Meeting Minutes

Institution: Northwestern University Feinberg School of Medicine

Meeting Date: February 26, 2026

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
Reed, Craig	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: Arrieta, Rose; Kopp, Sarah

Staff: Smith, Jennifer; Abdullah-Johnson, Shaakira

Call to Order: The IBC Chair called the meeting to order at 11:00 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 10/22/2025 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Hanauer, Stephen
Sponsor:	Tr1X, Inc.
Protocol:	TRX103-02 A Phase 1/2a, Open Label, Dose Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX103 in Subjects with Moderate to Severe Treatment-Refractory Crohn's Disease.
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: TRX103-02 is a non-randomized, interventional, open-label Phase I/IIa study sponsored by Tr1X, Inc and designed to assess the safety and tolerability of TRX103 in adult participants with moderate to severe treatment-refractory Crohn's Disease. TRX103 consists of a polyclonal population of allogeneic CD4+ T cells engineered to recapitulate the major regulatory functions of type 1 regulatory (Tr1) cells, notably through expression of IL-10. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent TRX103 consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, therefore BSL-2 containment is the minimum containment level under the NIH Guidelines II-A-3.

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. 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 reminded the Site to send the formal BBP training certificate when it is available.
  - The Site confirmed that a biohazard waste sign, with no biohazard symbol, is placed by the door of the biohazard waste storage area and confirmed that this area is access-limited to only hospital staff. The Committee stipulated that the Site work with the hospital to install a biohazard symbol on the main door to the biohazard waste area of the Feinberg Loading Dock and send an updated photo by 3/26/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Site confirmed that there is a biohazard sticker affixed to the water bath.
  - The Committee recommended that the Site verify that appropriate signage is located in areas with eyewashes and add signs as necessary.
  - The Committee stipulated that the Site work with the hospital to install a biohazard symbol on the door of the Soiled Utility Room in Galter 15 and send an updated photo by 3/26/26. 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 work with the hospital to install a biohazard symbol on the main door to the biohazard waste area of the Feinberg Loading Dock and send an updated photo by 3/26/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site work with the hospital to install a biohazard symbol on the door of the Soiled Utility Room in Galter 15 and send an updated photo by 3/26/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 11:27 AM

Post-Meeting Pre-Approval Note: None