

PART I - Activities Performed (See instructions for definitions)

Name of Facility: _____

Facility Activities (check all that apply):

For Tissue Resources Program use only
New Application
Amended Application

Facility ID _____
Date Received _____

Limited Tissue Procurement (see instructions for definition) - Attach DOH-2973(a)

Procurement of Tissue¹, 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 qualification of reproductive tissue donors, collection or arranging for the collection of reproductive tissue.

Processing of Tissue¹, Hematopoietic Progenitor Cells, or Human Milk - Attach DOH-2973(b)

Processing of Reproductive Tissue - Attach DOH-2973(b1)

Storage and Distribution of Tissue¹, Hematopoietic Progenitor Cells, or Human Milk - Attach DOH-2973(b)

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

Transplantation of Tissue¹ 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 - 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.

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.

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.

Provide the Federal Employer Identification Number (FEIN):

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	
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 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 10NYCRR 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. Except for facilities established pursuant to Public Health Law article 28 and government entities, 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.

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 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:

Names(s)	Address(es)

Explain/describe any convictions or charges:

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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:

Names(s)	Address(es)

Explain/describe any convictions or charges:

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PART V - Checklist

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

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

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: tissue@health.ny.gov

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