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

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

Place a checkmark in each box to indicate the donor source and the activity performed. Check here to indicate no changes from current license: ☐

	Allogeneic	Autologous	Donor Qualification and Selection[1]	Recovery/ Collection	Processing	Storage & Distribution from this facility	Storage & Distribution from other facilities
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 source(s) below							
Peripheral Blood	☐	☐	☐	☐	☐	☐	☐
Bone Marrow	☐	☐	☐	☐	☐	☐	☐
Umbilical Cord Blood	☐	☐	☐	☐	☐	☐	☐

[1] ***Donor Qualification and Selection*** includes, but is not limited to, consent, social and medical history, 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

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 resume or curriculum vitae, specifically identifying 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 resume or curriculum vitae, specifically identifying education, employment, and professional experience.

☐ Check if same as the tissue bank director or hematopoietic progenitor cell bank director.

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

PART III – Medical Advisory Committee

List all medical advisory committee members, including areas of expertise, pertinent positions held and location of employment (attach additional sheets if necessary). The medical advisory committee must be composed of at least five members.
A tissue bank medical advisory committee must include one or more members with expertise in microbiology, clinical pathology or infectious disease.
An HPC bank medical advisory committee must include one or more members with experts in the areas of infectious disease, hematology, oncology, histocompatibility and transfusion medicine, as well as physicians affiliated with HPC transplantation facilities.
This section is not applicable for facilities that only conduct storage of tissue or HPCs.

Name	Area of Expertise/Position Held

PART IV – Donor Qualification, Selection, and Testing. Not Applicable for Tissue or HPC Storage Only Facilities

A. Submit copies of donor medical and social history questionnaire forms, consent forms, and applicable donor selection criteria and protocols.

B. Indicate all laboratory and infectious disease tests performed on tissue or HPC donors and indicate site of testing. 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
Indicate CLEP PFA or CLIA number as applicable:	CLEP	CLIA	

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

	Name		
	Street		
	City	State	Zip
Indicate CLEP PFA 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 or HPCs.

PART V – Premises and Equipment

A. Description of Premises

1. Is the space contiguous? ☐ Yes ☐ No

If not, indicate other location(s):

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

B. Equipment

Indicate 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

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

B. Indicate or submit a complete list of all sites in New York State to which tissues or HPCs are distributed by the applicant, including processing, storage, distribution, and transplantation facilities (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**