Tissue Resources Program

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

Form B-1 Application for Licensure – Human Tissue Bank

For Comprehensive Reproductive Tissue Procurement, Processing, Storage, and Distribution Facilities

PART I – Activities Performed

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

Place a checkmark in each box to indicate the donor source and the activity performed. Check here to indicate no changes from current license:

	Donor Qualification and Selection ¹	Recovery and Collection	Processing	Storage & Distribution from this facility	Storage & Distribution from other facilities
Semen					
Anonymous Donor					
Directed Donor					
Client Depositor					
Testicular Tissue, Epididymal Aspirate					
Directed Donor					
Client Depositor					
Oocytes					
Anonymous Donor					
Directed Donor					
Client Depositor					
Ovarian Tissue					
Anonymous Donor					
Directed Donor					
Client Depositor					
Embryos					
Anonymous Donor					
Directed Donor	-				
Client Depositor					
Other Reproductive Tissue - List All:					

¹ Donor Qualification and Selection includes, but is not limited to, consent, social and medical history, 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

A. Specify reproductive tissue bank director (must meet requirements of 10 NYCRR 52-2.5(a)(2)). Submit a copy of current resume or curriculum vitae, specifically identifying education, employment, and professional experience.

Name			Title	
Facility name				
Facility address				
City	State	Zip		Telephone
Days and hours present on site		E-Mail Ad	ddress	

B. Specify reproductive tissue bank medical director (must meet requirements of 10 NYCRR 52-2.5(a)(3)). Submit a copy of current resume or curriculum vitae, specifically identifying education, employment, and professional experience.

Check if same as the reproductive tissue bank director.

Name			Title		
Facility name					
Facility address					
City	State	Zip			Telephone
License number of medical director				New `	York or other state where issued
Days and hours present on site		E-Mail Ad	ddress		

PART III – Medical Advisory Committee

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, clinical pathology or related fields. Facilities recovering and collecting reproductive tissue from donors must include a qualified geneticist.

This section is not applicable to facilities that only conduct storage of reproductive tissue.

Name	Area of Expertise/Position Held

PART IV – Donor Qualification, Selection and Testing. Not Applicable for Reproductive Tissue Storage Only Facilities

A. Submit copies of reproductive tissue donor medical and social history questionnaire forms, consent forms and applicable donor selection criteria and protocols.

B. Indicate all laboratory tests performed on reproductive tissue donors and indicate 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
pIndicate CLEP PI	FA or CLIA number as applicable:	CLEP	CLIA

	Name			
	Street			
	City	State		Zip
Indicate CLEP PI	A or CLIA number as applicable:	CLEP	CLIA	

	Name			
	Street			
	City	State		Zip
Indicate CLEP PE	A or CLIA number as applicable:	CLEP	CLIA	

Indicate CLEP PFA or CLIA number as applicable:

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

A. Description of Premises

No 1. Is the space contiguous? Yes

If not, indicate other location(s):

- 2. Indicate the total approximate square footage of the work space:
- B. Equipment

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

PART VI – Reproductive Tissue Providers and Receivers

A. Indicate or submit a complete list of all reproductive tissue banks that provide reproductive tissue to the applicant, including reproductive tissue donor qualification and selection, limited procurement, recovery and collection, processing, storage, and distribution facilities (submit additional sheets if necessary). Indicate "NA" if not applicable.

B. Indicate or submit a complete list of all sites in New York State to which reproductive tissues are distributed by the applicant, including processing, storage, distribution, insemination and implantation facilities (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	