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Division of Cellular Therapy

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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 prospective autologous or allogeneic donors in the Adult Blood and Marrow Transplant (ABMT) program.

2 INTRODUCTION

2.1 Informed consent is the process used to obtain permission to proceed with donation after the prospective donor is educated about the donation process, the risks and benefits of donation, as well as the intent of donating for treatment and/or research. The consent process must be performed, in terms of written and spoken language, that the donor and/or legally authorized representative(s) can understand. If English is not the donor's or legally authorized representative(s)'s first language, an interpreter will be present for all meetings to assist with communication. The donor and/or legally authorized representative(s) is also informed that all medical information is protected and kept confidential as required by law and that Federal Privacy Regulations provided safeguards for privacy, security, and authorized access.

2.2 The consenting process is also used to inform the donor and/or legally authorized representative(s) about any data submission and subsequent chart and/or data audits by internal and/or external regulatory agencies that required information about donors and/or the recipients of their donation. The donor and/or legally authorized representative(s) is also informed about the inclusion of data regarding their donation in any donor or transplant registries.

2.3 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.

2.4 The donor always has the right to refuse to donate or withdraw consent without penalty. The allogeneic donor and/or legally authorized representative(s) shall be informed of potential consequences of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.

2.5 After sufficient education about the donation process and time to review a written consent is given, the donor and/or legally authorized representative(s) signs the consent to give permission for the donation.

3 SCOPE AND RESPONSIBILITIES

3.1 The donor informed consent for the cellular therapy product donation shall be obtained and documented by a physician, or designee under a physician's oversight, knowledgeable with the donation procedure.

3.2 Informed consent from an allogeneic donor shall be obtained and documented by a physician, or designee under a physician's oversight, other than the intended recipient's primary transplant team.

3.3 The attending physician shall have oversight of the consenting process in its entirety.

3.3.1 The attending physician may delegate responsibilities to a designee, but oversight will be maintained.

3.3.2 The designee must be a licensed health care professional in the "clinician" category, which includes advanced practice providers (APPs).

3.4 Unrelated donors are consented by their respective donor center or the National Marrow Donor Program (NMDP) team.

4 DEFINITIONS/ACRONYMS

4.1	APP	Advanced Practice Provider
4.2	BM	Bone Marrow
4.3	FACT	Foundation for the Accreditation of Cellular Therapy
4.4	G-CSF	Granulocyte Colony Stimulating Factor
4.5	IRB	Investigational Review Board
4.6	NMDP	National Marrow Donor Program
4.7	PBC	Peripheral Blood Collections

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 A consent form is prepared in the donor's or legally authorized representative(s)'s native language if possible, if their first language is not English. If this is not possible, the consent will be read to them by the physician or designee and interpreted in the native language of the donor and/or legally authorized representative(s) by a qualified translator, who is not a family member or legally authorized representative of the donor.

8.2 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 and/or legally authorized representative(s) along with the significance of a positive result and are documented in the donor records as well as recommendations for follow up care.

The donor and/or legally authorized representative(s) has the rights to review such test according to applicable laws.

8.3 The allogeneic donor and/or legally authorized representative(s) shall give informed consent and authorization prior to release of the donor's health and appropriateness to donate per the Foundation for the Accreditation of Cellular Therapy (FACT) guidelines, to the recipient's transplant attending physician or designee and/or the recipient and/or legally authorized representative(s).

8.4 The attending physician or designee meets with the donor and/or legally authorized representative(s) and explains the type of planned donation (e.g. Bone Marrow (BM) or peripheral blood collections (PBC).

8.5 The attending physician or designee informs the donor and/or legally authorized representative(s) as to whether or not they will need to be treated with granulocyte colony stimulating factor (G-CSF) or other cytokines prior to their donation. If so, the risks and benefits and methods of administration of this therapy are reviewed.

8.6 The attending physician or designee informs the donor about cellular therapy product storage, when and/or whether to discard or dispose of said product, including actions taken when an intended recipient no longer requires the cellular therapy product. This includes information that in the event of death of the recipient or if the recipient no longer requires the cells, the cells may be discarded.

8.7 If the donor needs a central venous catheter, the attending physician or designee describes the placement of this device and the risks and benefits associated with the catheter. Ongoing care of the catheter is also reviewed.

8.8 The attending physician or designee gives the donor and/or legally authorized representative(s) a copy of the written consent document to read and review. The donor and/or legally authorized representative(s) are encouraged to prepare questions to ask the medical team at the formal consenting session.

8.9 The donor and or legally authorized representative(s) meets with the donor coordinator after the physician or designee 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, peripheral blood donation, general anesthesia, post donation care, as indicated by the planned type of donation for the particular donor.

8.10 The donor coordinator reviews the consent with the donor and/or their legally authorized representative(s).

8.11 The donor/transplant coordinator schedules a second appointment for the attending physician or designee to meet with the donor and/or legally authorized representative(s). In some circumstances, the informed consent may be obtained during the initial visit.

8.12 The attending physician or designee and donor/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 has

interpreted the consent for them. They answer any other questions the donor and/or legally authorized representative(s) may have with an interpreter present, if applicable.

8.13 The attending physician or designee and donor/transplant coordinator witness the donor and/or legally authorized representative(s) signing the consent form. The signatory must initial each page and sign and date the last page. The attending physician or designee also signs and dates the last page of the consent form. If an interpreter is used, the interpreter will also sign the consent to verify they were present at the time of consenting and they interpreted the consent in the native language read by the attending physician or designee to the donor and/or legally authorized representative(s).

8.14 A copy of the signed consent form is provided to the donor and/or legally authorized representative(s) before they leave.

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

8.16 If indicated, the donor may be given a prescription for supplemental medications as applicable for the donor. 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.

8.18 Document Storage:

8.18.1 Additional copies of the signed consent form are made and distributed to the donor's chart in the Stem Cell Laboratory, Hospital Medical Records, ABMT data management team, and the recipient's chart where applicable. If applicable, a copy is sent to the Research Team for storage according to research policies.

9 RELATED DOCUMENTS/FORMS

9.1 NA

10 REFERENCES

10.1 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). *Standards for hematopoietic progenitor cell collection, processing & transplantation* (Current ed.)

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
08	Jennifer Frith Mary Christen	- The term "physician" updated to "attending physician or designee" throughout to align with institutional consent wording. - Section 2 updated to provide better readability and to group like items together - Section 3 updated to specify oversight by the attending physician and to group like items together. - Section 4 updated to reflect all acronyms used in the document. - Section 8 updated to provide better readability and align with institutional and regulatory wording per FACT (8th edition).

Signature Manifest

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