

**Instructions for Submitting an
Application for Licensure
as a Human Tissue/Nontransplant
Anatomic Bank Pursuant to
Subpart 52-2 of 10 NYCRR**

I. Application for Licensure as a Tissue Bank

- A. Complete application form DOH-2973, Application for Licensure – Human Tissue/Nontransplant Anatomic Bank, and include:
1. a completed form DOH-2973(f) Disclosure of Ownership and Control Interest Statement, unless an Article 28 facility;
 2. if a corporation, a copy of the certificate of incorporation;
 3. if a partnership, a copy of the partnership agreement; and
 4. all supplemental forms required based on the type(s) of tissue services performed (see B. below and definitions in section III.)
- B. Supplemental forms to be submitted:
1. Form A. (DOH-2973 (a)) Complete and include with the application if the bank or site is a Limited Tissue Procurement Service.
 2. Form B. (DOH-2973 (b)) Complete and include with the application if the bank or site is a Comprehensive Tissue Procurement Service, Tissue Processing Facility, and/or Tissue Storage Facility.

Form B-1. (DOH-2973(b)(1)). Complete and include with the application if the bank or site is a Reproductive Tissue Bank.

Form B-2. (DOH-2973(b)(2)). Complete and include with the application if the bank or site is a Hematopoietic Progenitor Cell (HPC) Bank.

Please note that Form B, Form B-1, and Form B-2 call for submission of additional attachments, including:
 - a. resumes or curricula vitae of the Tissue Bank or Hematopoietic Progenitor Cell Bank director and medical director, specifically identifying all other employment, and a letter describing experience as to how the director and medical director meet minimum qualification specified in section 52-2.5 or section 58-5.2, as applicable;
 - b. copies of donor health history forms, consent forms, and applicable donor selection criteria and protocols, if donor selection is an activity performed;
 - c. a copy of the New York State clinical laboratory permit or CLIA certificate and a copy of the state laboratory license (required unless there is no program in the state);
 - d. a list of all Tissue Banks or HPC Banks that provide tissues or HPCs to the applicant, including Limited and Comprehensive Tissue Procurement Services, Tissue Processing Facilities, and Tissue Storage Facilities; and
 - e. 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.
 3. Form C. (DOH-2973 (c)) Complete and include with the application if the bank or site is a Tissue Transplantation Facility. Please note that Form C calls for designating a Tissue Bank Compliance Officer and listing all Tissue Banks from which tissues for transplantation are obtained.
 4. Form D. (DOH-2973 (d)) Complete and include with the application if the bank or site is an Insemination/implantation Site. Please note that Form D calls for submission of additional attachments, including:
 - a. resumes or curricula vitae of the tissue bank director and medical director, specifically identifying all other employment; and
 - b. a list of all Tissue Banks from which gametes or embryos for artificial insemination or assisted reproductive procedures are obtained.
 - c. written procedures for receipt, storage, issuance and tracking of semen and embryos, as applicable.

II. Application for Licensure as a Nontransplant Anatomic Bank

- A. Complete application form DOH-2973 and include:
1. a completed DOH-2973(f) Disclosure of Ownership and Control Interest Statement, unless an Article 28 facility;
 2. if a corporation, a copy of the certificate of incorporation; and
 3. if a partnership, a copy of the partnership agreement;
- B. Complete supplemental Form E (DOH-2973 (e)) and include:
1. if applicable, a list of all entities that provide nontransplant anatomic parts to the applicant;
 2. if applicable, a list of all sites in New York State to which nontransplant anatomic parts are distributed by the applicant; and
 3. copies of donor solicitation protocols and consent forms, if donor solicitation and/or tissue recovery are performed.

RETURN TO: New York State Department of Health
Blood and Tissue Resources Program
Wadsworth Center
P.O. Box 509
Albany, NY 12201-0509

btraxess@health.state.ny.us

III. Definitions

Limited Tissue Procurement Service means a facility or organization whose tissue acquisition activities are limited to donor selection and solicitation by its own staff or the provision of staff, training or equipment for tissue acquisition activities to assist a Comprehensive Tissue Procurement Service in retrieving 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 requesting organ and/or tissue donations, or referring potential donors or next-of-kin to licensed Comprehensive Tissue Procurement Services are not subject to the licensure requirements in 10NYCRR Subpart 52-2.

Comprehensive Tissue Procurement Service means a facility or organization that engages in donor selection, solicitation, and retrieval activities related to tissues 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 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 for transplantation, transfer, artificial insemination and/or implantation, except insemination/implantation sites storing, for less than six months, semen collected and processed by a semen bank appropriately licensed by the department.

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

Insemination/implantation Site 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.

Nontransplant Anatomic Bank means any person or facility that solicits, retrieves, performs donor selection and/or testing, preserves, transports, allocates, distributes, acquires, processes, stores or arranges for the storage of 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 10NYCRR 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 10NYCRR Section 52-11.3(d).

Tissue Bank means any person or facility that solicits, retrieves, performs donor selection and/or testing, preserves, transports, allocates, distributes, acquires, processes, stores or arranges for the storage of human tissues for transplantation, transfer, therapy, artificial insemination or implantation, including autogeneic 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.

Reproductive Tissue means any 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.

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

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.

Donor Solicitation means approaching a prospective living donor or family and/or friends of a prospective cadaveric donor for the purposes of obtaining written consent, medical history, and/or social history.

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

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.