INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Tuesday, November 19, 2024** |
| **Time:** | 11:00 am Mountain Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Asthma and Allergy Associates, PC, Colorado Springs, CO |
| **Principal Investigator:** | **Daniel F. Soteres, MD, MS, MPH** |
| **Protocol:** | Intellia Therapeutics, Inc., **ITL-2002-CL-301** |
| **Meeting Type:** | Initial Review of Protocol and Site |
| **Title:** | HAELO: A Phase 3, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2002 in Participants With Hereditary Angioedema (HAE) |

**1. Call to order:**

The Meeting was called to order at 10:59 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 one 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:**

The 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 NTLA-2002 since it consists of a CRISPR/Cas-based gene editing product that can permanently modify cellular genomes.

The Committee determined that IBC oversight will continue for **6 months after the last subject's last dose of NTLA-2002 locally**, provided that all biosafety criteria for study closure are met.

**8. Vote on the Protocol:**

The Committee voted for the following determination on the Protocol:

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|---|---|
| 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 Institutional Representative stated that the study agent will be prepared in Research Exam Room 2 and then the subject will be brought into the room for dosing.
2. The Institutional Representative stated that the countertop will be decontaminated with Caviwipes2 before and after study agent preparation. The Committee recommended that Biosafety SOP Section 3.3 be revised to reflect this.
3. The Committee recommended that absorbent material, such as a Chucks pad, be placed on the countertop during study agent preparation and that Biosafety SOP Section 3.3 be revised to reflect this.
4. The Committee recommended that Biosafety SOP Section 5 be revised to indicate Section 5.1 for Spills and 5.2 for Exposures.
5. The Committee discussed the procedure for flushing the eye in the event of an eye exposure. The Committee noted that eyewash bottles could be used first and the subject would then be escorted to the nearest plumbed eyewash.
6. The Committee recommended that eyewash signs be placed on the wall above the plumbed eyewash as well as where the disposable eyewash bottles are kept. The Committee recommended that photos of the posted signs be provided to IBC Services.
7. The Committee recommended that expiration dates of the disposable eyewash bottles be checked on a regular basis.
8. The Committee recommended that the study agent specific biohazard sign be posted during study agent handling activities, including preparation and dosing.
9. The Committee discussed the biohazardous waste storage location on the outdoor patio and noted that the storage bin is in close proximity to a table that may be used by staff for eating and drinking. The Institutional Representative stated that the patio has a locked gate and the biohazardous waste bin has a padlock. The Committee recommended that the table be moved at least six feet away from the waste storage bin and that the institution explore installing a barrier between the table and bin.
10. The Committee noted that the outdoor biohazardous waste storage bin can be labelled with an orange biohazard sticker; the study agent specific biohazard sign is not required.

**11. Site requirements:**

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

**12. Vote on the Site:**

The Committee voted for the following determination on the Site:

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|---|---|
| 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 11:30 am Mountain Time.

**15. Post-meeting notes:** None.

**Documents reviewed:**

Agenda
Protocol, Version 1.0, dated 07-26-2024
Investigator's Brochure, Version 4.0, dated 07-17-2024
Pharmacy Manual, Version 1.1, dated 07-27-2024
Biological Risk Assessment and Summary, dated 08-22-2024

Site Map, dated 10-30-2024
Site Inspection Checklist, dated 9-25-2024, updated 10-30-2024
Photos, Asthma and Allergy Associates, dated 10-31-2024
Biohazard Sign, BSL-2, dated 09-26-2024
SOP, Biosafety for NTLA-2002, dated 10-31-2024
Training, Shipping Certification, dated 05-25-2023
CV, Soteres, D., signed 07-09-2024