



Maryland Department of Health and Mental Hygiene
Office of Health Care Quality - Laboratory Licensing Programs
7120 Samuel Morse Drive
Second Floor
Columbia, Maryland 21046
Phone: 410.402.8025 Fax: 410.402.8213

Instructions for Completion of State of Maryland Tissue Bank Application

It is important that you fill out the application completely, including signatures where required. If the application is incomplete it will delay the licensing process.

Please submit no money at this time. Once your application is reviewed for completeness and compliance with the applicable regulations, you will be issued an invoice for the application fee as well as other fees as outlined in COMAR 10.50.01.06 (D).

Once your payment is received, the appropriate license will be issued.

Any Tissue Bank located in Maryland that is not accredited will be issued a provisional permit. A survey will be scheduled to determine compliance with the Tissue Bank requirements (COMAR 10.50.01) before obtaining a permit.

*****Important*****


Please note that if any medical laboratory tests are performed in the tissue bank (i.e., compatibility testing, semen analysis, HIV or hepatitis testing, etc.) you must request a separate medical laboratory permit application.

If you have any questions, please telephone Paul Celli at (410) 402-8022.

Before submitting your application, please review the checklist on the last page.

Tissue Bank Application

Official Use Only

State of Maryland Department of Health Laboratory Licensing Programs Office of Health Care Quality 	Date/Amt Paid
	Invoice #
	Check #

I. Tissue Bank Information

Changes? Director Name Site Ownership Tissue type

Laboratory Practice/ Entity Name		State Permit Number
Street Address		
City	State	Zip Code
Telephone	Fax Number	Email Address
Mailing Address (if different than above)		Contact Person (other than Director)

II. Medical Director Information

Director Name	Degree	Full-Time	Part-Time (Hours/Week)
Certification by American Specialty Board (Name, Date, Number)		State Medical License Number	

III. Technical Director Information

Name	Degree	Full-Time	Part-Time (Hours/Week)
Certification by American Specialty Board/Registry (Name, Date, Number)			

IV. Ownership Information

List names and addresses for individuals and the EIN for organizations having direct or indirect ownership or a controlling interest (greater than 5%) in the entity. List any additional names and addresses on a separate sheet. If more than one individual is reported and any of the individuals are related to each other, this must be reported. If the disclosing entity is a corporation, list names and addresses of the Director and EINs for corporations on a separate sheet.

Name(s)	Address	EIN (Federal Tax ID #)
---------	---------	------------------------

V. Accreditation Information

Is the laboratory accredited by an approved non-profit accrediting organization?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, list the name of the accrediting organization (i.e. CAP, COLA, JCAHO, etc) and the date of the last on-site survey.	
Name	Date

VI. Tissue Types

Please check all the tissue types associated with your tissue bank. If a previously checked type is no longer needed, mark a line through the type name. List any additional types on this page.

BLOOD (e.g. whole blood, blood products)

CARDIOVASCULAR (e.g. valve, vein)

EYE

HUMAN BREAST MILK

MUSCULOSKELETAL TISSUE BANK (e.g. bone, cartilage, cultured tissue, demineralized bone matrix, fascia lata, ligament, musculoskeletal tissue, tendons, etc.)

PROGENITOR/STEM CELLS (e.g. bone marrow, periperal blood stem cells, cord blood)

REPRODUCTIVE (e.g. embryo, epididymal aspirates, ovarian tissue, reproductive tissue, sperm, testicular tissue)

SKIN

List any additional types of tissue.

Is laboratory testing performed, i.e. compatibility testing, cell counts, infectious disease testing, cultures, etc? Yes No
If answered "Yes" a separate medical laboratory permit application must be submitted for this facility to be properly licensed.

VI. Attestation

I certify that the information provided in this application is true and complete, understanding that any willful false statement or representation, or failure to fully and accurately disclose the requested information in this application, may be prosecuted under applicable federal or State laws, may lead to a denial, suspension or revocation of the tissue bank license for this entity, or could result in termination of participation in State or federal reimbursement programs. I further understand that compliance with State laws may not assure compliance with federal laws.

Signature of Medical Director

Date

To prevent a delay in processing your application please check to make sure all of the following are included:

Completed application.

The required documentation for the Medical and Technical Director:

Medical Director: copies of medical school diploma, medical license from Maryland or state the lab is located in, and a CV.

Technical Director (Must be on-site full time if the Medical Director is not): copies of diploma (must be at least a Bachelor's degree in biological science or medical technology), any Tissue Bank certifications and a CV.

**** Foreign credentialing documentation must be submitted for all degrees received outside the USA. In addition, transcripts showing the conferral of the appropriate degree may be substituted for the diploma.**

Applies to out-of state only: a copy of your state tissue bank permit, a copy of the most recent survey, which includes cited deficiencies and corrective actions, and a list of suppliers/clients (also required to have a tissue bank permit).

Signature of Medical Director must match Director name in section II of application (Medical Director Information).