Montefiore Medical Center
BRANY INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
Wednesday, August 19th,2025 Via Telephone Conference [1]

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

MMC IBC Members Present:

1. Brian Currie, MD
2. James Wetmur, PhD
3. Alan Yood
4. Izzy Fujiwara

Guest Scheduled to Attend:

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

This meeting was called to order at 2:32 PM with a quorum[2] present.

[2]*Note: According to the roster registered with NIH on 2/26/24, 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.

III. Vice Biosafety Liaison for all Montefiore Studies – Man Yu Chen

A. **Minutes** – Minutes from August 28th, 2024 continuing review meeting

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

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

B. **Continuing Review**

1. **Protocol Title: Phase I/II, open label, multicenter study of rapcabtagene autoleucel in adult patients with CLL/SLL, 3L + DLBCL, r/r ALL and 1L HR LBCL**
   Principal Investigator: Dennis Cooper, MD
   BRANY File # IBC23-011-01

   Materials Provided for Review:
   1. Continuing Review Application (07/24/2025)
      a. License: Dennis Cooper, MD
      b. Consent forms
      c. Letter to investigators - Last Patient First Treatment Notification
      d. DMC recommendation15-Apr-2025
      e. Monitoring Visit Follow Up Letter - 01 Apr 2025
   2. Protocol, VERSION: 9.0 (Dated April 1st, 2025)

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3. Investigators Brochure Edition 8 (Dated June 14th, 2023)

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 risk assessment or 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. No subjects have been consented or enrolled since the last review at this site. Therefore, the study drug has not been administered since the last review. Overall, 45 other participating sites have enrolled 167 participants with no significant bio-hazard issues reported.

The Data Monitoring Committee met on and recommended the study continue as is.

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 2:37 PM (EST).

Respectfully submitted,

Vanessa Rodriguez
Vanessa Rodriguez, CIP IRB/IBC Coordinator

Brian Currie MD
Brian Curie, MD, IBC Chairman