PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Autologous and Allogeneic Donor Consenting Procedure

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PBMT-GEN-059
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 in the Pediatric Transplant and Cellular Therapy Program.

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 for proceeding with donation as described. To protect the health of the donor and the recipient, tests to screen 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 of follow up care. The donor has the right to review such tests according to applicable laws and regulations. The consent process must be performed in terms of written and spoken language that the donor and/or their parent(s) or legally authorized representative(s) can understand. The donor and/or their parent(s) or legally authorized representative(s) are 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 parent(s) or legally authorized representative(s) shall be informed of potential consequences to recipient of such refusal including the risks to the recipient if the donor refuses donation after the recipient has started the preparative regimen. 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 require 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 provide 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 their parent(s) or legally authorized representative(s) signs the consent to give permission for the donation. If the consent cannot be prepared in the native language of the donor and/or parent(s) or legally authorized representative(s), it will be read to them by a physician and interpreted in the native language of the donor and/or parent(s) 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.

3.1.1 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 harvest procedure.

3.1.2 Informed consent from the 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 physician.

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

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

3.2.2 The designee must be a licensed health care professional in the "clinician" category, which can include a mid-level practitioner or physician assistant.

4 DEFINITIONS/ACROYNMS

4.1	BM	Bone Marrow
4.2	FACT	Foundation for the Accreditation of Cellular Therapy
4.3	GCSF	Granulocyte-colony stimulating factor
4.4	IRB	Institutional Review Board
4.5	PBC	Peripheral Blood Cells

5 MATERIALS

5.1 Educational materials

5.2 Consent form(s)

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

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

8.2 If the donor, parents and/or legally authorize representatives are not fluent in English, the consent is read to the donor and/or their parent(s) or legally authorized representative(s) by a translator in the native language of the donor and/or parent(s) or legally authorized representative(s). Family members and legally authorized representative will not serve as translators for the consenting process.

8.3 If English is not the patient and or parents(s) or legally authorized representative(s)'s first language, an interpreter will be present for all meetings to assist with communication.

8.4 The attending physician or designee meets with the donor and/or their parent(s) or legally authorized representative(s) and explains the type of planned donation (e.g., Bone Marrow (BM) or Peripheral Blood Cells (PBC), which may include CAR-T cells).

8.5 The attending physician or designee informs the donor as to whether or not they will need to be treated with granulocyte-colony stimulating factor (GCSF) or other cytokines prior to their donation. If so, the risk 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, discard or disposal, 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 clinical team describes the placement of this device and the risks and benefits associated with the catheter. Ongoing care of the catheter is reviewed also.

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

8.9 The nurse coordinator meets with the patient donor, and/or parent(s) or legally authorized representative(s) 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.

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

8.11 The nurse coordinator schedules a second appointment for the attending physician or designee to meet with the donor and/or parent(s) or their legally authorized representative(s), and have an interpreter present if applicable.

8.12 The attending physician or designee and nurse coordinator meet with the donor and/or parent(s) or their legally authorized representative(s) for a second time. At this meeting, they review the questions the donor and/or parent(s) 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 patient and/or parent(s) or legally authorized representative(s) may have with an interpreter present if applicable.

8.13 The attending physician or designee and nurse coordinator witness the donor and/or their parent(s) 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 document to verify they were present at the time of consent signing and that they interpreted in the native language the information read by the attending physician or designee to the patient and/or patient(s) or legally authorized representative(s).

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

8.15 Additional copies of the signed consent form are made and distributed to the donor's chart in the Stem Cell Laboratory, Hospital Medical Records, and the donor section of the recipient's red chart where applicable (i.e. directed allogeneic donors in pediatrics). If applicable, a copy is sent to the Research Team for storage according to research policies.

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

8.17 If indicated, the donor may be provided prescriptions for supplemental medications as applicable for the patient (i.e. iron, calcium and/or vitamin K). Instructions for administration of these medications are discussed.

8.18 If indicated, a directed donation of red blood cells is arranged for the donor.

8.19 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

Revision No.	Author	Description of Change(s)
08	Sally McCollum	- The term "physician" updated to "attending physician or designee" throughout to align with institutional consent wording. - Scope section updated to specify oversight by the attending physician - Scope section updated to group like items together. - Section 8.6 clarified further with more details.

Signature Manifest

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