

PART I - ACTIVITIES PERFORMED

Current New York State tissue bank facility ID #, if applicable: _____

☐ No changes to this section from current license.

Place a checkmark in the applicable boxes below to indicate the donor sources and activities performed.

| | Donor Qualification ¹ | Recovery/ Collection | Processing | Storage and Distribution |
|---|----------------------------------|--------------------------|--------------------------|-----------------------------|
| Semen, Testicular Tissue, Epididymal Aspirates | | | | |
| Anonymous Donor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Directed Donor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Client-Depositor ² | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Oocytes, Ovarian Tissue | | | | |
| Anonymous Donor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Directed Donor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Client-Depositor ² | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Embryos | | | | |
| Anonymous Donor | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Directed Donor | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Client-Depositor ² | | | <input type="checkbox"/> | <input type="checkbox"/> |
| Other Reproductive Tissues (List all) | | | | |

1. **Donor Qualification** includes, but is not limited to, consent, social and medical history, physical exam, and disease testing.

2. **Client-Depositor** does not include intended parents providing reproductive tissue for use by a gestational carrier.

If your organization intends to conduct assisted reproductive procedures for a gestational surrogacy agreement, submit DOH-2973(g) - Application for ARTSP Registration, available at <https://www.wadsworth.org/regulatory/tissue-resources>.

PART II – ADMINISTRATIVE RESPONSIBILITY

☐ No changes to this section from current license.

A. Specify reproductive tissue bank director (must meet requirements of 10 NYCRR 52-2.5(a)(2) and 52-8.3).

Submit a copy of current résumé or curriculum vitae, specifically identifying required education, employment, and professional experience.

| | | | |
|------------------------|-------|----------------|-------|
| Name | | Title | |
| Facility Name | | | |
| Facility Address | | | |
| City | State | ZIP | Phone |
| Days and hours on site | | E-Mail Address | |

B. Specify reproductive tissue bank medical director (must meet requirements of 10 NYCRR 52-2.5(a)(3)).

Submit a copy of current résumé or curriculum vitae.

| | | | |
|------------------------------------|-------|----------------------------|-------|
| Name | | Title | |
| Facility Name | | | |
| Facility Address | | | |
| City | State | ZIP | Phone |
| License number of medical director | | State where license issued | |
| Days and hours on site | | E-Mail Address | |

PART III – MEDICAL ADVISORY COMMITTEE

☐ No changes to this section from current license.

This section not applicable to facilities that are only storing and distributing reproductive tissue.

List all medical advisory committee members, including areas of expertise, pertinent positions held and location of employment (attach additional sheets if necessary). The medical advisory committee must be composed of at least five members with experience and expertise in human fertility, and infectious disease or related fields. Facilities recovering and collecting reproductive tissue from donors must include a qualified geneticist.

| Name | Area of Expertise/Position Held | Pertinent Positions | Location of Employment |
|------|---------------------------------|---------------------|------------------------|
| | | | |
| | | | |
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PART IV – DONOR QUALIFICATION, SELECTION, AND TESTING

☐ No changes to this section from current license.

- A. Submit copies of donor medical and social history questionnaire forms, consent forms, and donor selection criteria and protocols – not applicable for facilities that are only storing and distributing reproductive tissue.
- B. List all laboratory and infectious disease tests performed on reproductive tissue donors and provide site of testing – not applicable for facilities that are only storing and distributing reproductive tissue. If tests are performed at the applicant facility, indicate “on-site” (submit additional sheets if necessary).

Test and Reference Laboratory

| | | | |
|--|--------|-------|------|
| Test | Name | | |
| | Street | | |
| | City | State | ZIP |
| CLEP PFI or CLIA number as applicable: | | CLEP | CLIA |

| | | | |
|--|--------|-------|------|
| Test | Name | | |
| | Street | | |
| | City | State | ZIP |
| CLEP PFI or CLIA number as applicable: | | CLEP | CLIA |

| | | | |
|--|--------|-------|------|
| Test | Name | | |
| | Street | | |
| | City | State | ZIP |
| CLEP PFI or CLIA number as applicable: | | CLEP | CLIA |

Submit copies of the CLIA certificates and, where required, the state license.

- C. Submit standard operating procedures, as required by 52-3.5(a)(6), for collection, processing, storage and/or distribution of reproductive tissue.

PART V – PREMISES AND EQUIPMENT

☐ No changes to this section from current license.

A. Description of Premises

1. Is the space contiguous? ☐ Yes ☐ No

If not, provide other location(s):

2. Provide the total approximate square footage of the work space: _____

B. Equipment

Provide or submit a complete list, including a brief description, of equipment used
(submit additional sheets if necessary):

PART VI – REPRODUCTIVE TISSUE PROVIDERS AND RECEIVERS

☐ No changes to this section from current license.

- A. Provide or submit a complete list of all tissue banks that provide reproductive tissue, including those responsible for donor qualification and selection, limited procurement (as defined in 52-1.1(ad)(2)), recovery and collection, processing, storage, and distribution (submit additional sheets if necessary).
Indicate “NA” if not applicable.

- B. Provide or submit a complete list of all sites in New York State to which reproductive tissues are distributed, including those responsible for processing, storage, distribution, insemination and implantation (submit additional sheets if necessary). Indicate “NA” if not applicable.

PART VII – SIGNATURE

Tissue Bank Director's Name: _____

Tissue Bank Director's Signature: _____ Date: _____

Medical Director's Name: _____

Medical Director's Signature: _____ Date: _____

Name and Title of person completing form: _____

Signature: _____ Date: _____