Meeting Minutes

Institution:	The Cystic Fibrosis Institute
Meeting Date:	October 30, 2025
Meeting Time	10:00 AM 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
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Reed, Craig (left at 10:12 AM CT)	Yes	Core Member: Biosafety Expert/HGT Expert
Helm, Allen	Yes	Local Unaffiliated Member
Bivona, John	Yes	Local Unaffiliated Member
Roszko, Karolina	No	Site Contact

Invited Members Not in Attendance:	None
Guests:	None
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 10:04 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

Previous Meeting Minutes: Minutes from 12-17-24 were approved by the IBC with no changes.

New Business:

Meeting Minutes

PI:	Boas, Steven
Sponsor:	Arcturus Therapeutics, Inc.
Protocol:	ARCT-032-02 A Phase 2, Open-label, Multiple Ascending-Dose Study to Evaluate the Safety, Tolerability and Efficacy of ARCT-032 in People with Cystic Fibrosis
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ARCT-032-02 is a Phase 2, open-label, multicenter, multiple -ascending dose study sponsored by Arcturus Therapeutics Inc. and designed primarily to evaluate the safety and tolerability of ARCT-032 in adults with Cystic Fibrosis (CF). ARCT-032 consists of a mutation-agnostic mRNA encoding the full-length CF transmembrane conductance regulator gene (CFTR) and complexed in a lipid nanoparticle for topical delivery by aerosolization to the airways. The investigational product (IP) is administered by Inhalation with PARI eFlow® nebulizer.

Biosafety Containment Level (BSL): The study agent ARCT-032 consists of RNA-liposome complex that is not associated with disease in healthy human adults equivalent to a Risk Group 1 (RG1) organism, therefore BSL-1 containment is recommended under the *NIH Guidelines*. Administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens 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. 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.
  - In response to a question from the Committee, the Site confirmed that disposable eyewash bottles are transferred with the IP and are present in the room during dosing. The Committee recommended that the Site consider installing a plumbed eyewash station when the next renovation is feasible.
  - In response to a question from the Committee, the Site confirmed that the Biohazard Sign is posted on the administration room door and the door is kept closed during administration.
  - The Committee noted that the Biohazard Waste container is overfull and recommended that the Site instruct personnel not to overfill the box and send Sabai an updated photo of the box.
  - The Committee discussed the safety features of the PARI eFlow® nebulizer and the use of face masks versus N95s by support personnel when administering the IP. The Committee noted that the nebulizer handset/hand-held unit has a one-way inspiratory valve and one-way exhalation filter to capture and prevent aerosol exposure to the surrounding air. The Committee noted that face masks should be mandatory, but recommended the optional use of N95s.
  - The Committee noted that it is best practice to prepare the IP in a BSC for both product and personnel protection and acknowledged that the Site does not have a BSC but does have a table top laminar flow hood. The Site indicated that the Sponsor and FDA insisted that, at minimum, a laminar flow hood must be used for IP preparation. The Committee discussed the practice of using the laminar flow hood instead. The Site acknowledged that use of a laminar flow hood with the blower on presents a hazard to the preparer and indicated that the laminar flow hood is used in the off position as an isolated preparation area. The Committee agreed with this practice.
  - In response to a question from the Committee, the Site confirmed that staff are trained to keep the laminar flow hood off during preparation. The Committee recommended that the Site place a sign on the laminar flow hood and the Site had no concerns.
  - In response to a question from the Committee, the Site confirmed that the cardboard biohazard waste container is where the biohazard waste is collected from other locations and picked up by the vendor.
  - In response to a question from the Committee, the Site confirmed that the plastic on the carpet adheres directly to the carpet and does not stick to shoes. The Committee suggested that the Site consider removing the carpet when the next renovation is feasible.

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 10:55 AM

Post-Meeting Pre-Approval Note: None