

PART I – Activities Performed

No changes to this section from current license.

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

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

| | Donor Qualification¹ | Recovery/ Collection | Processing | Storage & Distribution |
|---|--|-----------------------------|-------------------|-----------------------------------|
| Semen, Testicular Tissue, Epididymal Aspirates | | | | |
| Anonymous Donor | | | | |
| Directed Donor | | | | |
| Client-Depositor | | | | |
| Oocytes, Ovarian Tissue | | | | |
| Anonymous Donor | | | | |
| Directed Donor | | | | |
| Client-Depositor | | | | |
| Embryos | | | | |
| Anonymous Donor | | | | |
| Directed Donor | | | | |
| Client-Depositor | | | | |
| Other Reproductive Tissue – List All | | | | |

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

If your organization intends to conduct assisted reproductive procedures for a gestational surrogacy agreement, submit the 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)). 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 | Telephone |
| Days and hours present 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.

Check if same as the reproductive tissue bank director.

| | | | |
|------------------------------------|-------|----------------------------|-----------|
| Name | | Title | |
| Facility name | | | |
| Facility address | | | |
| | | | |
| City | State | Zip | Telephone |
| License number of medical director | | State where license issued | |
| Days and hours present on site | | E-Mail Address | |

PART III – Medical Advisory Committee No changes to this section from current license.

This section not applicable for 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, infectious disease or related fields. Facilities recovering and collecting reproductive tissue from donors must include a qualified geneticist.

| Name | Area of Expertise/Position Held |
|------|---------------------------------|
| | |
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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 tissue, milk or HPCs.
- B. List all laboratory and infectious disease tests performed on tissue, milk or HPC donors and provide site of testing – not applicable for facilities that are only storing and distributing tissue, milk or HPCs. If tests are performed at the applicant facility, indicate “on-site” (submit additional sheets if necessary).

| Test | Reference Laboratory Name and Address | | |
|------|--|-------|------|
| | Name | | |
| | Street | | |
| | City | State | Zip |
| | CLEP PFI or CLIA number as applicable: | | CLIA |
| | Name | | |
| | Street | | |
| | City | State | Zip |
| | CLEP PFI or CLIA number as applicable: | | CLIA |
| | Name | | |
| | Street | | |
| | City | State | Zip |
| | CLEP PFI or CLIA number as applicable: | | 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 to the applicant, 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 by the applicant, including those banks responsible for processing, storage, distribution, insemination and implantation (submit additional sheets if necessary). Indicate “NA” if not applicable.

PART VII

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