

TO: Transplant Center IRB

FROM: Roberta King, M.P.H.
NMDP IRB Administrator

DATE:

SUBJECT: Protocol analysis to determine if an unrelated donor is a human research subject or a third party in research

To ensure that the rights and welfare of unrelated donors are protected when their recipients are participating in research protocols that may also involve them, the NMDP has developed an algorithm to help transplant centers determine if an unrelated donor is a human research subject or a third party in research on a recipient research protocol. The NMDP implemented the algorithm in December 2007, and requires transplant centers to test all their research protocols involving unrelated donors against the algorithm.

If it is determined that the unrelated donor is a human research subject on the protocol, then the study must also be reviewed and approved by the NMDP IRB. If it is determined that the unrelated donor is not a human research subject but is, however, a third party in research, then the NMDP IRB Office must be informed of the patient's research activity, and the donor must be informed of his/her risks and allowed to consider these risks as a part of the decision to donate.

Attached is the completed Algorithm Analysis Worksheet for this study. NMDP requires that this worksheet is given to the transplant center IRB at the time of initial review (or at the time of continuing review for a study that is already in progress).