

Meeting Minutes



Institution:	DM Clinical Research - Kool Kids Pediatrics		
Meeting Date:	October 01, 2026		
Meeting Time	3:00 PM Central Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	Member	Voting	Member Type
	Bavaret, Tammy	Yes	Chair: Biosafety Expert/HGT Expert
	Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
	Kotkar, Shalaka	Yes	Local Unaffiliated Member
	Zuno, Vicente	Yes	Local Unaffiliated Member
	Trier, Miranda	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Guests:	Gonzales, Vanessa		
Staff:	Payne, Kaylie		

Call to Order: The IBC Chair called the meeting to order at 3:03 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

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New Business:

PI:	Ali, Kashif
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), 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 and children. The investigational product (IP) is administered intranasally.

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 or splashes 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.

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- 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 Committee discussed that the study could be approved at BSL-1 plus standard precautions or BSL-2. At the request of the Site, BSL-1 plus standard precautions were approved which is consistent with biocontainment requirements for the agent based on the Risk Assessment.
 - The Committee discussed the risks of shedding after administration and asked if caregivers are given information on their risks of exposure. The Site agreed to gather additional information and update the Committee accordingly.
 - The Site confirmed that they do not have a plumbed eyewash on Site and have disposable eye wash bottles available where the study agent is present. The Committee encouraged the Site to consider installing a plumbed eyewash station.
 - The Committee discussed the exposure and spill response procedures listed in the Clinical Biosafety Manual.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

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

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 3:49 PM

Post-Meeting Pre-Approval Note: None