NEW YORK STATE DEPARTMENT OF HEALTH
Blood and Tissue Resources Program
Wadsworth Center
P.O. Box 509
Albany, New York 12201-0509

Form B-2
Application for Licensure – Human Tissue Bank
For Hematopoietic Progenitor Cell Banks

For Comprehensive HPC Procurement Services/HPC Processing Facilities/
HPC Storage Facilities

PART I – Activities Performed

Place a checkmark in each box, as applicable, to indicate the donor source and the activity performed when HPCs are intended for use in hematopoietic reconstitution.

	Donor solicitation and selection	**Hematopoietic progenitor cell collection**	**Hematopoietic progenitor cell processing**	**Hematopoietic progenitor cell storage**	**Hematopoietic progenitor cell distribution**
Hematopoietic progenitor cells – Allogeneic – Related derived from					
peripheral blood	☐	☐	☐	☐	☐
bone marrow	☐	☐	☐	☐	☐
umbilical cord blood	☐	☐	☐	☐	☐
Hematopoietic progenitor cells – Allogeneic – Unrelated derived from					
peripheral blood	☐	☐	☐	☐	☐
bone marrow	☐	☐	☐	☐	☐
umbilical cord blood	☐	☐	☐	☐	☐
Hematopoietic progenitor cells – Autogeneic derived from					
peripheral blood	☐	☐	☐	☐	☐
bone marrow	☐	☐	☐	☐	☐
Hematopoietic progenitor cells – Private Storage derived from					
peripheral blood	☐	☐	☐	☐	☐
bone marrow	☐	☐	☐	☐	☐
umbilical cord blood	☐	☐	☐	☐	☐
Placenta					
placental blood - allogeneic	☐	☐	☐	☐	☐
placental blood - autogeneic	☐	☐	☐	☐	☐
placental blood - private storage	☐	☐	☐	☐	☐
Other sources of cells intended for purposes of hematopoietic reconstitution List all					

PART II – Administrative Responsibility (Please print or type)

A. Specify hematopoietic progenitor cell bank director (must meet requirements of 10 NYCRR 58-5.2(e)). Attach resume or curriculum vitae, specifically identifying all other employment, and a letter describing experience and how minimum requirements are met.

Name			
Name of bank or site			
Bank or site business address			
City	State	Zip	Telephone ( )
Days and hours present on site			

B. Hematopoietic progenitor cell bank medical director (must meet requirements of 10 NYCRR 58-5.2(f)). Attach resume or curriculum vitae, specifically identifying all other employment, and a letter describing experience and how minimum requirements are met.
[ ] check if the same as HPC bank director.

Name			
Name of bank or site			
Bank or site business address			
City	State	Zip	Telephone ( )
License number of medical director		New York or state where issued	
Days and hours present on site			

PART III – Medical Advisory Committee (Please print or type)

List all medical advisory committee members, including areas of expertise, pertinent positions held and location of employment. (Attach additional sheets if necessary.) Membership must include experts in the areas of infectious disease, hematology, oncology, histocompatibility and transfusion medicine, as well as physicians affiliated with hematopoietic progenitor cell transplantation facilities.

Name	Area of Expertise/Position Held	Location of Primary Employment

PART IV – Donor Selection and Testing (Please print or type)

A. Attach copies of donor health history forms, consent forms, and applicable donor selection criteria and protocols.

B. List all laboratory tests performed on donors or hematopoietic progenitor cells and indicate site of testing. If tests are performed at the applicant bank, indicate "on-site." (Attach additional sheets if necessary.)

Analyte/condition	Reference Laboratory Name and Address		
	Name		
	Street		
	City	State	Zip

	Name		
	Street		
	City	State	Zip

	Name		
	Street		
	City	State	Zip

For any bank or testing laboratory located, or performing collection, in New York State, provide a copy of the NYS permit held by the laboratory providing clinical laboratory testing services. The permit must specify all categories required for tissue, or blood donor testing.

For banks located outside of New York State, provide a copy of the CLIA certificate and, where required, the state license.

Each document must specify the categories for which licensure has been granted.

PART V – Premises and Equipment (Please print or type)

A. Description of Premises

1. Is the space contiguous? ☐ Yes ☐ No If not, please indicate other location(s).

2. What is the total approximate square footage of the work space?

3. Is the tissue bank physically located within the space occupied by any other health service purveyor?

☐ Yes ☐ No If yes, please explain.

B. Equipment

Attach a complete list, including a brief description, of equipment used.

PART VI (Please print or type)

A. Describe the tissue bank's proposed or existing service areas for the acquisition and distribution of tissue, as applicable.

B. Attach a complete list of all tissue banks that provide hematopoietic progenitor cells to the applicant, including limited and comprehensive tissue procurement services, tissue processing facilities, and tissue storage facilities. Indicate "NA" if not applicable.

C. Attach a complete list of all sites in New York State to which tissues are distributed by the applicant, including tissue processing facilities, tissue storage facilities, tissue transplantation facilities, and insemination/implantation sites. Indicate "NA" if not applicable.

D. Attach a copy of all existing tissue acquisition and/or processing agreements. Indicate 'NA" if not applicable.

E. Attach a brief description of any educational programs provided by the tissue bank, including those programs designed to encourage tissue donation. Indicate "NA" is not applicable.

PART VII

Director's Name	**Director's Signature**	**m d y**
Medical Director's Name	**Medical Director's Signature**	**m d y**