ADVOCATE HEALTH		
Title: Disposal of Hematopoietic Progenitor Cell Products Policy and Procedure (NCBH)		**Document Number: 55160**
Document Type: ☒ Policy ☐ Procedure ☐ Guideline ☐ Other		**Last Review/Revision Date: 06/25/2023**
Content Applies to Patient Care: (Select all that apply) **☒ Adults** **☐ Pediatrics (Under 18)**	**Content Applies to: (Select One)** **☒ Clinical** **☐ Administrative**	**Effective Date: 06/25/2023**
Scope: ☐ Enterprise ☐ MW Region ☐ SE Region **☐ WI ☐ IL ☐ Greater Charlotte Market ☐ Navicent Market ☐ Wake Market ☐ Floyd Market** **☒ Entity Only (Entity Name): NCBH ☒ Department Only (Department Name): SCTCT**		

I. PURPOSE

As stated in the Bone Marrow Cell and Hematopoietic Progenitor Cell (HPC) Storage Consent form, it is the policy of the Stem Cell Transplant and Cellular Therapy (SCTCT) Lab to store progenitor cells products for 10 years or until the patient's death. Subsequently the cells may be used for research and the advancement of medical science or destroyed unless instructed otherwise.

II. SCOPE

This document applies to the Stem Cell Transplant and Cellular Therapy Laboratory at AHWFBH.

III. DEFINITIONS/ABBREVIATIONS

HPC: Hematopoietic Progenitor Cell

Genetically modified cell: A cell that has been modified by replacing a disease-causing gene with a healthy copy of the gene, inactivating a disease-causing gene that is not functioning properly, or introducing new or modified gene into the body to help treat a disease.

IV. POLICY

A. Vials may only be destroyed after product for that patient is 100% infused, the patient has achieved engraftment, and the patient is greater than 100 days post transplant. This is recorded on the ***Vial Release Form, SCT-FORMS-0210.***
B. Product bags will only be destroyed after 10 years in storage or upon the patient's death
C. An older version of the consent form (circa 2007) did not account for disposal of products after 10 years; these products will be retained in by the BMT lab until patient expiration can be confirmed or a new Storage Consent signed.
D. Patient death must be confirmed in the electronic medical record or by the cancer registry death list provided to the SCTCT lab by the nurse coordinators.
E. Two technologists must verify the identity of vials or product bags being discarded.
F. SCTCT Program Medical Director must sign for release or destruction of any product bags; vials do not require a signature.

G. The state of North Carolina does not have additional requirements for the disposal of genetically modified cells, and they can be disposed of in the red biohazard bins in the Processing Room.

V. PROCEDURE

A. CRYOVIAL DISPOSAL

1. Record vial locations on the Vial Release Form, BMT.Forms.1060 when patient is 100% infused and >100 days post engraftment.
2. Check the Vial Release Form monthly and update Freezer Inventory to reflect vials that can be discarded.
    a. Vials that can be discarded are circled in red pen in the Freezer Inventory.
3. Remove vials indicated for release from the freezer, with two technologists checking identity as vials are removed.
    Protective Equipment: Cryogloves, Lab Coat, Face Shield
4. Dispose of cells in a red biohazard container according to PPB-WFBMC-138, Management of Regulated and Nonregulated Medical Waste. (Online and in the Safety Manual, Section 25).
    Note: The state of North Carolina does not have additional requirements for the disposal of genetically modified cells, and they can be disposed of in the red biohazard bins in the Processing Room.
5. Sign the Vial Release Form documenting the removal/disposal of vials.
    a. Both technologists checking the vials should sign the form.
6. Document vial destruction in the patient's chart.
7. Update Freezer Inventory to reflect vial destruction.

EXPECTED OUTCOME RESULTS: Vials are destroyed; the destruction is documented.
ACCEPTABLE RANGES: n/a

B. PRODUCT BAG DISPOSAL

1. Receive notification that a patient has expired.
    a. Patient expiration must be confirmed in the electronic medical record or by the cancer registry death list provided by the nurse coordinators.
2. Record Patient Name and Medical Record Number, the source of information documenting patient expiration, and any product bag and vial locations on the Bone Marrow/Hematopoietic Progenitor Specimen Release Form, SCT-FORMS-0126.
3. Send the Bone Marrow/Hematopoietic Progenitor Specimen Release Form to the nurse coordinators to obtain signature of SCTCT Program Medical Director accepting the release or destruction of product bags.
    a. SCTCT Program Medical Director must sign for release BEFORE cells are removed from freezer.
4. Remove bags indicated for release from the freezer, with two technologists checking identity as bags are removed.
    Protective Equipment: Cryogloves, Lab Coat, Face Shield
5. Dispose of cells in a red biohazard container according to PPB-WFBMC-138, Management of Regulated and Nonregulated Medical Waste. (Online and in the Safety Manual, Section 25).

    Note: The state of North Carolina does not have additional requirements for the disposal of genetically modified cells, and they can be disposed of in the red biohazard bins in the Processing Room.

6. Sign the Bone Marrow/Hematopoietic Progenitor Specimen Release Form documenting the removal/disposal of vials.
    a. Both technologists checking the bags should sign the form.
7. Document bag destruction in the patient's chart.
8. Update Freezer Inventory to reflect product bag destruction.

EXPECTED OUTCOME RESULTS: Bags are destroyed; the destruction is documented.
ACCEPTABLE RANGES: n/a

C. VIAL OR PRODUCT BAG TRANSFER TO RESEARCH

1. Send the Bone Marrow/Hematopoietic Progenitor Specimen Release Form to the nurse coordinators to obtain signature of SCTCT Program Medical Director accepting the release of product bags.
    a. SCTCT Program Medical Director must sign for release BEFORE cells are removed from freezer.
2. Remove bags indicated for release from the freezer, with two technologists checking identity as bags are removed.
    Protective Equipment: Cryogloves, Lab Coat, Face Shield
3. Sign the Bone Marrow/Hematopoietic Progenitor Specimen Release Form documenting the removal/disposal of vials.
    a. Both technologists checking the bags should sign the form.
4. Receiving person from the research area obtaining the product bags should sign the
    a. Specimen Release Form to document transfer of the product bags.
5. Document bag transfer in the patient's chart.
6. Update Freezer Inventory to reflect product bag destruction.

EXPECTED OUTCOME RESULTS: Bags are transferred to a research lab; the transfer is documented.
ACCEPTABLE RANGES: n/a

VI. CROSS REFERENCES

Bone Marrow/Hematopoietic Progenitor Specimen Release Form
Product Release Form
Vial Release Form

VII. RESOURCES AND REFERENCES

FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration.

VIII. ATTACHMENTS

Not Applicable