PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Transplant Patient Consenting Procedure

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PBMT-GEN-061
TRANSPLANT PATIENT CONSENTING PROCEDURE

1 PURPOSE

1.1 To describe the process of obtaining written informed consent from a prospective transplant patient and or their parent(s) or legally authorized representative(s).

2 INTRODUCTION

NOTE: When the term "interpreter" is utilized in this document it refers to either a Duke supplied medical interpreter or the patient request interpreter

2.1 Informed consent is the process used to educate the prospective patient and/or their parent(s) or legally authorized representative(s) about the risks, benefits and details of the transplant process and to obtain written permission to proceed with therapy as described. As part of the consenting process, results of tests performed during the patient's pre-transplant work-up to assess organ function, infectious disease status, and primary disease status are reviewed. These test results are explained to the patient and/or their parent(s) or legally authorized representative(s) emphasizing the significance of any positive results. Results of organ function tests are explained with specific attention to any additional risks organ dysfunction could to the overall risks or success associated with the transplant process. If the patient is found to be infected with an opportunistic organism, the need for and type of treatment is discussed. The contribution to transplant-related morbidity and mortality is also explained. The impact of patient's primary diagnosis and stage of disease on transplant outcomes is also explained. Donor selection and the reasons for the choice of a particular donor for the patient is also discussed.

2.2 The patient and or their parent(s) or legally authorized representative(s) undergo an extensive educational process to learn about the treatment, their donor, potential risks and benefits and processes involved with transplantation therapy before signing the written consent form.

2.3 The consent process must be performed in terms that the patient or their parent(s) or legally authorized representative(s) can understand. If English is not the patient's and/or parent(s) or legally authorized representative(s) first language, a medical interpreter is used for all meetings and/or conversations with the patient and relevant parties. If the patient and/or legally authorized representative(s) requests to use a "family member, friend, or free-lance interpreter" instead of the sponsored medical interpreter, the patient and/or legally authorized representative(s) must complete the following: Patient/Companion Waiver: Refusal to Use a Duke University Health System Sponsored Interpreter, which must be signed and entered into the medical record prior to consenting.

2.4 Whenever possible, written materials are translated into the corresponding language for each family as needed, but if not possible, they are verbally translated during the in person meetings with the patient/family/legally authorized representative(s). The patient 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 (e.g., allogeneic vs autologous, related vs unrelated, PBPC vs BM vs UCB). Alternative treatment options must also be explained. Parents' consent for pediatric patients less than (<) 18 years of age, but children greater than (>) 12 years of age also assent to treatment if they are developmentally and medically able to participate in the consenting process. Any patient and/or their parent(s) or legally authorized representative(s) always has the right to refuse treatment.

2.5 The consenting process is also used to inform the patient and/or their parent(s) or legally authorized representative(s) about any data submission and subsequent chart or data audits by internal or external regulatory agencies that required information about patients or donors. The patient and or their parent(s) or legally authorized representative(s) are also informed about inclusion of data about their transplant or their donor's course in any donor or transplant registries.

2.6 After sufficient education about the procedure and time to review a written consent form document, the patient and or their parent(s) or legally authorized representative(s) sign(s) the consent to give permission for the transplantation process. The consent form is prepared, whenever possible, in the native language of the patient and or their parent(s) or legally authorized representative(s). If this is not possible, the consent is read by the physician and interpreted in the native language of the patient and/or the parent(s) or legally authorized representative(s) by the interpreter. The interpreter also signs the consent to document they were present at the time of consent signing and that they interpreted in the native language of the patient and or parent(s) or legally authorized representative(s).

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure applies to or is referenced when consenting a patient for treatment.

3.2 Physician and Nurse Coordinator Required. Often assisted by social workers, medical psychologists, child-life therapists, and nurse practitioners.

3.3 A sponsored medical interpreter may be required.

4 DEFINITIONS/ACRONYMS

4.1 PBSC Peripheral Blood Stem Cells

4.2 TBI Total Body Irradiation

4.3 UCB Umbilical Cord Blood

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 STEPS

8.1 The written consent document is prepared. If necessary, it is translated into the patient's native language. If written translation is not possible, the consent is read to the patient by a medical interpreter in the patient's native language.

8.2 If the patient and/or parents(s) or legally authorized representative(s)'s are not fluent in English a medical interpreter will be present for all critical meetings to assist with communication.

8.3 The physician and nurse coordinator jointly meet with the patient and/or their parent(s) or legally authorized representative(s) and explaining the planned treatment including type of donor (e.g., autologous or allogeneic, related or unrelated, Bone Marrow, Umbilical Cord Blood (UCB) or Peripheral Blood Stem Cells (PBSC).

8.4 The physician and nurse coordinator describes the placement of central venous catheter devices and the risks and benefits associated with the catheter(s). Ongoing care of the catheter(s) is also reviewed. Note: The surgical team is responsible for administration of the surgical consent.

8.5 The physician meets with the patient and their parent(s) or legally authorized representative(s) to outline their workup, treatment plan, clinical protocol enrollment, expected reactions, risks and benefits and overall details of the procedure.

8.6 The physician or provider gives the patient and or their parent(s) or legally authorized representative(s) a copy of the written consent document(s) to read and review. The patient and or their parent or legally authorized representative(s) are encouraged to prepare questions to ask the physician or transplant coordinator.

8.7 The nurse coordinator meets with the patient and their parent(s) or legally authorized representative(s) multiple times during the pre-transplant evaluation to educate him/her on the following at a minimum: the risks and benefits of the transplant procedure, the processes of catheter placement, catheter care, general anesthesia, Total Body Irradiation (TBI) (if applicable), administration and expected side effects of high dose chemotherapy, supportive care, hospitalization, isolation, infection prophylaxis, mouth care, neutropenic precautions, discharge planning, home health care and expectations for hospital discharge as indicated by the planned type of care for the particular patient.

8.8 Prior to the final consenting session, the nurse coordinator reviews the consent with the patient and/or their parent(s) or legally authorized representative(s) answering any questions they may have. If the patient and/or their parent(s) or legally authorized representative(s) are not fluent in written English a medical interpreter reads the consent, or the nurse coordinator will read the consent and the medical interpreter will interpret.

8.9 The physician and nurse coordinator meet with the patient and their parent(s) and or their legally authorized representative(s) for a subsequent meeting. At this meeting, they review the questions the family had after reading the consent form. They answer any other questions the family may have.

8.10 If cells were collected for use of the patient, then during the final consenting session, the patient and their parent(s) or legally authorized representative(s) is informed of discard of collected cells in the event of patient death or if they no longer require the cells, after reconfirmation with patient and or family or legally authorized representative(s).

8.11 The physician and nurse coordinator witness the patient and/or their parent(s) or legally authorized representative(s) signing the consent form. The signer must initial each page and sign and date the last page. The physician also signs and dates the last page of the consent form. If an interpreter is used, the interpreter will also sign the consent to document they were present at the time of consent signing and that they interpreted in the native language the information read by the physician to the patient and/or parents(s) or legally authorized representative(s).

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

8.13 Document storage:

8.13 Additional copies of the signed consent form are made and sent to medical records and a copy is placed in the associated laboratory folder, as applicable.

8.13 The original copy of the signed consent form goes into the patient's associated research folder and/or red chart, as applicable.

9 RELATED DOCUMENTS/FORMS

9.1 Policy/Procedure: DUHS Communication with Non-English-Speaking Patients, current revision.

9.2 Policy/Procedure: DUHS Communication for Patients with Special Needs, current revision

9.3 Policy/Procedure: DUHS Informed Consent, current revision

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
08	Sally McCollum	• Section 2.3 updated to include waiver information. • Section 3.3 updated to include "sponsored". • Related documents section: updated to include associated hospital policies.

Signature Manifest

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