INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, October 15, 2026**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Rossana Sanchez Russo, MD, FACMG**
Protocol:	iECURE, **ECUR-506-OTC-101**
NCT Number:	NCT06255782
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2/3 First-in-Human, Open-Label, Dose-Escalation Study to Evaluate the Safety and Efficacy of a Single Intravenous (IV) Administration of ECUR 506 in Males Less than 9 Months of Age with Genetically Confirmed Neonatal Onset Ornithine Transcarbamylase (OTC) Deficiency

1. Call to order:

The Meeting was called to order at 1:01 pm Eastern 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 not publicly posted due to institutional policy.

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 noted changes since the last review.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for ECUR-506, since it consists of two adeno-associated viral (AAV) vectors and is designed to edit the cellular genome. 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 ECUR-506 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

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 discussed the use of non-safety needles to withdraw the initial volume of concentrated study agent from the vial, noting that all other steps involving diluted study agent use a dispensing pin. An Institutional Representative confirmed that standard pharmacy practices are to use needle-free devices but that they utilize the Sponsor-provided kit for preparation of this study agent. The Committee recommended that the Institution confirm with the Sponsor whether a dispensing pin or needle-free adapter could be used for the initial withdrawal of study agent as this is the riskiest step of preparation in terms of a needlestick and that Biosafety SOP Section 3.3 be revised as needed.
2. An Institutional Representative confirmed that infusion syringes and tubing are placed in a biohazardous waste bag immediately after use and the closed bag is then placed into a biohazardous waste container. The Committee recommended that biohazardous waste containers be removed from the dosing rooms and transported to the central biohazardous waste storage rooms at the end of each workday and to revise Biosafety SOP Section 3.5 to reflect this.
3. An Institutional Representative confirmed that the study agent-specific biohazard sign is affixed to the internal transport container whenever it contains the study agent. The Committee recommended that an updated photo of the labeled transport container be provided to IBC Services.
4. An Institutional Representative confirmed that the black hazardous waste buckets are only used for waste that is greater than 5 ml and that the study agent-specific biohazard sign is affixed to the black hazardous waste container if they have biohazardous waste of this volume that must be disposed of. The Committee determined this to be 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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:19 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 10.0, dated 04-17-2026
Investigator's Brochure, Edition 4.0, dated 03-06-2026
Pharmacy Manual, Version 7.0, dated 01-15-2026
Research Modification Evaluation, Protocol, Version 9.0
Research Modification Evaluation, Protocol, Version 10.0
Research Modification Evaluation, Investigator's Brochure, Edition 4.0
Research Modification Evaluation, Pharmacy Manual, Version 4.0
Research Modification Evaluation, Pharmacy Manual, Version 6.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Biological Risk Assessment and Summary, dated 07-27-2026
Site Map, AMBH, 3rd Floor, IDS Pharmacy, dated 10-02-2025
Site Map, AMBH, 14th Floor, Dosing, dated 10-02-2025
Site Inspection Checklist, AMBH, 3rd Floor IDS Pharmacy, 14th Floor Dosing, expires 10-02-2027, updated 12-03-2025

Photos, AMBH, 3rd Floor, IDS Pharmacy, dated 12-03-2025
Photos, AMBH, 14th Floor Dosing, dated 12-03-2025
Biohazard Sign, ECUR-506, dated 09-15-2025
Biological Safety Cabinet Certification, IDS Pharmacy, 3rd Floor, expires 02-2027
SOP, Biosafety for ECUR-506, dated 12-03-2025
Training, Shipping Certifications, expire 10-2026, 12-2026
CRRF, dated 07-08-2026
Prior Meeting Minutes, Initial, dated 10-31-2025