NEW YORK STATE DEPARTMENT OF HEALTH
Tissue Resources Program
Wadsworth Center, Empire State Plaza
Albany, NY 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

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

☐ No changes to this section from current license.

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

Donor Source	Sources		Donor Qualification[1]	Recovery/ Collection	Processing	Storage and Distribution
	Allogenic	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 - HPCs (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	Phone
Days and hours 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)), or storage facility director (must meet requirements of 52-2.5(c)(3)). 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	Phone
License number of medical director	New York or state where issued		
Days and hours on site	E-Mail Address		

PART III – MEDICAL ADVISORY COMMITTEE

☐ No changes to this section from current license.

The medical advisory committee must be composed of at least five members - 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.

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.

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.

Name	Area of Expertise/Position Held	Pertinent Positions	Location of Employment

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 and Reference Laboratory

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

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

Test	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 – SIGNATURE

Director's Name: _____

Director's Signature: _____ **Date:** _____

Medical Director's Name: _____

Medical Director's Signature: _____ **Date:** _____

Name and Title of person completing form: _____

Signature: _____ **Date:** _____