

Meeting Minutes



Institution: Northwestern University Feinberg School of Medicine

Meeting Date: October 22, 2025

Meeting Time: 11:00 AM Central 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
Wang, Anthony	Yes	Core Member: Biosafety Expert/HGT Expert
Helm, Allen	Yes	Local Unaffiliated Member
Bivona, John	Yes	Local Unaffiliated Member
Foreman, Robert	Yes	Biological Safety Officer

Invited Members Not in Attendance: None

Guests: Kopp, Sarah; Sokalski, Suzanne

Staff: Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 11:01 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 7/22/2025 were approved by the IBC with no changes.

New Business:

PI:	Shah, Sanjiv
Sponsor:	Intellia Therapeutics, Inc.
Protocol:	ITL-2001-CL-301 MAGNITUDE: A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ITL-2001-CL-301 is a Phase III study sponsored by Intellia Therapeutics, Inc., and designed to assess the safety, efficacy, and immunogenicity of NTLA-2001 in adult participants (18 to 90 years of age) with a cardiomyopathy phenotype of wild-type or hereditary transthyretin amyloidosis (ATTR). The study agent NTLA-2001 (nexiguran ziclumeran) is an in vivo administered CRISPR/Cas9-based gene editing system used to disrupt the transthyretin (TTR) gene involved in the pathogenesis of ATTR-CM. The investigational product (IP) is administered by Intravenous (IV) infusion.

Biosafety Containment Level (BSL): The study agent NTLA-2001 contains synthetic RNAs (sgRNA and mRNA) that are non-infectious, incapable of replication and do not encode for known hazardous transgenes (e.g., toxins or oncogenes); therefore, BSL-1 containment may be considered as the minimum biocontainment level. Additional safety practices and procedures, and/or increased containment level, may be warranted based on the IBC’s independent assessment of the exposure risks associated with handling an investigational product such as NTLA-2001 that is capable of in vivo gene editing. The administration of this agent in a clinical setting requires compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030).

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/or 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 Annual Review Report, 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 Committee noted that the BSC will be due for recertification soon and reminded the Site to send Sabai the updated certification report when it is available. The Site had no concerns.
 - The Committee discussed the containment level most appropriate for handling the study agent and agreed that, due to the study agent resulting in in vivo gene knockdown of the target gene, BSL2 containment would provide additional safety precautions for handling the agent. As such, the Committee agreed that BSL2 would be the recommended containment level for study agent handling at the Site. The Site had no concerns and indicated that they are already effectively operating at BSL2.
 - The Biohazard Sign will be administratively updated to BSL2.
 - The Site Photos will be administratively updated to remove the photos of the BSC certification stickers since current certification reports are provided instead.
 - The Committee stipulated that the Site request the addition of a biohazard sign on the door of the Hazardous Waste Hold Room in the pharmacy and send Sabai an updated photo, if the hospital agrees to post it, by 11/22/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Motion: A motion of Approval with Stipulations 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:
 - The Committee stipulated that the Site request the addition of a biohazard sign on the door of the Hazardous Waste Hold Room in the pharmacy and send Sabai an updated photo, if the hospital agrees to post it, by 11/22/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

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Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:28 AM

Post-Meeting Pre-Approval Note: None