Meeting Minutes

Institution:	Forward Clinical Trials, LLC dba ForCare Clinical Research		
Meeting Date:	August 10, 2026		
Meeting Time	2:00 PM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	[redacted]	[redacted]	[redacted]
	Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Schofield, Elizabeth	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Gasper, Brittany	Yes	Local Unaffiliated Member
Guests:	[redacted]		
Staff:	Mahrt, Elena		

Call to Order: The IBC Chair called the meeting to order at 2:01 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: Minutes from 08/11/2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Forman, Seth MD
Sponsor:	[redacted]
Protocol:	[redacted] A Phase I/II, randomized, placebo-controlled, multi-arm, dose-finding study to evaluate the safety, efficacy and immunogenicity of an acne mRNA vaccine candidate in adults with moderate to severe acne 18 to 45 years of age.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: [redacted] is a first-in-human (FIH), dose-finding, multi-center Phase I/II trial sponsored by [redacted] and designed to assess the evaluate the safety, efficacy and immunogenicity of the Acne mRNA vaccine candidate in adults aged 18 to 45 years with moderate to severe acne. The Acne mRNA vaccine candidate is composed of [redacted] The investigational product (IP) is administered by intramuscular (IM) injection.

Biosafety Containment Level (BSL): The Acne mRNA vaccine candidate consists of non-infectious and non-replicative synthetic nucleic acids complexed within a LNP. The mRNAs also do not encode for known hazardous transgenes. Therefore, BSL-1 containment can be considered for handling the Acne mRNA vaccine under the NIH Guidelines. Administration of the study agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens (BBP) Standard (29 CFR 1910.1030).

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 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 participants will remain in the dosing room for the study agent dosing dwell period.
  - The Site confirmed the location of storage and preparation on the Site Map. The Site Map will be administratively revised to clarify storage and preparation.
  - The Committee noted that the Biosafety Cabinet (BSC) in the Pharmacy was not labeled with a biohazard symbol and stipulated that one be applied and an updated photo provided. The Site confirmed that a biohazard sticker or sign could be applied to the BSC during study agent preparation.
  - The Committee discussed the stacked biohazard waste boxes in the Biohazard Waste Storage room and reminded the Site that the containers should be appropriately sealed once full and not stacked. The Committee noted that if containers must be stacked, it should be done in such a manner as to prevent tippage or spillage. The Site confirmed that cardboard biohazard waste boxes are sealed when full and provided an updated photo during the meeting of the cardboard biohazard waste boxes showing that they are not stacked and they are kept lidded during use. The Site Map + Photos document will be administratively revised to reflect include this photo.
  - The Site confirmed that non-sharps biohazardous waste is disposed of in a red, leak proof, foot pedal operated lidded, biohazardous waste container lined with a red biohazard bag in the Pharmacy, similar to the container depicted in the dosing room. The Site Map + Photos document will be administratively revised to reflect this practice. The Committee had no concerns.

Motion: A motion of Approval with Stipulations 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:

- The Committee stipulated that a biohazard symbol be applied via a sticker or sign to the Biosafety Cabinet (BSC) in the Pharmacy and an updated photo provided by 09/10/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 2:35 PM

Post-Meeting Pre-Approval Note: None