Meeting Minutes

Meeting Date:	July 18, 2025 at 9:00 AM Eastern Time
Meeting Place:	Teleconference (Remote)
Members in Attendance:	Hauke, Caitlyn Rastein, Daniel Campbell, Mark Marino, Irene Cocco, Emiliano
Members Not in Attendance:	Piedra, Terry
Guests:	Palmer, Karenda
Staff:	Poole, Jessica
Institution:	Research Centers of America, LLC

Call to Order: The meeting was called to order at 9:00 AM. 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:	Rondon, Juan, MD, JD, CPI, FCLM, Esq.
Sponsor:	Pfizer Inc.
Protocol:	C5211001
	A Phase 1, Randomized, Double-Blind, Third-Party–Unblinded Study to Evaluate the Safety and Tolerability of a Vaccine Against E coli in Healthy Adults
Review Type:	Initial Review
NIH Guidelines:	III-C

Trial Summary: C5211001 is a Phase I, randomized, double-blind, third-party–unblinded study sponsored by Pfizer Inc. and designed to evaluate the safety and tolerability of the study agent E. coli FimH modRNA vaccine and other vaccine components for the prevention of invasive Escherichia coli (E coli) disease (IED) in healthy adults.

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, 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.
    - According to the Facility Details Form, the Site does not have a sink in Exam Room 11, but uses a central sink. The Committee asked if it is notated that personnel will use hand sanitizer before leaving the exam room. This Chair confirmed this information is provided in the Site Checklist. The Committee had no additional questions or concerns.
    - The Committee discussed that some of the exam room photos do not include the biohazard waste container in the photo. The Site photos will be administratively updated to add a statement that biohazard waste containers are located in the rooms but are not present in the pictures.

Motion: A motion of Full Approval for the study at BSL-1 plus Standard Precautions 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: 9:23 AM

Post-Meeting Pre-Approval Note: None