

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 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**, email CMResearch@nmdp.org with the protocol.
- 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 sent to CMResearch).
- 2. If it is determined that the unrelated donor is either a research subject or is participating in research support activities, follow the procedures above.

Visit https://network.nmdp.org/research/institutional-review-board/study-level-submissions/ for:

- Algorithm Analysis
- Instructions for submitting an application to the NMDP IRB

For questions contact:

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