Montefiore Medical Center
BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
Wednesday, February 18, 2026[1]

[1]The materials for this agenda were made available electronically to all appropriate parties.

MMC Members Present:
1. Brian Currie, MD (IBC Chair)
2. James Wetmur, PhD (Member)
3. Alan Yood (Member)
4. Izzy Fujiwara (Non-Affiliated Community Member)

Guests Present:
1. Vanessa Rodriguez, CIP, IRB/IBC Supervisor
2. Kyla Sumter, Junior Associate IRB/IBC Coordinator

This meeting was called to order at 3:12 PM with a quorum[2] present.

[2]Note: According to the roster registered with NIH on 03/06/2025, the MMC BRANY IBC membership totals 5, making the members required for quorum 3 or greater.

Announcements

I. IBC members were reminded to disclose any potential conflicts of interests prior to reviewing items on this agenda by recusing yourself. Contact BRANY IBC staff in advance of the meeting if this is the case.

II. IBC members were reminded to state their names when joining or leaving the call ensures that all of the meeting proceedings occur with quorum present.

Minutes:

- Minutes of the 2/21/2025 Montefiore BRANY IBC Meetings
- Minutes of the 2/26/2025 Montefiore BRANY IBC Meetings

IBC Action and Vote: Having no comments or concerns, the committee voted to accept the minutes as submitted

Continuing Review

1. **Protocol Title:** A PHASE 1/2 MULTI-CENTER STUDY EVALUATING THE SAFETY AND EFFICACY OF LYL314, A CD19/CD20 DUAL-TARGETING CHIMERIC ANTIGEN RECEPTOR T-CELL THERAPY IN PARTICIPANTS WITH AGGRESSIVE B-CELL NON-HODGKIN LYMPHOMA

   Principal Investigator: Dennis Cooper, MD
   BRANY File # IBC24-002-01 (Montefiore Medical Center)

   Materials Provided for Review:
   1. Continuing Review Application (Signature dated 2/17/2026)
      a. License: Dennis Cooper
   2. Updated Consent Forms
   3. DSMB
   4. Protocol, Version: 6.0
      a. Protocol Clarification Letter (dated 14 July 2025)
      b. Sponsor Memo (dated 16 July 2025)
   5. Dear Investigator's Letters: (2/5/2025, 2/25/2025, 7/16/2025)

6. Drug Brochure, Edition Number: 7.0

Materials Provided for Reference:
1. Acknowledgment Letter
    a. Protocol Administrative Change Letter Section 9.12 (dated 4/4/2025)

Discussion: The IBC discussed the continuation of this study, noting that there have been no material changes to the study protocol or study agent affecting the biosafety considerations for this research. The committee noted the study continues to fall under sections III-C-1 and III-D-1 of the NIH Guidelines.

The site reported that there have not been any emergencies, potential biohazard problems, spills, significant safety issues, or contamination since the last IBC review.

This site is actively enrolling new subjects. To date a total of 3 subjects have been enrolled: 1 subject is ongoing and 2 are deceased. The study drug has not been administered since the last review with no subjects reporting benefits or complaints. No SAE's or unanticipated problems have been reported since the last review.

The DSMB met on August 22, 2025, and recommended continuing the study.

The informed consent form remains adequate.

The designated Biosafety Liaison for this project has not changed since the last IBC review. There have been no changes to the staff or to the facility used for this research and it continues to be adequate.

The risks assessment has not changed since the prior review of this project. There were no concerns that would necessitate termination of the protocol. The biosafety level remains unchanged (BL 2).

IBC Action and Vote: Having no further comments or concerns, the committee voted unanimously to continue its approval for this project for a period of 12 months.

Total: 4 For: 4 Against: 0 Abstentions: 0

2. **Protocol Title:** A Phase 3, Randomized Study of CG0070 versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)

   Principal Investigator: Alexander Sankin, MD
   BRANY File # IBC24-003-01 Montefiore Medical Center

   Materials Provided for Review:
   1. Continuing Review Application (Signature dated 2/11/2026)
   2. Updated Consent Forms
   3. Updated Protocol, Version: 3.0
       a. Protocol Clarification Letter (dated 13 June 2025)
   4. Updated Drug Brochure, Edition Number: 8.0

Discussion: The IBC discussed the continuation of this study, noting that there have been no material changes to the study protocol or study agent affecting the biosafety considerations for this research. The committee noted the study continues to fall under sections III-C-1 and III-D-1 of the NIH Guidelines.

The site reported that there have not been any emergencies, potential biohazard problems, spills, significant safety issues, or contamination since the last IBC review.

This site is closed to enrollment. To date a total of 5 subjects have been enrolled: 2 subjects are undergoing research intervention, 1 subject is in follow-up, 1 subject was lost to follow up, and 1 subject was a screening failure. The study drug has been administered to 3 subjects since the last review with no subjects reporting benefits or complaints. No SAE's or unanticipated problems have been reported since the last review.

The DSMB report is not available.

The informed consent form remains adequate.

The designated Biosafety Liaison for this project has not changed since the last IBC review. There have been no changes to the staff or to the facility used for this research and it continues to be adequate.

The risks assessment has not changed since the prior review of this project. There were no concerns that would necessitate termination of the protocol. The biosafety level remains unchanged (BL 2).

IBC Action and Vote: Having no further comments or concerns, the committee voted unanimously to continue its approval for this project for a period of 12 months.

Total: 4 For: 4 Against: 0 Abstentions: 0

This meeting adjourned at 3:22 PM (EST).

Respectfully submitted,

Vanessa Rodriguez, CIP IRB/IBC Coordinator Brian Currie, MD, IBC Chairman