

## **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 <u>CMResearch@nmdp.org</u> 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

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