FAQ from Donors as Research Subjects algorithm training (November 2007)

Q1: Will future protocols issued by the major NIH funded consortium groups, such as the BMT CTN and ECOG, come with the appropriate determinations and approvals with regard to unrelated donors before we obtain them?

A1: NMDP is the coordinating center for the BMT CTN. Therefore, any protocols issued by that group which involve unrelated donors will go through the NMDP IRB for approval. If your site is involved in the study, you will be informed of NMDP IRB approval and will not have to apply the algorithm to the protocol at your individual site. We will investigate how this process will work with other consortium groups.

Q2: For research protocols where it is determined that the unrelated donor is a third party in research, does the recipient consent form need to be approved by the TC IRB before it is sent to the NMDP?

A2: No. We will prepare the donor information sheet based on the information in the protocol. We ask for the recipient consent form simply because it may help us with wording for the donor information sheet.

Q3: If we determine that the unrelated donor is a research subject on a research protocol, do we need to wait to enroll patients on the protocol until the study is approved by the NMDP IRB?

A3: No, you do not need to wait for NMDP IRB approval before enrolling patients on the protocol.

Q4: If we determine that the unrelated donor is a third party in research on a protocol, do we need to wait to enroll patients on the protocol until we hear back from the NMDP that it has undergone administrative review?

A4: No, you do not need to wait to hear back from the NMDP before enrolling patients on the protocol.

Q5: When donors are requested for a "standard treatment" protocol, do we still have to complete the Algorithm Analysis Worksheet?

A5: Transplant centers vary on how they handle transplant protocols. Some sites facilitate most transplants under "standard treatment" protocols. Other sites require **all** transplant protocols to be facilitated as "research studies." The way to determine if the algorithm needs to be applied is quite simple. If the study has been submitted to or approved by the center's IRB, then it is research, and the algorithm needs to be applied.

Q6: Are our IRBs aware that these algorithm worksheets will be coming?

A6: Although it is the transplant center's primary responsibility to educate their IRBs on this process and what will be submitted to them, the NMDP IRB staff is willing to help in communicating with the TC's IRB.

Q7: If the study has already been approved by the NMDP's IRB, do we still need to do the algorithm worksheet?

A7: No, there is no need to complete the Algorithm Analysis Worksheet on a study that has already been approved by the NMDP IRB.

Q8: If the patient has advanced disease, but the protocol is not a research protocol, it is my understanding that the donor is not a research subject even though the prognosis of the patient is poor. Is this correct?

A8: Correct. If the protocol is not a research protocol (and has not been submitted to your IRB), then the donor is not a research subject. Also, if the protocol is not a research protocol, then you don't have to complete the Algorithm Analysis Worksheet.

Q9: What about studies involving unrelated cord blood units?

A9: Cord blood is a specimen and does not involve a live human. Therefore, research that only involves cord blood does not involve NMDP unrelated donors and does not need to be tested against the algorithm.

Q10: What about research protocols from other departments on which BMT patients are eligible?

A10: Any research protocol that will involve an unrelated donor must be tested against the algorithm.

Q11: Is the "phase" of the study considered?

A11: No. It does not matter what phase the study is. If a recipient research protocol involves unrelated donors, the protocol must be tested against the algorithm.

Q12: Who at the transplant center should be responsible for submitting the materials to the NMDP?

A12: We recommend that the person at the transplant center who is submitting the protocol and IRB application materials to the TC's IRB be the one who completes the Algorithm Analysis Worksheet and completes/submits any necessary materials to the NMDP.

Q13: How is "futile transplant" defined, and how does it fit the algorithm?

A13: A "futile transplant" is one in which there is an increased risk of death for the recipient. Research protocols that focus on sub-populations not normally eligible for transplant, such as elderly patients or patients with existing co-morbidities or extremely advanced disease, may fall into this category. In general, the research activity is focused on ways to reduce transplant-related mortality or further eradicate advanced disease. Because such protocols may put the unrelated donor at greater risk of donating for a futile transplant, the donor may be considered a third party to research, and should be informed of his/her risks on the research protocol.