# Autologous and Allogeneic Donor Consenting Procedure

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ABMT-GEN-024
AUTOLOGOUS AND ALLOGENEIC DONOR CONSENTING PROCEDURE

1 PURPOSE

1.1 To describe the process of obtaining written informed consent from a prospective autologous or allogeneic stem and progenitor cell donor.

2 INTRODUCTION

2.1 Informed consent is the process used to educate prospective donors about the risks, benefits and details of the donation process and to obtain permission or proceed with donation as described. To protect the health of the donor and the recipient, tests to screen donors for risks associated with transmission of blood borne pathogens are a necessary part of the donor workup. These tests are explained to the donor along with the significance of a positive result. Abnormal results are documented in the donor records and recommendations for follow up care. The donor has the rights to review such test according to applicable laws and regulations. The consent process must be performed in terms and written and spoken language that the donor and/or legally authorized representative(s) can understand. The donor and/or or legally authorized representative(s) are also given the opportunity to ask questions and to discuss alternative options for donor procurement. The donor always has the right to refuse donation without penalty. The allogeneic donor and/or legally authorized representative(s) shall be informed of potential consequences to receipt of such refusal. In the case of a minor donor, informed consent shall be obtained from the donor’s legally authorized representative in accordance with applicable laws and regulations and shall be documented.

2.2 The consenting process is also used to inform the donor about any data submission and subsequent chart or data audits by internal or external regulatory agencies that required information about donors and/or the recipients of their donation. The donor is also informed about inclusion of data about their donation in any donor or transplant registries. The donor is informed that all medical information is kept confidential as required by law and that Federal Privacy Regulations provided safeguards for privacy, security, and authorized access.

2.3 After sufficient education about the procedure and time to review a written consent form document, the donor and/or legally authorized representative(s) signs the consent to give permission for the donation. The consent form is prepared in the donor’s native language if possible, if their first language is not English. If the consent cannot be prepared in the native language of the donor and/or legally authorized representative(s), it will be read to them by a provider and interpreted in the native language of the donor and/or legally authorized representative(s) by the interpreter, who is not a family member or legally authorized representative of the patient.
3 SCOPE AND RESPONSIBILITIES

3.1 This procedure describes the process for providing a full informed consent to an autologous or allogeneic donor giving cellular therapy cells.

3.2 Informed consent from the allogeneic donor shall be obtained by a license health care professional other than the intended recipient’s primary transplant team.

3.3 MD/NP/PA required. Note: Unrelated donors are consented by their respective donor center or national Marrow Donor program (NMDP) staff.

4 DEFINITIONS/ACRONYMS

4.1 MD Medical Doctor

4.2 NP Nurse Practitioner

4.3 PA Physician’s Assistant

4.4 PBPC Peripheral blood progenitor cells

4.5 G-CSF Granulocyte colony stimulating factor

4.6 IRB Investigational Review Board

5 MATERIALS

5.1 Educational materials

5.2 Consent form(s)

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 The allogeneic donor and/or legally authorized representative(s) shall give informed consent and authorization prior to release of information on the donor’s health and appropriateness to donate to the transplant physician or the recipient and/or legally authorized representative(s).

8.2 The written consent document is prepared. If necessary it is translated into the donor’s native language. If this is not possible, the consent is read to the donor and/or legally authorized representative by a translator, who is not a family member or legally authorized representative of the patient, in the native language of the donor and/or legally authorized representative(s).

8.3 The provider meets with the donor and/or their parent or legal guardian and explains the type of planned donation (e.g. Bone Marrow or PBPC). If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).
8.4 The provider informs the donor as to whether or not they will need to be treated with G-CSF or other cytokines prior to their donation. If so, the risks and benefits and methods of administration of this therapy are reviewed. If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).

8.5 The provider informs the donor that in the event of death of family member or if the family member no longer requires the cells, the cells will be discarded. If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).

8.6 If the donor needs a central venous catheter, the provider describes the placement of this device and the risks and benefits associated with the catheter. Ongoing care of the catheter is also reviewed. If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).

8.7 The provider gives the donor and/or legally authorized representative(s) a copy of the written consent document to read and review in the native language of the patient or legally authorized representative(s). The donor and/or legally authorized representative(s) are encouraged to prepare questions to ask the physician or transplant coordinator at the formal consenting session. If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).

8.8 The transplant coordinator meets with the patient donor and or legally authorized representative(s) after the physician is finished to review the risks and benefits of the donation procedure, the processes of administering G-CSF, the procedure of catheter placement, catheter care, bone marrow harvesting, general anesthesia, post donation care, as indicated by the planned type of donation for the particular donor. If the donor and/or legally authorized representative(s) do not speak English, then an interpreter, who is not a family member or legally authorized representative of the patient, is present to interpret in the native language of the donor and/or legally authorized representative(s).

8.9 The transplant coordinator reviews the consent with the donor and/or legally authorized representative(s). When possible, the consent is translated into the native language of the donor and/or legally authorized representative(s). If English is not their native language, a translator, who is not a family member or legally authorized representative of the patient, reads the consent to them in their native language.
8.10 The transplant coordinator schedules a second appointment for the provider to meet with the donor and/or legally authorized representative(s), and have an interpreter, who is not a family member or legally authorized representative of the patient, present if applicable. Note: In some circumstances, the informed consent may be obtained during the initial visit.

8.11 The physician and transplant coordinator meet with the donor and/or legally authorized representative(s) for a second time. At this meeting, they review the questions the donor and/or legally authorized representative(s) had after reading the consent form or after an interpreter, who is not a family member or legally authorized representative of the patient, have interpreted the consent for them. They answer any other questions the and/or legally authorized representative may have with an interpreter, who is not a family member or legally authorized representative of the patient, present if applicable.

8.12 The provider witnesses the donor and/or legally authorized representative(s) signing the consent form. The signer must initial each page and sign and date the last page. The provider also signs and dates the last page of the consent form. If an interpreter is used, the interpreter, who is not a family member or legally authorized representative of the patient, will also sign the consent to document they were present at the time of consent signing and they used an interpreter, who is not a family member or legally authorized representative of the patient, in the native language the information ready by the physician to the patient and/or legally authorized representative(s).

8.13 The transplant coordinator makes a copy of the signed consent form for the patient and/or legally authorized representative(s). This is given to the patient and/or legally authorized representative(s) before they leave.

8.14 Additional copies of the signed consent form are made and distributed to the donor’s chart in the Stem Cell Lab, Duke Medical Records, and the BMT data management team.

8.15 The donor and/or legally authorized representative(s) is given the appointment for their next visit and their donation.

8.16 The donor is given a prescription for any outpatient medications that will be administered related to the donation procedure. Instructions for administration of these medications are discussed.

8.17 Documentation of consent shall be available to the collection facility staff prior to the collection procedure.

9 RELATED DOCUMENTS/FORMS

9.1 NA

10 REFERENCES

10.1 NA
11 REVISION HISTORY

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ABMT-GEN-024 Autologous and Allogeneic Donor Consenting Procedure

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Management

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Medical Director

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