Tissue Resources Program
Wadsworth Center
New York State Department of Health
Empire State Plaza
Albany, New York 12237

Form B
Application for Licensure – Human Tissue Bank

For Comprehensive Tissue and Hematopoietic Progenitor Cell (HPC)
Procurement, Processing, Storage, and Distribution Facilities

PART I – Activities Performed

☐ **No changes to this section from current license.**

Current New York State tissue bank facility ID #, if applicable: _____

Place a checkmark in the applicable boxes below to indicate the donor sources and activities performed.

	Sources		Donor Qualification[1]	Recovery/ Collection	Processing	Storage & Distribution
	Allogeneic	Autologous				
Cardiovascular Tissue	☐		☐	☐	☐	☐
Musculoskeletal Tissue	☐	☐	☐	☐	☐	☐
Skin Tissue	☐	☐	☐	☐	☐	☐
Eye Tissue	☐		☐	☐	☐	☐
Nerve Tissue	☐		☐	☐	☐	☐
Amniotic Membrane	☐		☐	☐	☐	☐
Human Milk	☐		☐	☐	☐	☐
Other tissues – list all	☐	☐	☐	☐	☐	☐
Tissue Derived Products[2] – list sources	☐	☐	☐	☐	☐	☐
Hematopoietic Progenitor Cells – select sources below						
Peripheral Blood	☐	☐	☐	☐	☐	☐
Bone Marrow	☐	☐	☐	☐	☐	☐
Umbilical Cord Blood	☐	☐	☐	☐	☐	☐

[1] ***Donor Qualification*** includes, but is not limited to, consent, social and medical history, physical exam, and disease testing.

[2] ***Tissue Derived Products*** include, but are not limited to, products that contain hematopoietic progenitor cells from other sources than above, mesenchymal stem cells, or other cells derived from tissue.

PART II – Administrative Responsibility

☐ No changes to this section from current license.

A. Specify tissue bank director (must meet requirements of 10 NYCRR 52-2.5(a)(2)), HPC bank director (must meet requirements of 10 NYCRR 58-5.2(e)), or storage facility director (must meet requirements of 10 NYCRR 52-2.5(c)(2)). Submit a copy of current résumé or curriculum vitae, specifically identifying required education, employment, and professional experience.

Name		Title	
Facility name			
Facility address			
City	State	Zip	Telephone
Days and hours present on site		E-Mail Address	

B. Specify tissue bank medical director (must meet requirements of 10 NYCRR 52-2.5(a)(3)) or HPC bank medical director (must meet requirements of 10 NYCRR 58-5.2(f)). Submit a copy of current résumé or curriculum vitae, specifically identifying required education, employment, and professional experience.

☐ Check if same as the tissue bank director or HPC bank director.

Name		Title	
Facility name			
Facility address			
City	State	Zip	Telephone
License number of medical director		State where license issued	
Days and hours present on site		E-Mail Address	

PART III – Medical Advisory Committee

☐ No changes to this section from current license.

This section not applicable for facilities that are only storing and distributing tissue, milk or HPCs.

List all medical advisory committee members, including areas of expertise, pertinent positions held and location of employment (attach additional sheets if necessary).

A tissue bank medical advisory committee must include one or more members with expertise in infectious disease. A milk bank medical advisory committee must include physicians with experience in pediatrics, neonatology, blood banking, nutrition and/or other appropriate fields, and at least one member with expertise in infectious disease. The medical advisory committee must be composed of at least five members.

An HPC bank medical advisory committee must include one or more members with expertise in the areas of infectious disease, hematology, oncology, histocompatibility and transfusion medicine, as well as physicians affiliated with HPC transplantation facilities.

Name	Area of Expertise/Position Held

PART IV – Donor Qualification, Selection, and Testing

☐ No changes to this section from current license.

A. Submit copies of donor medical and social history questionnaire forms, consent forms, and donor selection criteria and protocols – not applicable for facilities that are only storing and distributing tissue, milk or HPCs.

B. List all laboratory and infectious disease tests performed on tissue, milk or HPC donors and provide site of testing – not applicable for facilities that are only storing and distributing tissue, milk or HPCs. If tests are performed at the applicant facility, indicate "on-site" (submit additional sheets if necessary).

Test	Reference Laboratory Name and Address		
	Name		
	Street		
	City	State	Zip
CLEP PFI or CLIA number as applicable:	CLEP	CLIA	

	Name		
	Street		
	City	State	Zip
CLEP PFI or CLIA number as applicable:	CLEP	CLIA	

	Name		
	Street		
	City	State	Zip
CLEP PFI or CLIA number as applicable:	CLEP	CLIA	

Submit copies of the CLIA certificates and, where required, the state license.

C. Submit standard operating procedures, as required by 52-3.5(a)(6), for collection, processing, storage, and/or distribution of tissue, milk or HPCs.

PART V – Premises and Equipment

☐ No changes to this section from current license.

A. Description of Premises

1. Is the space contiguous? ☐ Yes ☐ No

If not, provide other location(s):

2. Provide the total approximate square footage of the work space:

B. Equipment

Provide or submit a complete list, including a brief description, of equipment used (submit additional sheets if necessary):

PART VI – Tissue and HPC Providers and Receivers

☐ No changes to this section from current license.

A. Provide or submit a complete list of all tissue, milk and HPC banks that provide tissue, milk or HPCs to the applicant, including those responsible for donor qualification and selection, recovery and collection, processing, storage, and distribution (submit additional sheets if necessary). Indicate "NA" if not applicable.

B. Provide or submit a complete list of all sites in New York State to which tissues, milk or HPCs are distributed by the applicant, including those responsible for processing, storage, distribution, and transplantation (submit additional sheets if necessary). Indicate "NA" if not applicable.

PART VII

Tissue or HPC Bank Director's Name	**Tissue or HPC Bank Director's Signature**	**Date**
Medical Director's Name	**Medical Director's Signature**	**Date**
Name and title of person completing form	**Signature**	**Date**