

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, September 12, 2025
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: Renown Regional Medical Center, Reno, NV
Principal Investigator: Thomas To, MD
Protocol: AskBio Inc., ASK-CHF2-CS201
NCT Number: NCT05598333
Meeting Type: Continuing Review of Protocol and Site
Title: A phase 2, adaptive, double-blinded, placebo controlled, randomized, multi-center trial to evaluate the efficacy, safety and tolerability of intracoronary infusion of AB-1002 in adult subjects with New York Heart Association (NYHA) Class III heart failure and non-ischemic cardiomyopathy (GenePHIT)

1. Call to order:

The Meeting was called to order at 9:01 am Pacific Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were two Institutional Representatives 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. No public comments were received by the site or the Committee regarding this review.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for AB-1002 since it consists of a recombinant adeno-associated virus (AAV) administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of AB-1002 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

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 disposable eyewash bottles be made available in rooms without plumbed eyewashes and that site documents be revised to reflect this.
2. The Committee recommended that a photo of the posted biohazardous waste signage on the entrance door to the biohazardous waste storage area be provided to IBC Services.
3. The Committee recommended that a photo of the biohazardous waste container (non-sharps) in the preparation room be provided to IBC Services.
4. The Committee discussed a previous IBC recommendation which noted that there is potential for aerosol generation when the study agent is transferred to the microcentrifuge tube as this is performed outside of a biological safety cabinet. The Committee recommended that site documents be revised to reflect this.
5. An Institutional Representative stated that only wall-mounted sharps containers are allowed in the dosing rooms per institutional policy. The Committee found this to be acceptable.
6. The Committee recommended that SOP section 5.1.4b.i be revised to state the contents of the freshly prepared 10% bleach solution (1 part household bleach and 9 parts water).
7. An Institutional Representative confirmed that multiple study staff members have current IATA/Shipping training.
8. The Committee discussed the location of sinks and eyewash stations near the dosing rooms, specifically [REDACTED]. An Institutional Representative stated that a hand washing sink and plumbed eyewash is located just outside [REDACTED] (as seen on the site map). The Committee recommended clarification on how study staff members get to that sink/eyewash station.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:17 am Pacific Time.