

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, March 18, 2026  
**Time:** 9:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Children's National Research Institute of Children's National Medical Center, Washington, DC  
**Principal Investigator:** Anastassios Koumbourlis, MD  
**Protocol:** Arcturus Therapeutics, Inc., ARCT-032-02  
**NCT Number:** NCT06747858  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A Phase 2, Open-label, Multiple Ascending-Dose Study to Evaluate the Safety, Tolerability and Efficacy of ARCT-032 in People with Cystic Fibrosis

### 1. Call to order:

The Meeting was called to order at 9:00 am Eastern Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Seven voting members were present, including two local members unaffiliated with the institution and the Institution's two Biosafety Officers. Also present were the Principal Investigator, one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

### 4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

### 5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

### 7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for ARCT-032 since it consists of lipid nanoparticle (LNP)-encapsulated mRNA administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ARCT-032 locally**, provided that all biosafety criteria for study closure are also met.

### 8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 7

NO: 0

ABSTAIN: 0

### 9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

## INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

### **10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

#### **Points of Discussion:**

1. The Committee recommended that the Institution confirm whether study agent vial retention will be required and that Biosafety SOP Section 4.1 be revised to remove the language pertaining to retention of vials if it is not required.
2. The Committee recommended that Biosafety SOP Section 5.1.2 be revised to list out the personal protective equipment (PPE) required for decontaminating spills.
3. The Committee recommended that Biosafety SOP Sections 5.2.2 and 5.2.3 be revised to include the institutional policy number being referenced.
4. The Committee discussed at-home subject dosing and recommended that the Institution provide any educational materials to IBC Services that will be given to subjects to ensure that they are aware of the biohazardous nature of the study agent and the requirements for at-home dosing.
5. The Committee recommended that the Institution confirm if subjects will be instructed in how to decontaminate work surfaces and any spills that may occur during at-home dosing and whether they will be provided with an appropriate disinfecting agent for at-home use or provided a list of appropriate disinfectants.
6. The Committee recommended that the internal transportation container, as shown in the IDS Pharmacy Photos, be labeled with a red/orange colored biohazard sticker.
7. The Institutional Representative could not confirm whether the black hazardous waste container, as shown in the 4 Main Pharmacy Photos, will be used for disposal of biohazardous waste. The Committee recommended that the Institution follows up with IBC Services regarding this and that the container be labeled with a biohazard symbol if it will be used for biohazardous waste.
8. The Institutional Representative could not confirm whether the internal transportation container, as shown in the 4 Main Pharmacy Photos, will be used to transport study agent vials to the dosing rooms. The Committee recommended that the container be labeled with a biohazard symbol if it is used for internal transport and if not, that the Institution provide a photo of the correct internal transportation container to IBC Services.
9. The Committee recommended that the Biohazard Sign be revised to enlarge the font for the special precautions section.
10. The Committee noted that the Biological Safety Cabinets (BSCs) are due for re-certification in April 2026 and recommended that the new certification reports be provided to IBC Services when available.
11. A Biosafety Officer confirmed that the BSCs are recertified on a semi-annual basis.
12. The Institutional Representative confirmed that although there are curtains to separate the chairs in the dosing room, only one subject will be dosed in the room at any given time.
13. The Institutional Representative confirmed that only necessary staff will be allowed in the dosing room during subject dosing and that staff will wear a mask while in the dosing room.
14. The Institutional Representative confirmed that children and pregnant women would not be allowed to enter the dosing room for at least one hour after subject dosing.
15. The Institutional Representative confirmed that the Biohazard Sign will be posted at the entrance to the dosing room during subject dosing.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officers, the Principal Investigator, and the Institutional Representative.

## INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 7

NO: 0

ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 9:27 am Eastern Time.

**15. Post-meeting notes:** None.

### **Documents reviewed:**

Agenda

Protocol, Version 4.0, dated 01-16-2026

Investigator's Brochure, Version 4.0, dated 09-05-2025

Pharmacy Manual, Version 2.0, dated 09-08-2025

Investigational eFlow Nebulizer System, Mouthpiece Filter Assembly, received 06-17-2025

Investigational eFlow Nebulizer System, Instructions for Use, received 06-17-2025

Biological Risk Assessment and Summary, updated 03-16-2026

Site Map, Floor 3.5, IDS Pharmacy, R144 R146, dated 12-22-2025

Site Map, Floor 3, Clinical Research Unit, dated 03-03-2023

Site Map, Floor 1, Hospital Loading Dock, dated 04-06-2021

Site Map, 4 Main Pharmacy, dated 02-05-2026

Site Inspection Checklist, expires 08-29-2026, updated 02-09-2026

Photos, Floor 3.5, IDS Pharmacy, R144 R146, dated 06-18-2025

Photos, Floor 3, Clinical Research Unit, dated 02-21-2023

Photos, Floor 1, Hospital Loading Dock, dated 03-10-2023

Photos, 4 Main Pharmacy, dated 02-25-2026

Biohazard Sign, ARCT-032, dated 11-13-2025

Biological Safety Cabinet Certifications, 4 Main Pharmacy, expire 04-2026

SOP, Biosafety for ARCT-032, dated 02-09-2026

Training Shipping Certifications, expire 10-08-2026, 02-03-2027

CV, Koumbourlis, A., signed 11-06-2025