

Meeting Minutes



Institution: Northwestern University Feinberg School of Medicine

Meeting Date: September 30, 2026

Meeting Time: 10:00 AM Central Time

Meeting Type: Virtual Platform Teleconference (Remote)
Open to the Public

Members in Attendance:

Member	Voting	Member Type
Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Ridge, Robert	Yes	Local Unaffiliated Member
Bivona, John	Yes	Local Unaffiliated Member

Invited Members Not in Attendance: Robert Foreman, Biological Safety Officer

Guests: None

Staff: Payne, Kaylie

Call to Order: The IBC Chair called the meeting to order at 10:02 AM. A quorum was present as defined in the Sabai IBC Charter. The Chair noted that the Site Representative informed Sabai they would be tardy for an indeterminate time and thus no Site Representative would be present on the Call. The Chair reviewed Sabai IBC Charter criteria that allow meetings to be held without the Site present and noted that this meeting fits those criteria. After discussion, the Committee unanimously agreed that the meeting may move forward without a Site Member present.

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 2-26-26 were approved by the IBC with no changes. There were no votes against and no abstentions.

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 and Change in Research
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 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. 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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. 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 reviewed the Change in Research to add the new Administration Rooms.
 - The Committee discussed the disposal of sharps waste while using the BSC. The Committee stipulated that the Site provide a response whether a sharps container can be placed inside the BSC for disposal of sharps waste, or if not, the Site provide additional details on mitigation strategies and administrative controls for safe sharps disposal outside of the BSC.
 - The Committee stipulated that the Site confirm whether sharps and non-sharps biohazardous waste are segregated and provide clarification on the type of non-sharps waste containers used in the Pharmacy (red biohazardous waste containers, yellow chemo container or black pharmaceutical waste containers).
 - The Site Map will be updated to reflect the sharps containers available in the Pharmacy. This will be administratively updated.

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 Site to provide a response whether a sharps container can be placed inside the BSC for disposal of sharps waste, or if not, the Site provide additional details on mitigation strategies and administrative controls for safe sharps disposal outside of the BSC by 10/29/2026. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
 - The Site to confirm whether sharps and non-sharps biohazardous waste are segregated and provide clarification on the type of non-sharps waste containers used in the Pharmacy (red biohazardous waste containers, yellow chemo container or black pharmaceutical waste containers) by 10/29/2026. 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 10:36 AM

Post-Meeting Pre-Approval Note: After the meeting adjourned, Sabai identified an administrative error and inconsistency with the study's containment level (BSL-2) previously approved by the Committee compared to the containment level listed on the annual review's facility form submission. The Chair noted the changes for the annual review were limited to rotating one dosing floor with an equivalent dosing floor with no corresponding changes to facility features, safety practices, or containment level. Given the consistent nature of the current and previous facilities, practices, and controls, the Chair administratively approved the correction of the biocontainment level in the form to reflect the accurate and approved containment level of BSL-2.