STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Disposing of Unused-Outdated Cryopreserved Recipient Products

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STCL-SOP-045
DISPOSITION OF UNUSED/OUTDATED CRYOPRESERVED RECIPIENT PRODUCTS

1 PURPOSE

1.1 To describe the procedure by which cryopreserved products are targeted for disposal and how this disposal process is documented.

2 INTRODUCTION

2.1 The Stem Cell Laboratory (STCL) processes a large volume of HPC-A, HPC-M, and HPC-C products for cryopreservation. Since freezer space is limited, it is necessary to have a system available to make freezer space available for other recipient products, as needed. During the work up phase, before a recipient comes for transplantation, each recipient signs a release form (consent) stating that upon their death, we have authorization to discard all remaining cellular product collected on their behalf (autologous or allogeneic products). On occasion, freezer release forms have been mailed to recipients requesting signatures to authorize product disposal on recipients still alive. Therefore, products stored on recipients who have expired, and products that have signed release forms permitting disposal may all be discarded.

3 SCOPE AND RESPONSIBILITIES

3.1 Medical Technologists culling these products are responsible for making certain all products slated to be discarded meet the necessary criteria before the products are disposed..

3.2 A Record of Discard must be generated and signed before cellular products can be disposed. Designated STCL employees are responsible for filing records that document the disposal of each cellular product.

3.3 The Medical Director, Laboratory Manager, and Stem Cell Laboratory staff is responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACROYNMS

4.1	HPC-A	Hematopoietic Progenitor Cells - Apheresis
4.2	HPC-M	Hematopoietic Progenitor Cells – Marrow
4.3	HPC-C	Hematopoietic Progenitor Cells – Cord Blood
4.4	ABMT	Adult Bone Marrow Transplant
4.5	PBMT	Pediatric Bone Marrow Transplant
4.6	STCL	Stem Cell Laboratory
4.7	LN2	Liquid Nitrogen

4.8 LIS Laboratory Information System

5 MATERIALS

5.1 Insulated cryogenic gloves

5.2 Safety goggles

5.3 Biohazard waste can liners

6 EQUIPMENT

6.1 Cooler (*for transporting samples to waste container*)

6.2 Biohazard waste disposal container

7 SAFETY

7.1 Wear appropriate personal protective equipment when handling any/all potentially hazardous blood and body fluids to include, but not limited to, cryogeneic gloves, lab coats, goggles, face shield, etc..

CAUTION:
When working with liquid nitrogen (LN2), additional personal protective equipment should be used to protect the employee and minimize exposures should a product container break, crack, LN2 splashes, etc.

8 PROCEDURE

NOTE: NEVER discard a cellular product without the appropriate authorization; *Record of Discard* form should be initiated to capture authorization signatures BEFORE a cellular product can be discarded or released for research.

8.1 Products from **LIVING** recipients:

8.1.1 The medical director or designee, in consultation with the recipient and the recipient's physician (if applicable), shall determine the disposition of cellular products.

8.1.2 If remaining cells are identified to be discarded or released for research from a patient who is still LIVING, the recipient's treating physician must inform the recipient of the plan to do so before the remaining products can be discarded or released for research.

8.1.3 The recipient, along with the treating physician, *if applicable,* will also be required to sign the *Record of Discard* reflecting that they have approved the discard or release to research of any of their remaining cellular products.

8.1.4 Cellular products may be transferred to another transplant or storage facility at the request of the recipient and/or medical director. The recipient, in consultation with their referring physician, may request that remaining cellular products be transferred to another transplant or storage facility. The Duke physician, in consultation with the referring

physician and the recipient must sign an "*Inter-Institutional Agreement*" so that arrangements can be made to transfer the remaining cellular products. A validated dry shipper and data logger will be obtained when transporting cryopreserved cellular products to another transplant center so the temperature can be monitored during transport to make sure the temperature is maintained at $\leq$ -150°C.

8.2 Products from **DECEASED** recipients:

8.2.1 Upon receipt of a death notification, the medical technologist will determine if cellular products remain available in storage in the STCL or not. If products remain available in the STCL, storage locations of those cellular products will be confirmed.

8.2.2 Pull the deceased patient's laboratory file. If product remains in STCL freezers, initiate a *Record of Discard.* Once confirmation of death has been confirmed via obituary obtained from the internet or other sources, the medical director's (*or designee*) and QA/ Lab Manager's signatures must be obtained to authorize discard of the product(s). Once the *Record of Discard* has been completed and signature obtained, the product can then be discarded. Documentation will be filed in the recipient's laboratory file.

8.2.3 Index cards, reflecting storage locations of cellular products, were initiated for transplants done prior to May 2011. If no index card is found in the respective patient's lab file, there may be no remaining product available or the recipient may have been transplanted prior to May 2001. Use these cards to serve as a reference when investigating whether there are stored products remaining.

8.2.4 Prior to 5/1/2001, recipient information sheets were sometimes used to document cryopreservation procedures and/or to record date of death. If a recipient information sheet is found, update it to indicate that the recipient is deceased. If there is remaining product in storage, pull the information sheet, initiate a *Record of Discard,* obtain signatures from the medical director (*or designee*) and QA/ Lab Manager authorizing disposal of the product(s). File all remaining documentation together.

8.2.5 If there is no laboratory file found, the recipient's information may be located in the old adult database. Filing of information sheets was done by date of procedure up until 1999. Attempt to identify the date of the bone marrow harvest, the date of apheresis, or the date of transplant. There should be a recipient information sheet included with the recipient's paperwork. If a recipient information sheet is found, update it to indicate that the recipient is deceased.. If there is remaining product stored in STCL freezers, pull the sheet recipient's information sheet and initiate a *Record of Discard* and obtain signatures from the medical director (*or designee*) and QA/ Lab Manager authorizing disposal of the product(s).

8.2.6 If no laboratory records can be found to support a death notification, the notice of death (usually in the form of an e-mail from one of the

adult or pediatric clinical members) will be filed for future reference. Reflect "No cells remain available in the STCL" on the death notice if the patient was not transplanted or if the lab was "unable to locate the laboratory file" for patient files no longer in the STCL. The notification of death should then be filed in the **DEATH NOTICES** folder located in the processing section of the STCL.

8.3 Once remaining product has been located and the medical director, QA/Lab Manager, and treating physician (*if applicable*) have signed the *Record of Discard*, the product may be discarded or released for research.

8.3.1 Locate and pull the bags up in vapor phase of the respective LN2 freezer. **Two technologists must verify** the name and history number on each of the product bags being considered for discard to VERIFY that the information on the label(s) is accurate and matches the laboratory source documentation for the product to be discarded or released for research.

8.3.2 Allow bags (especially for older model freezer bags) to equilibrate in vapor phase for approximately 10-15 minutes before discarding them or releasing them for research to avoid a rapid change in temperature which could result in the bags bursting.

8.3.3 Discard designated bags in the biohazard trash only after documenting their disposal on the *Record of Discard* form or recipient information sheet.

8.3.4 Make sure all discarded product information is given to the technologist who is responsible for updating the designated spreadsheet (*Stem Cell Laboratory – Discarded Products*).

8.3.5 In lieu of discarding cellular products, bags may be sent to an approved researcher.

8.3.5.1 De-identify the products by removing all traces of recipient/donor identity. Label the product with the type of product, the date frozen, the recipient's initials, and the recipient's diagnosis (or note that cells were collected from a healthy allogeneic donor, if applicable).

8.3.5.2 Place the bags in the vapor phase of a freezer and email the laboratory supervisor or designee to notify the approved researcher that there is product available so arrangements can be made to retrieve those products.

8.4 Cleaning out old freezers – At times there is an insufficient freezer space available to meet the needs of the STCL so older freezers may be cleaned out.

8.4.1 Determine which freezer contains the oldest products.

8.4.2 Record all of the locations in that particular freezer.

8.4.3 As one technologist pulls up the canisters, opens them, reads the name and history number, the other technologist records the information, so the freezer is mapped to reflect the identity of all of the stored products.

8.4.4 Each name is then searched in any/all respective databases to discover if the recipient is dead or alive.

8.4.5 If the information is not available in the database then the LIS may be searched to see if a date of death is available.

8.4.6 Deceased recipients' products can be marked for discard.

8.4.7 All other product must remain in the freezer.

8.5 Documentation

8.5.1 **NEVER** discard a cellular product without the appropriate authorization. (FRM1) *Record of Discard* may be used in some of the scenarios listed in this procedure.

8.5.2 All pertinent information, reflecting the disposition of a cellular product, should be recorded in the laboratory records. Documentation of all cellular products that are removed from LN2 freezer inventories will be captured on the excel spreadsheet maintained on the shared drive.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-SOP-045 FRM1 Record of Discard Form

10 REFERENCES

10.1 NA

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
04	B. Waters-Pick	• Added LIS to Section 4 • Changed wording in Section 8.1.2 • Changed wording in Section 8.2 since we no longer use the Social Security Index to confirm dates of death.

Signature Manifest

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