INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, July 22, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Memorial Healthcare System, Hollywood, FL
Principal Investigator:	**Lance Cohen, 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 1:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were six Institutional Representatives, the Principal Investigator, 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:

An Institutional Representative confirmed that notice of the meeting was publicly posted, and a person visiting the clinic inquired about the nature of the meeting.

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: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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 biohazard symbols be placed on the study agent storage unit and the Biological Safety Cabinet (BSC) used for preparation and that new photos of each be provided to IBC Services.
2. The Committee recommended that the study agent specific Biohazard Sign be posted at the entrance to the areas where the study agent is handled and noted that the sign could be posted either on the door or the wall near the door.
3. The Committee discussed the transport container, as shown in site photos, and noted that it appears to be a biohazardous waste container that cannot be sealed. The Committee recommended that the institution obtain a hard-sided lidded container, labelled with a biohazard symbol, for study agent transport and that a photo of the container be provided to IBC Services.
4. The Committee recommended that absorbent material be placed inside Ziploc-style bag within the transport container and noted that the absorbent material could be either a paper towel or a spill pad.
5. The Committee recommended that the biohazard sign be revised to include a phone number that is monitored 24/7.
6. The Committee discussed eye protection for study staff and recommended that either safety goggles or a face shield be worn. The Committee recommended that the institution follow up with IBC Services on which one will be worn so that site documents can be revised accordingly.
7. The Committee discussed whether subjects and family members will need to wear eye protection for at home dosing. The Committee noted that sponsor documents do not address this and that the institution could follow up with the Sponsor for further guidance.
8. The Committee noted that the Biohazard Sign and Biosafety SOP indicate that children and pregnant women should not enter the room for at least one hour after dosing. However, the sponsor documents do not indicate if this restriction applies to at home dosing. The Committee recommended that subjects be given this information prior to dosing at home.
9. An Institutional Representative confirmed that one disposable eye wash bottle is available in each dosing room. The Committee recommended that the institution follow up with IBC Services on whether additional bottles are available onsite.
10. The Principal Investigator confirmed that study staff will wear N95 masks and that they are fit tested for the masks on an annual basis.
11. An Institutional Representative confirmed that the plumbed eyewash is flushed regularly and will follow up with IBC Services on the flushing frequency. The Committee recommended that it be flushed at least once weekly.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the Principal Investigator.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:35 pm Eastern Time.