

Donors as Human Research Subjects Algorithm Analysis

TRANSPLANT CENTER PROCEDURES

These procedures should be followed for all transplant center hematopoietic cell recipient research protocols that involve NMDP/Be The Match donors.

For research protocols not yet approved by transplant center IRB

1. Test the research protocol against the algorithm.
2. Determine if the unrelated donor is a research subject OR participating in research support activities OR neither.
3. If it is determined that the unrelated donor is a **research subject**, submit all NMDP **IRB** application materials to the NMDP IRB office for initial review.
4. If it is determined that the unrelated donor is not a research subject, but is **participating in research support activities**, submit all NMDP **SMDS** application materials to the NMDP IRB office for initial review.
5. If it is determined that the unrelated donor is **neither** a research subject nor participating in research support activities, no further action is needed.

For research protocols already approved by transplant center IRB

1. Follow the procedures above for any current/active research protocols that have not yet been tested against the algorithm (nor have they been reviewed by the NMDP IRB or NMDP SMDS).
2. If it is determined that the unrelated donor is either a research subject or is participating in research support activities, submit the appropriate application materials (as mentioned above) immediately to the NMDP IRB office for proper review.

Visit <https://network.bethematchclinical.org/Research/Institutional-Review-Board/> for:

- Algorithm Analysis
- NMDP IRB Application for Initial Review
- NMDP SMDS Application for Initial Review

Submit all materials to:

IRBStaff@nmdp.org

For questions contact:

Julia Tkachenko

Sr. Human Research Protection Program Specialist, IRB

Phone: 763-406.5890

Email: jtkachen@nmdp.org