



Donors as Human Research Subjects or Third Parties in Research Algorithm Analysis

TRANSPLANT CENTER PROCEDURES

These procedures should be followed for all transplant center stem 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 unrelated donor is a research subject, third party in research, or neither.
3. Complete the Algorithm Analysis Worksheet.
4. Submit the Algorithm Analysis Worksheet and cover memo from the NMDP to local IRB along with submission for *initial* review.
5. Submit appropriate materials to the NMDP IRB based on algorithm conclusion:
 - a. If it is determined that the unrelated donor is a **research subject**:
 - Submit all NMDP IRB application materials to NMDP IRB for initial review
 - Submit completed Algorithm Analysis Worksheet to NMDP IRB office
 - b. If it is determined that the unrelated donor is a **third party** in research:
 - Submit protocol and recipient consent form to NMDP IRB office
 - Submit completed Algorithm Analysis Worksheet to NMDP IRB office
 - c. If it is determined that the unrelated donor is neither a research subject nor a third party in research:
 - Submit completed Algorithm Analysis Worksheet to NMDP IRB office

For research protocols approved by transplant center IRB prior to December 1, 2007

Follow procedures above.

- All current, active research protocols should be tested against algorithm by June 30, 2008.
- Based on algorithm conclusion, Algorithm Analysis Worksheet and other appropriate materials should be submitted to NMDP IRB immediately (i.e., don't wait for continuing review).
- Algorithm Analysis Worksheet and cover memo should be submitted to local IRB at the time of *continuing* review.

Visit www.nmdpresearch.org for:

- Algorithm Analysis Worksheet
- Example cover memo for TC IRB
- NMDP IRB Application for Initial Review

Submit all materials to:

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Internal Use Only:

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