INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, October 31, 2025**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Rossana L. Sanchez Russo, MD, FACMG**
Protocol:	IECURE, **ECUR-506-OTC-101**
NCT Number:	NCT06255782
Meeting Type:	Initial 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 2:00 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 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. The Committee recommended that notice of the meeting be publicly posted for a week after today's meeting and that any comments/questions be forwarded to IBC Services.

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 ECUR-506, since it consists of two adeno-associated viral (AAV) vectors and is designed to edit the cellular genome.

The Committee 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.

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 the Site Inspection Checklist (#21) be revised to indicate “no” since there is not a sink in the preparation room. An Institutional Representative stated that the preparation room has hand sanitizer and that there is a sink located in the ante room just outside.
2. An Institutional Representative stated that the disposable eyewash bottles are 32 fl. oz and that there are two bottles at every station.
3. The Committee recommended that disposable eyewash bottles be made available in the preparation room and that the site map be revised to reflect this.
4. The Committee recommended that the study agent specific biohazard sign be posted at the entrance to all areas where the study agent is handled.
5. The Committee recommended that the study agent storage unit be labelled with a biohazard symbol sticker and that a photo showing this be provided to IBC Services.
6. The Committee discussed whether PDI Sani-Cloth AF3 wipes are effective against the study agent (AAV) and recommended that institution confirm this with IBC Services.
7. An Institutional Representative noted that PDI Super Sani-Cloth wipes are also available, and the Chair stated that these wipes are effective against AAV. The Committee recommended that these wipes be used where available and that site documents be revised to reflect this.
8. The Committee recommended that a hard-sided, lidded container, labelled with a biohazard symbol, be used for study agent transport since it is transported between rooms. The Committee recommended that a photo of this container be provided to IBC Services.
9. The Committee discussed how the study agent is prepared. The Chair stated that a study agent vial is thawed and then placed inside a Biological Safety Cabinet (BSC). The study agent is removed via a syringe and a needle, which is safely removed. The syringe is then connected to a dispensing pin, which is inserted into a mixing vial, and the study agent is added to that mixing vial. The study agent is transferred from the mixing vial to a syringe, which is capped for transport to the dosing room.
10. The Committee discussed how biohazardous waste is handled onsite. An Institutional Representative stated that sharps and non-sharps biohazardous waste is placed into the same container and not separated. The Committee recommended that sharps and non-sharps biohazardous waste be separated into different biohazardous waste containers per best biosafety practices.
11. The Committee also discussed how sharps biohazardous waste should be handled when staff are working inside a BSC. An Instiutional Representative stated that any sharps generated in the BSC are placed into a small waste bag, which is then disposed of into a sharps container located underneath the BSC.
12. The Committee noted that placing sharps into a bag is not considered safe for the user per best biosafety practices. The Committee recommended that a small sharps container be placed inside the BSC and that Biosafety SOP, Section 3.3 be revised to reflect this.
13. The Committee noted that the BSC certification says “Laminar Flow” on it; however, the BSC that will be used for study agent preparation is a Class II, Type A2 BSC per the model number.
14. The Committee noted the potential occupational health concerns associated with handling this study agent. An Institutional Representative stated that there are existing policies in place per the institution’s ECP.

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 2:36 pm Eastern Time.

15. Post-meeting note: After the meeting, the Chair determined that PDI Sani-Cloth AF3 wipes are effective against the study agent.

Documents reviewed:

Agenda
Protocol, Version 8.0, dated 08-05-2025
Investigator's Brochure, Edition 3.0, dated 09-13-2024
Pharmacy Manual, Version 3.0, dated 05-24-2024
Biological Risk Assessment and Summary, dated 08-27-2025
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
Photos, AMBH, 14th Floor Dosing, dated 09-15-2025
Photos, AMBH, 3rd Floor, IDS Pharmacy, dated 09-15-2025
Biohazard Sign, ECUR-506, dated 09-15-2025
Biological Safety Cabinet Certification, IDS Pharmacy, 3rd Floor, expires 02-2026
SOP, Biosafety for ECUR-506, dated 10-02-2025
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, Sanchez Russo, R., signed 02-19-2025