

# Form B-1

## Application for Licensure – Human Tissue Bank

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

### PART I – Activities Performed

Place a checkmark in each box, as applicable, to indicate the donor source and the activity performed.

	Donor Qualification and Selection <sup>1</sup>	Recovery and Collection	Processing	Storage	Distribution
<b>Semen</b>					
Anonymous Donor					
Directed Donor					
Client Depositor					
<b>Testicular Tissue, Epididymal Aspirate</b>					
Directed Donor					
Client Depositor					
<b>Oocytes</b>					
Anonymous Donor					
Directed Donor					
Client Depositor					
<b>Ovarian Tissue</b>					
Anonymous Donor					
Directed Donor					
Client Depositor					
<b>Embryos</b>					
Anonymous Donor					
Directed Donor					
Client Depositor					
<b>Other Reproductive Tissue - List All:</b>					

<sup>1</sup> **Donor Qualification and Selection** includes, but is not limited to, consent, social and medical history, and disease testing.

## 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 Address	

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 Address	

## 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
	Indicate CLEP PFI or CLIA number as applicable: CLEP CLIA		
	Name		
	Street		
	City	State	Zip
	Indicate CLEP PFI or CLIA number as applicable: CLEP CLIA		
	Name		
	Street		
	City	State	Zip
	Indicate 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**

A. Description of Premises

1. Is the space contiguous?      Yes      No

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 selection, 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**