DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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DOCUMENT TITLE:
Agreement and Consent for the Storage of Cellular Products in the Stem Cell Laboratory

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Form M03

DUKE UNIVERSITY HEALTH SYSTEM

Recipient Name:

Recipient History #:

Adult and Pediatric Blood and Marrow Transplant Programs
Duke University Medical Center
Durham, NC 27710
Dr. Joanne Kurtzberg, M.D, Medical Director
Dr. Nelson Chao, MD, Medical Director

Throughout this document, you may also refer to you or your minor child.

You need to read this form carefully. There may be words or parts of this document that you do not understand. You should ask your transplant program doctor or staff to explain any information that is not clear to you before signing this form. If there is anything you do not understand, please ask questions.

INTRODUCTION

Blood, bone marrow or other tissue, e.g. parathyroid tissue containing cells needed for you/your child's treatment require storage in the Stem Cell Laboratory of the Duke Adult and/or Pediatric Blood and Marrow Transplantation Programs. In order to keep the cells or tissue alive until they are needed, the laboratory prepares the cells or tissue in a way that allows them to be frozen and stored at very cold temperatures (at or below -150°C). If kept at or below this storage temperature, experience has shown that cells or tissue may be kept alive for as long as 20 years.

PURPOSE

The purpose of this agreement/consent is to inform you of the laboratory's policy regarding the storage and disposition of frozen cellular products.

PROCEDURES/POLICIES

All or a portion of the blood bone marrow or other tissue taken from you/your child or from your/your child's donor may be prepared for freezing in the Stem Cell Laboratory. In the laboratory the cells will be processed and mixed with chemicals that prevent injury to the cells or tissue during freezing. The cells or tissue will be frozen and then transferred to liquid nitrogen storage freezers and kept at or below -150°C until needed. The laboratory has procedures in place to monitor the storage temperature of the freezers to ensure that the cells or tissue remain at the appropriate temperature throughout storage.

The Stem Cell Laboratory will store cells or tissue for you/your child for as long as you/your child are alive in case those cells or tissue are needed for treatment. However, if you/your child do not survive, the laboratory, upon confirmation of the death notice, will no longer store the cells or tissue. Any remaining cells or tissue in storage will be discarded. You may also elect to have your/your child's cells or tissue transferred to another storage facility but you will be responsible for the cost incurred for this service, if applicable.

BENEFITS

The Stem Cell Laboratory has limited physical space for frozen product storage. By discarding unneeded cellular products or transferring them to an alternate storage facility, the laboratory will be better able to accommodate the storage of cellular products for other patients who are actively being treated.

_____ Recipient's / Guardian's Initials

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FINANCIAL OBLIGATIONS

There are no additional costs to you or your heirs to discard the stored cellular products when they are no longer needed. However, charges may be incurred if you choose to transfer frozen cells or tissue from the Stem Cell Laboratory to an alternate storage facility that requires fees for the transfer and/or storage of those products.

AGREEMENT/CONSENT

I acknowledge the following statements:

- This agreement/consent's purpose, procedures, benefits and financial obligations have been explained to me.
- I understand that my/my child's cells or tissue or cells or tissue donated for me or my child that are stored in the Stem Cell Laboratory will be discarded at the time of my/my child's death.
- I have had all of my questions answered to my satisfaction. If I did not understand this agreement/consent, I asked the transplant program doctor and/or the clinical staff to explain what I did not understand.
- I have been provided with the names of staff whom I may contact if I have additional questions.
- I will receive a signed and dated copy of this agreement/consent.

_____ Recipient's / Guardian's Initials

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DUKE UNIVERSITY HEALTH SYSTEM

Recipient Name:

Recipient History #:

Recipient Name (please print):

Recipient Signature or Legal Representative (relationship) Date

Print Name of Person Discussing and/or Obtaining This Agreement/Consent

Signature of Person Discussing and/or Obtaining This Agreement/Consent Date

Witness Signature (If Applicable) Date

_____ Recipient's / Guardian's Initials

Signature Manifest

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Title: Agreement and Consent for the Storage of Cellular Products in the Stem Cell Laboratory

All dates and times are in Eastern Time.

APBMT-COMM-040 Agreement and Consent for the Storage of Cellular Products in the Stem Cell Laborator

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