

PART I – Activities Performed

Place a checkmark in each box, as applicable, to indicate the donor source and the activity performed.

	Allogeneic	Autogeneic	Donor solicitation and selection	Tissue recovery/ collection	Tissue processing	Tissue storage	Tissue distribution
Cardiovascular tissue							
deceased donor							
living donor							
Musculoskeletal tissue							
deceased donor							
living donor							
Skin tissue							
deceased donor							
living donor							
Eye tissue							
deceased donor							
living donor							
Parathyroid tissue							
deceased donor							
living donor							
Nerve tissue							
deceased donor							
living donor							
Human Milk							
Amniotic membrane							
Other tissues – deceased donors list all							
Other tissues – living donors list all							
Cellular therapy products¹ – List source(s)							

¹ Cellular therapy products include, but are not limited to, products that contain mesenchymal stem cells derived from a human source, such as bone marrow, peripheral blood, umbilical cord blood, adipose tissue, menstrual blood, umbilical cord tissue, dental pulp, placenta, synovial fluid, amniotic fluid, and any other human tissue or fluid.

PART II – Administrative Responsibility**(Please print or type)**

A. Specify tissue bank director (must meet requirements of 10 NYCRR 52-2.5(a)(2)) or storage facility director (must meet requirements of 10 NYCRR 52-2.5(c)(2)). 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. Medical director (must meet requirements of 10 NYCRR 52-2.5(a)(3)). Attach resume or curriculum vitae, unless applicant is also the tissue bank director. check if same as the tissue 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 expertise in microbiology, clinical pathology or infectious disease. This section not applicable to the category of Tissue Storage Facility.

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 donated tissue 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 collecting tissue, in New York State, provide a copy of the NYS permit held by the laboratory providing clinical laboratory testing services. The permit must include all categories required for 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 tissue 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" if not applicable.

PART VII

_____ / _____ / _____
Tissue Bank Director's Name **Tissue Bank Director's Signature** **m d y**

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