NEW YORK STATE DEPARTMENT OF HEALTH
Blood and Tissue Resources Program
Wadsworth Center
P. O. Box 509
Albany, New York 12201-0509

Form C
Application for Licensure – Human Tissue Bank
For Tissue Transplantation Facilities

PART I – Tissues Transplanted

Place a checkmark in each box, as applicable, to indicate the type of tissue transplanted. Attach additional sheet, if necessary

	Allogeneic	[7]Autogeneic
Cardiovascular tissue		
Heart valves		
Vessels[1]		
Musculoskeletal tissue		
Bone, fresh[2]		
Bone, frozen[2]		
Bone, dried[2]		
Bone products[3]		
Soft tissues[4]		
Skin tissue		
Skin, fresh		
Skin, frozen		
Skin, dried		
Skin products[5]		
Eye tissue		
Cornea		
Sclera		
Other		
Hematopoietic progenitor cells		
peripheral blood source		
bone marrow source		
umbilical cord blood source		
Dura mater		
Parathyroid tissue		
Nerve tissue		
Human milk	✔	
Amniotic membrane		
Chorionic membrane		
Pancreatic islets		
Other human tissues – List all		
Cellular therapy products[6] **–** List source(s)		

*Definitions

[1] *Vessels* – arteries, veins, non-valved conduits, including but not limited to umbilical veins, saphenous veins, aortic arches, pulmonary patches.

[2] *Bone* – includes, but is not limited to, bone-tendon-bone grafts, osteochondral grafts, bone shafts, vertebral bodies, ear ossicles.

[3] *Bone products* - machined/morselized bone processed into injectibles, pastes, putties, DBM, cancellous/cortical bone.

[4] *Soft tissues* – include, but are not limited to, tendons, ligaments, cartilage, menisci, fascia, pericardium.

[5] *Skin products* - skin that is decellularized and/or combined with nonhuman materials or expanded by culturing.

[6] *Cellular therapy products* – include, but are not limited to, products that contain mesenchymal stem cells derived from various human sources, such as adipose tissue, menstrual blood, umbilical cord tissue, dental pulp, placenta, synovial fluid, amniotic fluid, and any other tissue or fluid.

[7] *Autogeneic* – tissue that was recovered from the patient in a previous surgical procedure, and processed by an appropriately licensed facility.

PART II – Administrative Responsibility (Please print or type)

A. Tissue Bank Compliance Officer

Name			
Title			
Name of bank or site			
Bank or site business Address			
City	State	Zip	Telephone ( )
Days and hours present on site			

I hereby affirm that all tissue transplanted in the facility is obtained from tissue banks licensed by the New York State Department of Health.

_____ _____/_____/_____

Signature **m d y**

B. For each transplantation service within the tissue transplantation facility, list the director, who must be a physician licensed and currently registered to practice medicine in New York State.

Name	License No.	Categories of tissues used for transplantation
		pasteurized donor human milk

PART III (Please print or type)

A. For each tissue transplantation service, describe how tissues are handled and stored within your facility. Include a list of major equipment used for storage (e.g., freezers, liquid nitrogen canisters, etc.) and the location of all such equipment. Attach sheet, if necessary.

Human donor milk is stored in a designated freezer at -20º C.

Equipment: designated freezer, use of PDHM information sheet, consent forms for use of PDHM, non-sterile gloves, breast milk warmer, labels for breast milk containers, containers for PDHM, NIST certified thermometer.

B. List names and addresses of all tissue banks from which tissues for transplantation are obtained. Attach sheet, if necessary.

TheNewYorkMilkBank, 401Columbus Avenue, Suite 104, Valhalla, NY 10595

PART IV

Attach written protocols/procedures for receipt, storage, issuance and tracking of tissue products.
Note: These procedures must be enclosed or the application may be returned.