DSMB Charter
[Research protocol for kidney transplantation from HIV+ donors into HIV+ recipients under the Final HIV Organ Policy Equity (HOPE) Act.]
[Yorg Azzi, MD]

The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to the Principal Investigator to monitor participant safety, data quality and evaluate the progress of the study.

This DSMB is independent of regulatory agencies, IRB and investigators.

This charter will be approved by its DSMB members as attested to by signature of the chairperson.

All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

DSMB Responsibilities

The DSMB will:

- review the research protocol, informed consent documents and plans for data safety and monitoring;
- evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome;
- consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
- review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator;
- protect the safety of the study participants;

The DSMB will discharge itself from its duties when the last participant completes the study.

Membership

Board Process

- The first DSMB meeting will be held before the first subject is enrolled. The study protocol and informed consent will be provided to members in advance of the meeting.

- At the first meeting the DSMB will discuss the protocol, suggest modifications, and establish guidelines. The DSMB report template should be customized based on this discussion.

- Meetings of the DSMB will be held every 12 months
- Meetings may be convened as conference calls or in-person.

- Attendance and minutes will be recorded for each meeting.

- The Principal Investigator and key members of the study team will attend the DSMB meeting in order to provide information and answer questions.

- The DSMB chair will lead the discussion.

- Discussion will focus on the conduct and progress of the study, including participant accrual, protocol compliance, adverse events, protocol deviations and problems encountered.

- The following material should be provided to the DSMB members for review: adverse event logs, protocol deviation logs, details of reportable events submitted to the IRB, monitoring reports, screen fails with reason subjects did not meet entry criteria, enrollment totals, new published scientific or therapeutic research that may have an impact on the safety of the participants or the ethics of the trial

- After discussion, the DSMB will vote on one of the following recommendations:

    - Continue the study with no modification. OR
    - Continue the study with modification(s). OR
    - Terminate the study.

- The vote will be recorded. The PI/study staff will not vote.

- In the event of a split vote in favor of continuation, a minority report should be contained within the regular DSMB report.

- A formal report containing the recommendation will be prepared by the DSMB chair or designee. The report will be sent to the PI within 5 days of the DSMB meeting.

- Any DSMB concerns about the research, recommendations for protocol modification or termination recommendations will be promptly submitted to the IRB.

DSMB Charter accepted by:

Signature of DSMB Chairperson Date

Dr. Rachel Bartash will be the chairperson for this DSMB

DSMB members:

Name	Clinical/Academic Specialty	email
Rachel Bartash	*Attending Physician* Division of Infectious Diseases	rbartash@montefiore.org
Beatrice Goilav	Pediatric - Nephrology	bgoilav@montefiore.org
Nicole Hayde	Pediatric - Nephrology	nhayde@montefiore.org