Meeting Minutes

Institution:	CHOC - Children's Hospital of Orange County (CHOC)
Meeting Date:	January 15, 2026
Meeting Time	9:30 AM Pacific Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
De Zoysa, Prashan	Yes	Local Unaffiliated Member
Lally, Rebecca	Yes	Local Unaffiliated Member
Stover, Alexander	Yes	Biological Safety Officer
Larson, Krista	No	Site Contact

Invited Members Not in Attendance:	None
Guests:	Chan, Dorian; Stockton, Winnie; Chen, Shirley; Chavan, Rishikesh
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 9:31 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 12/17/25 were approved by the IBC with no changes. There

were no votes against and no abstentions.

New Business:

PI:	Chavan, Rishikesh
Sponsor:	Eureka Therapeutics, Inc.
Protocol:	ETUS20AFPAR123 An Open-Label, Dose Escalation, Multi-Center Phase I/II Clinical Trial of ET140203 T Cells in Pediatric Subjects with Relapsed/Refractory Hepatoblastoma (HB), Hepatocellular Neoplasm-Not Otherwise Specified (HCN-NOS), or Hepatocellular Carcinoma (HCC)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: ETUS20AFPAR123 is an open-label, Phase I/II trial sponsored by Eureka Therapeutics, Inc. and designed to assess the safety, tolerability, and recommended phase II dose (RP2D) of ET140203 in pediatric participants ≥ 1 to ≤ 21 years of age with relapsed/refractory hepatoblastoma, hepatocellular neoplasm-not otherwise specified, or hepatocellular carcinoma. ET140203 consists of autologous T-cells engineered with a lentiviral vector to express an antibody T-cell receptor targeting tumor antigen alpha-fetoprotein (AFP) and a co-stimulatory molecule targeting Glypican 3 (GPC3). The investigational product (IP) is administered by intravenous infusions.

Biosafety Containment Level (BSL): Because the study agent ET140203 consists of primary human cells transduced with a recombinant derivative of a Risk Group 3 lentiviral vector, BSL2 containment is the recommended biocontainment level under the NIH Guidelines.

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, splashes and needlesticks 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 PI's credentials, 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.
  - The Site confirmed that the BBP training is completed annually and the completion date is located on page 2.
  - The Site confirmed that they have a spill kit in the lab.
  - The Committee recommended that the Site have disposable eyewash bottles available in the administration area. The Site had no concerns.

Motion: A motion of Full Approval for the study at BSL-2 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 9:57 AM

Post-Meeting Pre-Approval Note: None