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**State of Maryland Department of Health
Office of Health Care Quality
Laboratory Licensing
Tissue Bank Application**

A. Instructions
<p>It is important that you fill out the application completely, including signatures where required. Original (ink) signatures are required on all initial applications and must be mailed or hand delivered to our office. (Address listed above) Initial applications are not accepted through fax or email. If the application is incomplete it will delay the licensing process.</p> <p>Once your application is reviewed for completeness and compliance with the applicable regulations, the appropriate license will be issued.</p> <p style="text-align: center;">***Important***</p> <p>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 <u>separate medical laboratory permit application</u>.</p> <p>If you have any questions, please call (410) 402-8025.</p> <p>Before submitting your application, please review the checklist on the last page.</p>
B. Tissue Bank Information
Type of Change: <input type="checkbox"/> Director <input type="checkbox"/> Name <input type="checkbox"/> Site <input type="checkbox"/> Ownership <input type="checkbox"/> Tissue type
Laboratory Practice/Entity Name:
State Permit Number:
Street Address:
City, State, Zip Code:
Mailing Address (if different than Facility Address):
Mailing Address: City, State, Zip Code:
Business Phone:
Business Fax:
Business Email:
Contact Person (Other than Director):

B. Medical Director Information
Director Name:
Degree:
Full Time:
Part Time (Hours/Week):
Certification By American Specialty Board (Name, Date, Number):
State Medical License:
C. Technical Director Information
Technical Director Name:
Technical Director Degree:
Full Time:
Part Time (Hours/Week):
Certification By American Specialty Board (Name, Date, Number):
D. 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.
Owner's Name:
Owner's Address:
EIN (Federal Tax ID Number):
E. 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:

F. 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, peripheral 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.

G. 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:

Application Checklist

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).