

## Meeting Minutes

<b>Meeting Date:</b>	June 27, 2025 at 12:00 PM Mountain Time	
<b>Meeting Place:</b>	Teleconference (Remote) Meeting Open to Public	
<b>Members in Attendance:</b>	Andrews, Dalan AS	
	Campbell, Mark	
	Noriea, Nicholas	
	Ostrom, Lee	
	Rastein, Daniel	
	Anderson, Curtis	
<b>Members Not in Attendance:</b>	None	
<b>Guests:</b>	Casey McGuinness	
<b>Staff:</b>	Elena Mahrt	
<b>Institution:</b>	Clinical Research Prime Idaho Falls, LLC	

**Call to Order:** The meeting was called to order at 12:02 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:

<b>PI:</b>	Baker, Jeffrey MD
<b>Sponsor:</b>	ModernaTX, Inc.
<b>Protocol:</b>	mRNA-1647-P104: A Phase 1/2a Open-Label Dose-Ranging and Observer-Blind Placebo-Controlled, Safety and Immunogenicity Study of mRNA-1647 Cytomegalovirus Vaccine in Female and Male Participants 9 to 15 Years of Age and Participants 16 to 25 Years of Age
<b>Review Type:</b>	Annual Review
<b>NIH Guidelines:</b>	III-C

**Trial Summary:** mRNA-1647-P104 is an observer-blind, placebo-controlled Phase 1/2a study sponsored by ModernaTX, Inc. and designed to assess the safety, reactogenicity, and efficacy of mRNA-1647, a messenger RNA-liposome complex encoding six Cytomegalovirus (CMV) antigens, as a recombinant CMV vaccine in healthy participants 9 to 15 years of age who are CMV-seronegative or seropositive.

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

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### 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 Site confirmed that plumbed eyewash stations are flushed regularly, and the date of testing documented. A note will be administratively added to reflect this practice in the Site Map & Photos document. 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.
  - The Site confirmed that a device visible on the benchtop in an administration room is a length board. In addition, the Site confirmed that Exam Rooms 2 and 4 have the same layout and safety features. The eyewash bottles depicted in the photos have been removed and replaced with plumbed eyewash attachments on the sinks.
  - The Site confirmed that they will remove any live plants in the study agent handling areas. The Site Map & Photos document will be administratively updated to reflect this.
  - The Committee recommended the best practice of placing the Exam Room sharps container in a holder that prevents it from tipping over. The Site confirmed they could follow this recommendation.

**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.

**Adjournment:** 12:41 PM

**Post-Meeting Pre-Approval Note:** None