

Instructions for Submitting an Application for Licensure as a Human Tissue, Hematopoietic Progenitor Cell (HPC), or Nontransplant Anatomic Bank

PART I – APPLICATIONS FOR LICENSURE

A. Complete application form DOH-2973, Application for Licensure – Human Tissue, Hematopoietic Progenitor Cell, Nontransplant Anatomic Bank, and, if applicable, include:

1. A copy of the facility's certificate of incorporation if a corporation, not-for-profit corporation, limited liability corporation or professional corporation;
2. A copy of the facility's partnership agreement if a partnership, and;
3. All supplemental forms required based on the type(s) of tissue, hematopoietic progenitor cell, and/or nontransplant anatomic banking services performed (see B.8, below, and Part II. Definitions, of these instructions)

Article 28 facilities should complete Part III.A of the DOH-2973. All other facilities must complete Part III.A - E.

B. Complete the applicable form(s) below based upon the activities your facility performs (See Part II. Definitions):

1. **DOH-2973(a):** for Limited Tissue Procurement Services.
2. **DOH-2973(b):** for Comprehensive Tissue Procurement Services, including procurement, processing, storage, or distribution of tissue, hematopoietic progenitor cells (HPCs) or human milk.
3. **DOH-2973(b1):** for Comprehensive Tissue Procurement Services, including procurement, processing, storage, or distribution of **reproductive** tissue only.
4. **DOH-2973(c):** for Transplantation Facilities, including transplantation of tissue and/or hematopoietic progenitor cells (HPCs) or dispensing of human milk for clinic use.
5. **DOH-2973(d):** for Insemination/Implantation of reproductive tissue.
6. **DOH-2973(e):** for Nontransplant Anatomic Banking.
7. **DOH-2973(g):** to register as an Assisted Reproductive Technology Service Provider for purposes of gestational surrogacy.
8. Please note that application forms DOH-2973(b), DOH-2973(b1), DOH-2973(c), DOH-2973(d), and DOH-2973(e) require submission of additional materials, including, but not limited to:
 - a. Copies of current résumés or curricula vitae of the Tissue Bank Director, Medical Director, Hematopoietic Progenitor Cell Bank Director, Storage Facility Director, and/or Nontransplant Anatomic Bank Director, and a letter specifically identifying education, employment, and professional experience;
 - b. Medical Advisory Committee membership, if applicable;
 - c. Copies of donor medical and social history questionnaire forms, consent forms, and applicable donor selection criteria and protocols, if donor qualification is an activity performed;
 - d. All laboratory and infectious disease tests performed on tissue or hematopoietic progenitor cell donors including copies of the CLIA certificates and state licenses where required;
 - e. Copies of standard operating procedures, as required by 52-3.5(a)(6), for collection, processing, storage, and/or distribution of tissue, hematopoietic progenitor cells, and/or nontransplant anatomic specimens.

PART II – DEFINITIONS

Limited Tissue Procurement Service means a facility or organization whose tissue acquisition activities are limited to donor solicitation by its own staff or the provision of staff, training or equipment for tissue recovery activities to assist a Comprehensive Tissue Procurement Service in collection of tissue. Retrieval of tissues on the premises of the Limited Tissue Procurement Service shall be performed by the staff or agents of a Comprehensive Tissue Procurement Service. Hospitals whose tissue banking activities are limited to facilitating organ, tissue, and/or whole body donations, or referring potential donors or next-of-kin to licensed Comprehensive Tissue Procurement Services, are not subject to the licensure requirements in 10 NYCRR Subpart 52-2.

Comprehensive Tissue Procurement Service means a facility or organization that engages in donor qualification and selection; and tissue recovery and collection activities from living and/or deceased donors.

Tissue Processing Facility means a facility or organization that engages in any or all activities associated with processing, storage, and/or distribution of human tissues or HPCs for transplantation, transfer, artificial insemination, or implantation.

Tissue Storage Facility means a facility that engages in any or all activities associated with storage and distribution of human tissues or HPCs that were processed at other facilities and are intended for transplantation, transfer, artificial insemination and/or implantation, except insemination and/or implantation services storing, for less than six months, semen collected and processed by a semen bank appropriately licensed by the Department

Transplantation Facility means a facility that temporarily stores and transplants tissue or HPCs, other than tissue intended for autologous transplantation that does not leave the operating room for processing and/or storage.

Insemination/Implantation means a location at which artificial insemination or other assisted reproductive procedures are performed, using reproductive tissue from anonymous donors, directed donors and/or client-depositors. Semen processing, limited to washing, concentrating and storing semen from patients of physicians associated with the licensed insemination/implantation site or from the patients' regular sexual partners, and limited storage (less than six months' duration) may be undertaken without additional licensure.

Assisted Reproductive Technology (ART) Service Provider means a medical provider, fertility clinic, or reproductive tissue bank (Which shall include a gamete bank), or any other entity which either provides ART services in New York State or for which any component of the ART services arranged by the entity is performed in New York State.

Nontransplant Anatomic Banking Service means any person or facility that performs donor selection and qualification; recovery and collection; processing; storage or arranges for the storage; and/or distribution of whole bodies, body segments, nontransplant anatomic parts, including organs or tissues from living or deceased donors, for education and/or research purposes specifically authorized by Public Health Law Section 4302. The following **do not** constitute a nontransplant anatomic bank:

- (1) Any person or entity that stores nontransplant anatomic parts, except whole bodies and body segments, solely for purposes of research and/or education conducted by such person, provided the person or entity maintains on its premises a properly executed anatomical gift consent document consistent with 10 NYCRR Section 52-11.3, and:
 - (i) such person or entity is a legal donee pursuant to Public Health Law Section 4302 and obtains all organs/tissues from a tissue bank or nontransplant anatomic bank licensed by the department; or
 - (ii) is a general hospital conducting pathology services or research on nontransplant anatomic parts including whole bodies, recovered from within the facility from a living or deceased source;
- (2) Any person or entity whose activities within the State of New York are limited to distribution of nontransplant anatomic parts to a tissue bank or nontransplant anatomic bank licensed by the Department;
- (3) Any person or entity that uses prepared slides and/or human-derived cell lines for purposes of education and/or research; and
- (4) An employee of the federal government, provided an anatomical gift consent document has been executed in accordance with Public Health Law Section 4301 and 10 NYCRR Section 52-11.3(d).

PART II – DEFINITIONS (Continued)

Tissue Bank means any person or facility that performs donor selection and qualification; recovery and collection; processing, storage or arranges for the storage, and/or distribution of human tissues for transplantation, transfer, therapy, artificial insemination or implantation, including autologous procedures. Tissue banks may be issued a license in the specific category of tissue and type of tissue services and must comply with the standards applicable to the category or categories of tissue acquired, processed, stored and/or distributed.

Categories of tissue are:

Cardiovascular Tissue means human heart valves, aorta and other great vessels, pericardium, saphenous vein, umbilical vein, or any other cardiovascular tissue for transplantation.

Musculoskeletal Tissue means human bone, tendon, ligament, muscle, fascia, cartilage, dura, or any other musculoskeletal tissue for transplantation.

Skin Tissue means any human skin tissue for transplantation.

Eye Tissue means a human cornea or any other ocular tissue for transplantation.

Nerve Tissue means human nerve tissue for transplantation.

Amniotic Membrane means human amniotic membrane tissue for transplantation.

Human Milk means human milk for ingestion by a child other than the mother's own.

Other Tissues means any other human tissue.

Tissue Derived Products means any products or cells derived from human tissue.

Hematopoietic Progenitor Cells means human precursor or progenitor hematopoietic cells derived from bone marrow, peripheral blood or other tissue sources, such as cord blood obtained from the placenta or umbilical cord.

Reproductive Tissue means any human tissue from the reproductive tract intended for use in artificial insemination or any assisted reproductive procedure. This includes, but is not limited to, semen, oocytes, embryos, spermatozoa, ovarian tissue, testicular tissue, and epididymal aspirates.

Donor Qualification means obtaining and evaluating medical history, testing and/or physical examination records of a prospective donor for the purpose of determining donor eligibility.

Donor Selection means approaching a prospective living donor or family and/or friends of a prospective cadaveric donor for the purposes of preliminary assessment of donor suitability.

Tissue Bank Compliance Officer means an employee of a tissue transplantation facility who is responsible for communicating all department requirements pertinent to tissue/HPC transplantation services to each tissue/HPC transplantation service director in the facility and for responding to inquiries from the department regarding compliance with Department regulations.

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

Questions? E-mail: tissue@health.ny.gov
or
Call: 518-485-5341