members in Attendance:	Anderson, Curtis Andrews, Dalan AS Campbell, Mark Noriea, Nicholas Ostrom, Lee Rastein, Daniel
Members Not in Attendance:	None
Guests:	McGuiness, Casey
Staff:	Mahrt, Elena
Institution:	Clinical Research Prime Rexburg LLC

Call to Order: The meeting was called to order at 12:41 PM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC.

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Baker, Jeffrey MD
Sponsor:	Blue Lake Biotechnology Inc. - BLB-201-002
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:	Annual Review
NIH Guidelines:	III-C

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), a live recombinant parainfluenza virus 5 (PIV5) expressing the fusion protein from Respiratory Syncytial Virus (RSV), as an RSV vaccine in seropositive and seronegative infants (6-24 months of age) and children (18 to 59 months of age).

Biosafety Containment Level per Risk Assessment: BSL-1 Plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report 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 Committee discussed the Facility Details Form (FDF) that describes study agent preparation as occurring only in the BSC. The form will be administratively revised to reflect that the Committee previously approved preparation in both the BSC in the BSC room and the benchtop in the Lab. The Site confirmed that benchtop preparation in the Lab is only used when necessary. The FDF and Site Map & Photos document will be administratively revised to correct typos and room names.
    - The Site confirmed the ultralow freezer, labeled with a biohazard sticker, will be used for storage of this study agent and is in the room directly across the hall from the BSC room, called IP Storage Room. The Site will provide photos of this room and the storage unit. The Committee had no concerns with administratively updating the Site Map & Photos document to include photos of the ultralow freezer in the IP Storage Room.
    - The Committee discussed the BSC report and noted that the Biosafety cabinet type is listed as "A3". The BSC model type is likely an A2. Sabai will provide the Site with language to provide the certifying vendor at the next certification. The Committee noted that this clerical item does not impact the integrity of the testing completed or certification provided.
    - 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 Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Meeting Minutes

Adjournment: 1:22 PM

Post-Meeting Pre-Approval Note: None