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

Disclosure of Ownership and Controlling Interest Statement

Except for facilities established pursuant to New York State Public Health Law Article 28, submission of this statement to provide full and accurate disclosure of ownership and financial interests in the tissue bank or nontransplant anatomic bank is required by 10 NYCRR Section 52-2.1(a). Failure to do so may result in the denial of the application. Please answer all questions as of the date the Application for Licensure – Human Tissue/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.

PART I – Applicant information

Name of Facility			
Address/Location			
City	State	Zip	Telephone

PART II – 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 II Ownership Information (continued)

C. 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)

D. List names, and addresses, for individual owners, partners, corporation officers, and/or shareholders possessing 5 percent or more of the voting shares in the entity having direct or indirect ownership or controlling interest in the applying tissue bank/nontransplant anatomic bank. For facilities owned/operated by not-for-profit corporations, provide a list of the Board of Directors. If needed, list additional names and addresses on a separate sheet and attach to this statement.

Names and Addresses

E. Is any person with direct or indirect ownership or controlling interest in the applicant bank a licensed health professional authorized by law to order clinical laboratory tests and receive results? If yes, list name(s) and address(es) of individual(s) here:

Names and Addresses

PART III - Declaration

A. Has the director, medical director, or any person having a direct or indirect ownership or controlling interest in the applicant facility ever been convicted of healthcare fraud or misdeed, including, but not limited to, those related to the operation of a tissue bank, nontransplant anatomic bank, blood bank or clinical laboratory, and those related to the furnishing of, or billing for, laboratory or tissue banking services or medical care, services or supplies? Are such charges currently pending?

☐ Yes ☐ No

If yes, list name(s) and address(es) of person(s) here.

Name(s)	Address(es)

Explain/describe any charges and convictions.

B. Has the director, medical director, or any person having a direct or indirect ownership or controlling interest in the applying facility had sustained charges of administrative violations of local, state or federal laws, rules and regulations pursuant to the Public Health law or related statutes, concerning the provision of health care services or reimbursement for such services against them? Are such charges currently pending?

☐ Yes ☐ No

If yes, list name(s) and address(es) of person(s) here.

Name(s)	Address(es)

Explain/describe any charges and convictions.

Part IV - Signature

Providing false or misleading information in this statement may lead to prosecution under applicable federal or state in denial of the New York State Tissue Bank/Nontransplant Anatomic Bank License.

I hereby affirm under penalty of perjury that the information provided on this form and all attachments is true to the and belief.

Name of Authorized Representative	**Title**
Phone Number	**E-mail Address**
Signature (if submitting by mail)	**Date**

The completed Disclosure of Ownership and Controlling Interest Statement must be submitted to the Department of Health.

By e-mail as an attachment to:

btraxess@health.ny.gov

By mail to:

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