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

Application for Licensure
Human Tissue Bank,
Hematopoietic Progenitor Cell Bank,
Nontransplant Anatomic Bank

PART I - Activities Performed (See instructions for definitions)

Name of Facility: _____

For Tissue Resources Program use only
☐ New Application
☐ Amended Application

Facility ID _____
Date Received_____

Facility Activities (check all that apply):

☐ **Limited Tissue Procurement** (see instructions for definition) - Attach completed 2973(a)

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

☐ **Procurement of Reproductive Tissue** - Attach completed 2973(b-1)
Including qualification and selection of reproductive tissue donors, collection or arranging for the collection of reproductive tissue.

☐ **Processing of Tissue, Hematopoietic Progenitor Cells, or Human Milk** - Attach completed 2973(b)

☐ **Processing of Reproductive Tissue** - Attach completed 2973(b-1)

☐ **Storage of Tissue, Hematopoietic Progenitor Cells, or Human Milk** - Attach completed 2973(b)

☐ **Storage of Reproductive Tissue only** - Attach completed 2973(b1)

☐ **Distribution of Tissue, Hematopoietic Progenitor Cells, or Human Milk** - Attach completed 2973(b)

☐ **Distribution of Reproductive Tissue only** - Attach completed 2973(b1)

☐ **Transplantation of Tissue or Hematopoietic Progenitor Cells, and Dispensing of Human Milk** - Attach completed 2973(c)
Including temporary storage and issuance of tissue, HPCs or human milk for clinical use.

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

☐ **Nontransplant Anatomic** - Attach completed 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.

Tissue means cardiovascular tissue, musculoskeletal tissue, skin, eye, birth tissues, etc., other than reproductive tissues, and includes cells derived therefrom.

PART II - Facility and Contact Information

Name of Facility			
Street Address			
Street Address			
City	State	Zip	County
Telephone		Fax	
Website address			
Contact Name		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

All applicants other than Article 28 facilities must complete the remainder of Part III, below.
Failure to provide full and accurate disclosure of ownership and financial interests in the tissue bank, hematopoietic progenitor cell bank or nontransplant anatomic bank, as required by 10 NYCRR Section 52-2, may result in denial of the application. Please answer all questions as of the date the Application for Licensure – Human Tissue/Hematopoietic Progenitor Cell/Nontransplant Anatomic Bank is submitted.
Note: Submission of this statement does not eliminate the responsibility of the applicant to report all changes in ownership of the applying facility directly to the New York State Department of Health, Office of Health Insurance Programs, at One Commerce Plaza, Albany NY, 12210.

B. If owner name is not the same as the facility name, indicate 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

Indicate the Federal Employer Identification Number (FEIN):

If government-operated: indicate the name, principal office address of the government entity, and the name(s), title(s) and addresses 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
Principal Office Address

Administrator Name	Title
Administrator Address	

D. Definitions

1. **Direct ownership interest** means the possession of stock, equity in the capital, or any interest in the profits of the applying 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 applying facility.
3. **Controlling interest** means the ability to direct or control the operation or management of the applying facility, as specified in 10NYCRR Section 52-1.1(i).
4. **Management company** means any organization that operates or manages a business on behalf of the owner, with the owner retaining ultimate legal responsibility for the operation of the business.

Based on the definitions above, do any of the owners or board members of the applying 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. Except for facilities established pursuant to Public Health Law article 28 and government entities, indicate the name(s) of any officer(s) of the corporation or partner; and the name(s) of any principal stockholder or controlling person(s) with greater than ten percent ownership interest. If needed, list additional names on a separate sheet and attach to this statement.

Names

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 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:

Names(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 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:

Names(s)	Address(es)

Explain/describe any convictions or charges:

PART V - Checklist

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

- ☐ Form 2973a, 2973b, 2973b1, 2973c, 2973d, or 2973e
- ☐ A copy of the partnership agreement
- ☐ A copy of the certificate of incorporation
- ☐ CV or resumé for the Tissue Bank or Storage Facility Director and letter describing experience and qualifications
- ☐ CV or resumé 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.

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.

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.

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: btraxess@health.ny.gov

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