Meeting Minutes

Institution:	Research Centers of America, LLC		
Meeting Date:	March 05, 2026		
Meeting Time	9:30 AM 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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Marino, Irene	Yes	Local Unaffiliated Member
	Cocco, Emiliano	Yes	Local Unaffiliated Member
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Palmer, Karenda	No	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	None	N/A	N/A
Guests:	None		
Staff:	Poole, Jessica		

Call to Order: The IBC Chair called the meeting to order at 9:34 AM. 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

Meeting Minutes

Previous Meeting Minutes: Minutes from 9/30/2025 were approved by the IBC with no changes. There were no votes against and no abstentions.
New Business:

PI:	Shapiro, Craig
Sponsor:	ModernaTX, Inc.
Protocol:	mRNA-1273-P403 A Phase 3b/4, Open-label Study to Assess the Immunogenicity and Safety of mRNA COVID-19 Variant-containing Vaccine Formulations
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: mRNA-1273-P403 is an open-label, Phase IIIb/IV study sponsored by ModernaTX, Inc. and designed to evaluate the safety and immunogenicity of variant-containing formulations of the mRNA COVID-19 vaccine. The investigational product (IP) is administered by IM injection.

Biosafety Containment Level (BSL): mRNA-1273 variant-containing formulations consists of non-infectious synthetic mRNAs that are not associated with disease in healthy adults. The mRNAs are incapable of replication and do not express a known hazardous transgene(s). Therefore, BSL-1 containment may be considered as the minimum biocontainment level when handling these study agents.

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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.
    - 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 contact's Blood Borne Pathogen training is expiring on March 17, 2026. The Site contact confirmed that the yearly Blood Borne Pathogen training has been completed and will send the most up to date certificate to Sabai today.

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 9:52 AM

Post-Meeting Pre-Approval Note: None