Montefiore Medical Center
BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
Friday, October 24, 2025, Via Telephone Conference[1]

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

A. MMC IBC Members Present:

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

B. Guests Present:

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

This meeting was called to order at 3:00 PM with a quorum[2] present.

[2]Note: According to the roster registered with NIH on 3/06/25, the MMC BRANY IBC membership totals 5, making the members required for quorum 3 or greater.

C. Announcements

1. Please 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.

2. Reminder: Please state your name when you join or leave the call ensures that all of the meeting proceedings occur with quorum present.

D. Minutes

- 10/21/2024
- 11/01/2024
- 10/7/2025

IBC Action and Vote: The committee voted to accept the minutes with minor changes to the 11/01/24 minutes correcting typos.

Total: 6 For: 6 Against: 0 Abstentions: 0

E. Continuing Reviews

1. **Protocol Title:** A Phase 2, adaptive, randomized, open-label, assessorblinded active-controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus Standard of Care in patients suffering from systemic lupus erythematosus (SLE) with active, refractory lupus nephritis (LN)

   Principal Investigator: Wang, Shudan, MD
   BRANY File # IBC24-012-01 (Montefiore Medical Center)

Materials Provided for Review:

1. Sites application (10/17/2025)
   a. CV and Training: Wang, Shudan, MD
2. Consent forms
3. Protocol, VERSION: 0.0, 2/20/2024
4. Drug Brochure, Edition Number: 9.0, 6/25/2024

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 open to patient accrual. To date no subjects have been enrolled at this site. The study drug has not been administered since the last review. No SAE's or unanticipated problems have been reported since the last review.

The informed consent form remains adequate.

The designated Biosafety Officer (BSO) 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:** Master Protocol for the Phase 1 Study of Cell Therapies for the Treatment of Patients with Relapsed or Refractory Acute Myeloid Leukemia or High-risk Myelodysplastic Syndrome, Including Long-term Safety Follow-up

   Principal Investigator: Roberto Alejandro Sica, MD

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

BRANY File # IBC22-004-01 (Montefiore Medical Center)

Materials Provided for Review:

5. Sites application (10/17/2025)
    a. CV and Training: Roberto Alejandro Sica, MD
6. Consent form
7. Protocol, VERSION: 5.0, 11/28/2024
    a. Memos: 1/31/2025, 9/17/2025
8. Drug Brochure, Edition Number: 2.0, 2/27/2025

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 active; however, enrollment of new subjects is on hold. To date a total of 7 subjects have been enrolled, however, 1 was a screen failure, 5 were withdrawn, and 1 was detained by ice. The study drug has not been administered since the last review therefore no subjects have reported benefits or complaints. To date 3 other sites have enrolled 19 patients. The sponsor reported a grade 5 event that occurred in a subject on 17-September-2025, which put the study on hold per the study pausing rules pending evaluation by the CRC.

The informed consent form remains adequate.

The designated Biosafety Officer (BSO) 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 3:21 PM (EST).

Respectfully submitted,

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