INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, August 21, 2025**
Time:	11:00 am Mountain Time
Location:	Zoom Teleconference
Institution:	Intermountain Health - Salt Lake City, Salt Lake City, UT
Principal Investigator:	**Brad Hunter MD, MPH**
Protocol:	Eureka Therapeutics, Inc., **ETUS20GPC3AR124**
NCT Number:	NCT04864054
Meeting Type:	Initial Review of Protocol and Site
Title:	An open-label, dose escalation, multi-center phase I/II clinical trial of ECT204 T-Cell therapy in adults with Advanced Hepatocellular Carcinoma (HCC).

1. Call to order:

The Meeting was called to order at 11:29 am Mountain 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 three 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. 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-2 containment facilities and practices** are required for ECT204, since it consists of autologous T cells modified by a lentiviral vector

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of ECT204 locally**, provided all other criteria for study closure are 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 second to last sentence in Biosafety SOP Section 3.3 be revised to read as, " The appropriate volume…transfer device, which is removed and the syringe is capped prior to discarding it and the needle-free transfer device into a sharps or biohazardous waste container."
2. An Institutional Representative confirmed that the study agent infusion bag will be thawed in a waterbath on a separate cart in the dosing room. The Committee recommended that the Institution submit a photo of the cart/waterbath setup to IBC Services.
3. An Institutional Representative confirmed that the biohazard labeling outside of the biohazardous waste rooms is per the Institution's standard. The Committee found this acceptable.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:41 am Mountain Time.