

Hematopoietic Stem Cell Donor Selection Criteria

Guidelines for Autologous and Allogenic Stem Cell Donors

I. History and Physical

1. Potential donors must have a medical history taken, including a vaccination history, transfusion history, travel history and a series of questions assessing behavior to identify persons at high risk for significant transmissible infections as defined by USFDA for donors of cell and tissue based products. Reference will be made to the South Texas Blood and Tissue Center's screening questionnaire. A physical examination must be performed by a licensed physician at the collection center.
2. Particular attention should be given to findings that suggest an increased risk of transmission of blood-borne infection (e.g. HIV, hepatitis) or of potential problems with general anesthesia. Consultation with a board-certified anesthesiologist prior to consent to donate is strongly recommended for marrow donors if any potential problems with anesthesia are identified.

II. Reasons for potential exclusion:

1. Prior history of HIV, hepatitis, HTLV or syphilis.
2. Positive response to any questions on the HIV high-risk screen.
3. Receipt of transfused blood products within the past 12 months.
4. Potential problems resulting in a consultation by an anesthesiologist.
5. Current pregnancy (absolute exclusion).
6. Prior history of malignancy or marrow disease.
7. Previous exposure to chemotherapeutic agents or therapeutic radiation.
8. Positive test for current or past HIV infection.
9. Positive test indicating chronic active hepatitis.

III. Additional Testing

1. All potential marrow or peripheral blood hematopoietic stem cell donors must have a 12-lead electrocardiogram performed at the time of the pre-donation physical examination.
2. A chest x-ray must be performed on all donors.
3. ABO/Rh blood typing must be performed.
4. Pregnancy testing (blood) must be performed on all premenopausal female donors greater than 11 years of age. This testing may be omitted for women who have undergone hysterectomies.
5. At the time of the physical examination, all potential donors of peripheral blood hematopoietic stem cells will have a vascular access screening which will be assessed to determine whether the donor will be likely to require a central venous catheter in order to undergo apheresis. The results of this evaluation must be communicated to the donor at the time of the assessment.
6. All of these results must be documented in the medical record prior to collection.

IV. Reasons for potential exclusion

1. Positive pregnancy test (absolute exclusion)
2. Abnormal findings on EKG and/or CXR prompting a referral to an anesthesiologist or cardiologist for consultation prior to donation. Any abnormal findings evident in the pre-donation evaluation must be communicated to the donor or the donor's guardian while maintaining donor confidentiality. Appropriate referrals for further evaluation and management of identified problems must be made. Documentation of the referral and follow-up will be placed in the donor's medical record.

V. Final Review of Donor Suitability

1. The transplant physician must review the history and physical, histocompatibility typing, laboratory and other testing results and the informed consent documents to confirm that the donor is suitable to undergo collection of stem cells.
2. When all donor selection criteria have been met, the transplant physician must sign the completed donor suitability checklist documenting approval to donate prior to the start of mobilization with hematopoietic growth factors or prior to non-mobilized stem cell collection.
3. If stem cells are to be collected from a donor who does not meet all of the donor selection criteria (Exceptional Collection), either through abnormal findings or incomplete test results, the

transplant physician must document the rationale for such an Exceptional Collection. The donor suitability checklist must also be reviewed and approved by the collection center medical director prior to the start of collections. A supplemental consent, "Informed Consent for Exceptional Collection," explaining the unique potential hazards of the collection and use of this donor's stem cells must be reviewed with both the donor and recipient, and signed by both, before collection may begin. This additional informed consent will be placed in the medical records of both donor and recipient.

4. A copy of the signed donor suitability checklist is placed in the recipient's medical record and is sent to the collection site to inform these locations of the donor's suitability to undergo stem cell collection.