NEW YORK STATE DEPARTMENT OF HEALTH
Tissue Resources Program
Wadsworth Center, Empire State Plaza
Albany, NY 12237

Application for Licensure
Human Tissue Bank
Hematopoietic Progenitor Cell Bank

PART I - ACTIVITIES PERFORMED (See instructions for definitions)

Name of Facility: _____

Facility Activities (Check all that apply):

☐ **Limited Tissue Procurement** (See instructions for definition) – Attach DOH-2973(a)

☐ **Procurement of Tissue[1], Hematopoietic Progenitor Cells, or Human Milk** – Attach DOH-2973(b)
Including donor qualification, recovery, retrieval, or collection of tissues (other than reproductive tissue), HPCs, and human milk.

☐ **Procurement of Reproductive Tissue** – Attach DOH-2973(b1)
Including donor qualification, recovery, retrieval or collection of reproductive tissue.

☐ **Processing of Tissue[1], Hematopoietic Progenitor Cells, or Human Milk** – Attach DOH-2973(b)

☐ **Processing of Reproductive Tissue** – Attach DOH-2973(b1)

☐ **Storage and Distribution of Tissue[1], Hematopoietic Progenitor Cells, or Human Milk** – Attach DOH-2973(b)

☐ **Storage and Distribution of Reproductive Tissue** – Attach DOH-2973(b1)

☐ **Transplantation of Tissue[1] or Hematopoietic Progenitor Cells, or Dispensing of Human Milk** – Attach DOH-2973(c)
Including temporary storage (greater than 24 hours) and issuance of tissue, HPCs or human milk for clinical use.

☐ **Insemination/Implantation of Reproductive Tissue** – Attach DOH-2973(d)
Including temporary storage and issuance of reproductive tissue for clinical use.

☐ **Assisted Reproductive Procedures for a Gestational Surrogacy Agreement** – Attach DOH-2973(g)

☐ **Nontransplant Anatomic Banking** – Attach DOH-2973(e)
Including donor solicitation, acquisition, recovery, processing, use, or distribution to a site in New York, of whole bodies, body segments, or nontransplant anatomic parts for medical research and/or education.

[1]**Tissue** means cardiovascular tissue, musculoskeletal tissue, skin, eye, birth tissues, etc. including cells derived therefrom, other than reproductive tissues.

For Tissue Resources Program Use Only	
☐ New Application ☐ Amended Application	
Facility ID:	**Date Received:**

PART II - FACILITY AND CONTACT INFORMATION

Name of Facility			
Street Address			
City	State	ZIP	County
Telephone		Fax	
Website address			
Contact Name			
Contact Title			
Contact E-mail address(es)			

Days/Hours of Operation	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Start							
End							

Is your facility registered with the FDA as a Human Cell and Tissue Establishment? ☐ Yes ☐ No

Mailing address (if different from above):

PART III - OWNERSHIP INFORMATION

A. Nature of Site

☐ Medical School ☐ Hospital or other Article 28 facility ☐ Independent facility ☐ Physician's Office
☐ Government ☐ Other

B. If owner name is not the same as the facility name, provide owner name and address:

Name(s)
Address(es)

PART III - OWNERSHIP INFORMATION (Continued)

C. Ownership

☐ Individual ☐ Government ☐ Professional Corporation ☐ Not-for-profit Corporation
☐ Partnership ☐ Corporation ☐ Limited Liability Corporation
☐ Other (Specify) _____

If a partnership, submit a copy of the partnership agreement. If a corporation, not-for-profit corporation, limited liability corporation or professional corporation, include a copy of the certificate of incorporation.

If government-operated: Provide the name, principal office address of the government entity, and the name(s), title(s) and address(es) of the administrator responsible for the operation of the facility in conjunction with the director. If needed, list additional names and addresses on a separate sheet and attach to this statement.

Name
Principle Office Address
Administrator Name
Title
Administrator Address

D. Definitions - Not applicable to hospitals and other Article 28 facilities.

1. **Direct ownership interest** means the possession of stock, equity in the capital, or any interest in the profits of the facility.
2. **Indirect ownership interest** means the possession of stock, equity in the capital, or any interest in the profits of an entity with a direct or indirect ownership interest in the facility.
3. **Controlling interest** means the ability to direct or control the operation or management of the facility, as specified in 10 NYCRR Section 52-1.1(i).

Based on the definitions above, do any of the owners or board members of the facility have direct or indirect ownership or controlling interest in any other facilities (tissue banks, nontransplant anatomic banks, blood banks or clinical laboratories) licensed by New York State?

☐ Yes ☐ No If yes, provide the information requested below for each person:

Owner(s) Name(s)	Other facility(ies) name(s) and address(es)

E. Provide the name(s) of any officer(s) of the corporation or partnership; and the name(s) of any direct or indirect owner(s) with greater than five percent controlling interest. If needed, list additional names on a separate sheet and attach to this application. Not applicable to hospitals and other Article 28 facilities, or government entities.

Name(s)

PART IV - DECLARATION

A. Has the director, medical director, or any person having a direct or indirect ownership or controlling interest of five percent or more in the applicant facility ever been convicted of, or charged with, any crime or offense related to the operation of a tissue bank, nontransplant anatomic bank, blood bank or clinical laboratory, or related to the furnishing of, or billing for, laboratory or tissue banking services or medical care, services or supplies?

☐ Yes ☐ No If yes, list name(s) and address(es) of person(s) here:

Name(s)	Address(es)

Explain/describe any convictions or charges:

B. Has the director, medical director, or any person having a direct or indirect ownership or controlling interest of five percent or more in the applicant facility ever been convicted of, or charged with, administrative violations of local, state or federal laws, rules and regulations?

☐ Yes ☐ No If yes, list name(s) and address(es) of person(s) here:

Name(s)	Address(es)

Explain/describe any convictions or charges:

PART V - CHECKLIST

The following forms and supporting documentation are attached, as applicable:

- ☐ DOH-2973(a), DOH-2973(b), DOH-2973(b1), DOH-2973(c), DOH-2973(d), DOH-2973(e), and/or DOH-2973(g),
- ☐ A copy of the certificate of incorporation
- ☐ A copy of the partnership agreement
- ☐ CV or résumé for the Tissue Bank or Storage Facility Director and letter describing experience and qualifications
- ☐ CV or résumé for the Medical Director
- ☐ Medical Advisory Committee membership list
- ☐ Donor health history forms and selection criteria
- ☐ All policies and procedures
- ☐ Informed consent documents
- ☐ A copy of the NYS permit or CLIA certificate held by the laboratory providing clinical laboratory testing services

PART VI - SIGNATURE

Providing false or misleading information in this statement may lead to prosecution under applicable federal or state laws and may result in denial of the New York State Department of Health Tissue Resources Program Application for Licensure.

I hereby affirm under penalty of perjury that the information provided on this form and all attachments is true to the best of my knowledge and belief. **No tissue, hematopoietic progenitor cell or nontransplant anatomic banking activities, other than those identified in this application, are being conducted at this site without New York State licensure.**

Name of Authorized Representative: _____

Title: _____

Phone Number: _____

E-mail Address: _____

Signature: _____ **Date:** _____

The completed application, additional required forms, and supporting documentation must be submitted to the New York State Department of Health Tissue Resources Program.

By e-mail as a PDF (preferred) to: tissue@health.ny.gov

By mail to: Tissue Resources Program
Wadsworth Center
New York State Department of Health, Empire State Plaza
Albany, NY 12237