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National Marrow Donor Program®/Be The Match®
Donor Cells for Manufacturing Protocol Questionnaire

All questions below must be completed for the application to be reviewed by Donor Cells for Manufacturing Review Group.

Project Identification

1. Thank you for your application. The Scientific Merit and Donor Safety Committee has been discontinued. Requests where donors are asked to contribute material to support recipient research activities but are not considered research subjects according to federal regulations, are now managed operationally. The donors would only sign a consent if:
    1. There is potential commercial profit
    2. Cells could be used for a 3rd party patient or banking

Please confirm whether the above conditions apply to your study:

- ◯ Yes
- ◯ No

Principal Investigator/Sponsor:

Participating Sites:

Name of Recipient Study:

TC Protocol ID Number:

Summary of Activities

2. Summary of Study: *Use lay language that can be understood by the general public.*
    A. What is the research question (hypothesis)?
    B. What products (sample) are you requesting from the donor?
    C. How will these samples be used?

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Participant Population

3. Describe the transplant recipient population to be enrolled on this study:

   A. What is the total number of recipients to be enrolled at all participating centers?

   B. List all diseases included in the recipient eligibility criteria:

   C. What is the anticipated rate of accrual?

   D. How many months do you anticipate the study will last? (from time of approval to completion)

   E. What is the exact age range of eligible recipients to be enrolled?

4. Describe the donor population supporting this study.

   A. Will this study be requesting related or international donors through NMDP?

   ◯ Yes - *Answer the following:*

   - If international donors are being considered, will the study sponsor provide translations of the donor consent form?

     ◯ Yes ◯ No

   NOTE: International Registries may have additional requirements for study submission and review by their International Ethics Review Committees. You may be required to complete additional registry-specific forms. European Union General Data Protection Regulations (GDPR) may apply.

   - What is the expected number of related donors that will provide cells for recipients enrolled on this study?

   ◯ No

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B. For NMDP unrelated donors:

- What is the expected number of NMDP unrelated donors that will provide cells for recipients enrolled on this study?

- What is the anticipated rate of accrual for NMDP unrelated donors?

C. What is the preferred stem cell source?

- ○ HPC, Marrow
- ○ HPC, Apheresis
- ○ HPC, Cord Blood
- ○ MNC, Apheresis
- ○ Either HPC, Marrow or HPC, Apheresis accepted (no preference)
- ○ N/A: Study is not conducted in conjunction with a stem cell donation.

D. If the donor is unable/unwilling to provide the preferred stem cells, will an alternative be accepted?

- ○ Yes: List alternate cell sources that will be accepted:
- ○ No
- ○ N/A: Study is not conducted in conjunction with a stem cell donation

5. If the donor declines to support this research activity, but agrees to donate the hematopoietic cell (HPC) product, will you proceed with the donor's HPC donation, or will you search for an alternate donor?

- ○ Continue with hematopoietic cell donation
- ○ Search for alternate donor
- ○ N/A: Study is not conducted in conjunction with a hematopoietic cell donation

Comments:

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6. Will donors need to be screened outside of the NMDP Standard Donor Eligibility Determination process?

   ◯ Yes - Answer the following:

   - What will the donor be asked to provide for this screening (If donor will be asked to provide blood, also specify the volume of blood needed)?

   - At what time point(s) will the donor be asked to provide the blood/information for screening?

   ◯ No

7. Will supporting this research study increase the donor's chance of being asked to donate cells a second time for the recipient (e.g., do the research aspects of this study put the recipient at greater risk than normal for primary or secondary graft failure)?

   ◯ Yes - Estimate the percent of increased risk:

   ◯ No

Investigator's Statement:

As Principal Investigator of this study, I assure the NMDP Donor Cells for Manufacturing Review Group that all statements included in this application are true. I assure the NMDP Donor Cells for Manufacturing Review Group that resources necessary to protect study participants are in place. I agree that I will not initiate this research study until I have received approval to do so from the NMDP Donor Cells for Manufacturing Review Group.

_____ _____

Signature of Principal Investigator Date

The Donor Cells for Manufacturing Protocol Questionnaire and Study Protocol must be submitted in order to be reviewed by the NMDP for approval.

Send Protocol Questionnaire and all accompanying documents electronically to CMResearch@nmdp.org

If you have questions regarding the questionnaire or the NMDP Donor Cells for Manufacturing review process, email CMResearch@nmdp.org

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