

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 Qualification ¹	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

PART IV – Donor Qualification, Selection, and Testing☐ No changes to this section from current license.

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

- A. Submit copies of donor medical and social history questionnaire forms, consent forms and donor selection criteria and protocols.
- B. List all laboratory and infectious diseases tests performed on reproductive tissue donors and provide site of testing. 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: CLEP CLIA		
	Name		
	Street		
	City	State	Zip
	CLEP PFI or CLIA number as applicable: CLEP CLIA		
	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 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