

Health Regulations and Licensing Administration
Health Care Facilities Division
899 North Capital Street NE, 2nd FL
Washington, DC 2000

Tissue Bank Application

Provide written procedures and supporting documentation for each section of the Tissue Bank Regulation.

Tissue Bank

Title 22-Health

Chapter: 22-B3

- **Section: 305 INSPECTION**

305.1 inspections of tissue banks and their records as may be required in the enforcement of the Act and this chapter.

305.2 The tissue bank operator shall cooperate in any inspection to the extent of providing the necessary assistance to make an inspection.

***All federal, state, local government, and accrediting organizations regulations, rules, and laws must be followed.**

- **Section: 300 GENERAL PROVISIONS**

300.1 This chapter shall provide minimum standards for the establishment, maintenance, and operation of tissue banks; and shall carry out the stated purposes of the D.C. Tissue Bank Act, as well as to meet the requirements of § 4(b) of the Act.

300.2 The provisions of this chapter shall apply to the establishment, maintenance, and operation of tissue banks. (All tissue banks operating and providing services in Washington DC should operate under qualified supervision, reliable procedures, and appropriate quality assurance)

1. **Tissue bank facilities and physical security**
2. **Personnel and personnel records**
3. **Standard operating procedures, polices, and records.**
4. **Proficiency testing**
5. **Adverse reactions policies**
6. **Infectious disease testing**
7. **Equipment maintenance**
8. **Quality control and quality assurance procedures, policies, and records**
9. **Facility operating procedures, policies, and records**
10. **Donor documentation and records; and**
11. **Other records and files pertinent to this chapter**

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- **Section: 301 LICENSES**

301.1 No person shall operate or hold himself or herself out as operating a tissue bank in the District after May 25, 1963, without being licensed, or designated by the licensee, as required by the Act and this chapter, unless the tissue bank is operated by, or in connection with, a federal or District agency.

301.4 Each application for a license to operate a tissue bank shall be signed and certified correct by the operator, unless the application is made by a person or persons licensed to operate a hospital, in which case it shall be signed and certified by the person licensed to operate the hospital.

301.8 Nothing in this section shall be construed as relieving the licensee from complying fully with all the requirements of the Act and with this chapter.

- **Section: 302 OPERATION OF TISSUE BANKS**

302.1 Each tissue bank shall be directed by an operator who shall be a physician with authority and responsibility for the direction of the bank. (Licensed by the DC Board of Physicians)

Director Responsibilities: Shall be qualified by training and experience and may also serve as the Technical Director if the medical director remains on site at the tissue bank site during tissue bank's regular hours of operation.

1. Review and approve SOPM's; and
2. Quality assurance/quality control polices for medical efficacy
3. Establish donor suitability criteria
4. Evaluate and determine donor acceptability
5. Experience in evaluating and determining donor suitability particularly with regard to infectious disease testing that includes CMV/HTLV I/II testing, if serving as the Technical Director.
6. Approve exceptional releases of tissue (SOPM)
7. Establish policies and procedures regarding adverse events that include investigation, documentation, review, and reporting required by federal, state, or local law
8. Train technical staff

302.2 The tissue bank operator shall maintain a roster of all persons authorized by him or her to have access to the bank, and shall establish specific rules for the operation of the bank and for governing the conduct of persons permitted access to the bank.

1. Personnel written duties and responsibilities, personnel records, required continuing education, documented initial training and annual competency
2. **302.3** The roster and rules required in § 302.2 shall be made available upon request
3. **302.4** Whenever the licensee is a person licensed to operate a hospital, the licensee shall designate a physician who shall be the operator of the tissue bank

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Technical Director qualifications/responsibilities: In the absence of the director

1. Hold a bachelor's degree or higher in medical technology or a biological science from an accredited college/university; and be qualified by training/experience for the scope of activities conducted in a tissue bank; or hold an earned bachelor's degree in a discipline other than medical technology or a biological science from an accredited college/university and have five years' experience overseeing all technical aspects of tissue bank operations under the supervision of the medical director.
2. Provide onsite supervision of tissue bank operations and personnel during tissue bank hours of operation.
3. Supervise planning, organization, SOPM's, records, products.
4. Provide training/competency procedures of technical staff (collection, retrieval, processing, packaging, cryopreservation) and continuing education procedures
5. Oversee quality assurance/control procedures
6. Oversee facility operations and equipment

Technical staff qualifications/responsibilities:

1. Shall possess the education, experience, and training necessary and sufficient to assure that assigned duties are performed in accordance with tissue bank established procedures and standards.
2. Maintain and follow the policies and procedures established by the medical director and the technical director.
3. Maintain annual competency in assigned tasks and duties, participate in training and continuing education

• Section: 306 TRANSPORTATION OF TISSUE

306.1 Tissue may be transported to or from a tissue bank for any of the purposes of the Act or this chapter when accompanied by a signed copy of the applicable record required by § 303 of this chapter.

• Section: 303 RECORDS OF ACQUISITION AND WITHDRAWAL

303.1 No tissue may be placed in any tissue bank unless a proper record is made of its acquisition on a form that has been approved by the Director.

303.2 The record required in §303.1 shall consist of, but not be limited to, the following information:

1. Name of donor
2. Place of death
3. Date of death
4. Cause of death
5. Restrictions on the use of the tissue, if any, made by the donor or by the person having the right to the cadaveric donor
6. A complete description of the tissue, including categories of tissue and quantity of each category; and
7. The signature of the physician who removed the tissue from the cadaveric donor' and the signature of the operator

303.3 No tissue may be placed in any tissue bank which has been acquired from another tissue bank, without being accompanied by a copy of the original record of acquisition and a detailed listing of the quantity and category of tissue.

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303.4 No tissue may be withdrawn from a tissue bank unless a record of the withdrawal is made on a form approved by the Director.

303.5 The record of withdrawal required in §303.4 shall include, but not be limited to, the following information:

- 1. A completed description of the tissue withdrawn, including categories of tissue and quantities of each category sent; and**
- 2. The purpose of withdrawal, that is, whether the tissue is to be used for human transplantation or for medico-surgical research.**

303.6 Tissue shall be issued only to persons or institutions deemed qualified by the operator to use the tissue for the purposes set forth in the Act.

303.7 Whenever it becomes necessary to withdraw tissue from a tissue bank for any other purpose than for human transplantation or for medico-surgical research, a complete record of the withdrawal shall be made on a form approved by the Director.

303.8 The record of withdrawal required in §303.7 shall contain a complete description of the tissue withdrawn, the reasons for withdrawal, and the disposition made of the tissue.

• **Section: 304 PHYSICAL AND SANITARY REQUIREMENTS**

304.1 The tissue bank operator shall at all times maintain sanitary conditions and sterile precautions appropriate to the procurement, banking, and issue of tissues, which, are consistent with accepted medical practices.

- 1. Processing procedures**
- 2. Labeling**
- 3. Storage of distributable inventory**
- 4. Receipt and storage of containers and reagents**
- 5. Quarantine procedures**
- 6. Quality assurance and control of functions**

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304.2 The location of the tissue bank shall be one that will permit maintenance of the standard conditions and sterile precautions required in §304.1.

1. **Plumbing**
2. **Drainage**
3. **Lighting**
4. **Ventilation**
5. **Space**
6. **Handwashing facilities**

304.3 The facilities and other equipment provided for use by the bank shall be adequate for the purposes and scope of the bank as indicated in the application for license.

1. **Engineering**
2. **Fire**
3. **Safety**
4. **Health and**
5. **Sanitation**

COMMUNICABLE AND REPORTABLE DISEASE

Title 22-Health

Chapter: 22-B2

• Section 211 LABORATORIES AND BLOOD BANKS

211.2 A laboratory that tests a communicable disease specimen shall report its findings directly to the person who submitted the specimen.

211.3 Whenever a test made in a public or private laboratory is positive for syphilis, the laboratory shall report the positive test in writing within twenty-four (24) hours, giving the following information:

1. The name of the person requesting the test;
2. The address of the person requesting the test; and
3. All other information required by this section.

211.4 Whenever a test made in a public or private laboratory is positive for HIV or is indicative of an HIV diagnosis, including CD4 and viral load tests, the person shall report the positive test in writing, within forty-eight (48) hours, giving the following information:

1. The name of the subject of the test;
2. The name and address of the physician or provider requesting the test;
3. The patient's medical record number; and
4. All other information required under this section.

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211.5 Each public or private laboratory shall keep a record of its findings showing evidence of communicable disease for a period of at least one (1) year.

211.6 During the one (1) year period in which records of a communicable disease are kept, the records shall be available for inspection at any reasonable time.

211.8 Whenever, during its operations, a blood bank determines that a specimen of blood tests positive for syphilis, the physician in charge of the blood bank shall report the positive test in writing within twenty-four (24) hours. Whenever, during its operations, a blood bank determines that a specimen is positive for HIV, the physician or provider in charge of the blood bank shall report the positive test in writing within forty-eight (48) hours.

211.10 All bacteriological laboratories in the District, including bacteriological laboratories in public or private hospitals, shall report within forty-eight (48) hours in writing to the Director of Human Services, all positive acid fast bacilli results whenever determined by smear or culture or otherwise.

211.11 The reports required in § 211.10 shall be filed by the Director of the laboratory or the Director's designee, and shall contain, in addition to the bacteriological findings, the following information:

1. The full name and address of the patient; and
2. The name of the physician or facility responsible for the diagnosis, referral, or treatment of the patient.

• **Section 201 COMMUNICABLE DISEASE SURVEILLANCE**

201.1 The following diseases shall be considered communicable diseases for the purpose of communicable disease surveillance and shall be reported by telephone immediately upon provisional diagnosis or the appearance of suspicious symptoms, and confirmed in writing within twenty-four (24) hours:

1. Hepatitis A

201.2 The following diseases shall be considered communicable diseases for the purpose of communicable disease surveillance and shall be reported in writing within twenty-four (24) hours after provisional diagnosis or the appearance of suspicious symptoms:

1. Lymphogranuloma venereum (LGV, including atypical LGV)

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201.3 The following diseases shall be considered communicable diseases for the purpose of communicable disease surveillance and shall be reported in writing within forty-eight (48) hours after diagnosis or the appearance of suspicious symptoms:

1. Chlamydia tracomatis infection (including PID, perinatal, and trachoma)
2. Gonococcal infection
3. Granuloma inguinale
4. Hepatitis (acute B, C)
5. Human immunodeficiency virus (HIV) infection, and pregnancies in HIV-infected women)
6. Trichinosis (Trichinellosis)
7. Urethritis, atypical
8. Toxic shock syndrome (Staphylococcal, Streptococcal, and other)
9. Syphilis (all stages congenital)

Tissue Bank Application: Part II

- **Section: 300 GENERAL PROVISIONS: 300.2**, The provisions of this chapter shall apply to the establishment, maintenance, and operation of tissue banks.

Does the laboratory have written policies and procedures outlined in 1-11?

- **Section: 301 LICENSES**

Does the laboratory have a current tissue bank permit issued by DC Health?
(Submit a copy)

- **Section: 302 OPERATION OF TISSUE BANKS 302.1**, Each tissue bank shall be directed by an operator who shall be a physician with authority and responsibility for the direction of the bank. (Licensed by the DC Board of Physicians)

Does the tissue bank have a current qualified director licensed by the DC Board of Physicians?
(See Tissue Bank Application: Part III)

Does the laboratory have written duties and responsibilities for the tissue bank director outlined in 1-8?
(Submit a copy)

- **302.2** The tissue bank operator shall maintain a roster of all persons authorized by him or her to have access to the bank, and shall establish specific rules for the operation of the bank and for governing the conduct of persons permitted access to the bank.

Does the tissue bank have a current qualified technical director?
(Name and submit a copy of diploma/license)

Does the tissue bank have written duties and responsibilities for the technical director outlined in 1-6?
(Submit a copy)

Does the tissue bank have current qualified technical staff?
(Name(s) and submit a copy of diploma/certification)

Tissue Bank Application: Part II

Does the tissue bank have written duties and responsibilities for the technical staff outlined in 1-3?
(Submit a copy)

• **Section: 306 TRANSPORTATION OF TISSUE**

Does the tissue bank have written policies and procedures for tissue transportation and keep documentation of all records?

• **Section: 303 RECORDS OF ACQUISITION AND WITHDRAWAL**

Does the tissue bank have written policies and procedures for tissue acquisition/withdrawal and keep documentation of all records?

• **Section: 304 PHYSICAL AND SANITARY REQUIREMENTS**

Does the tissue bank have written policies and procedures for the physical and sanitary conditions of the tissue bank?

• **Section 211 LABORATORIES AND BLOOD BANKS: Communicable and Reportable Diseases**

Does the tissue bank have written policies and procedures for ensuring that tissue is free from infectious diseases and reporting policies?

Does the tissue bank keep documentation of all records of infectious diseased tissue?

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.

Medical Director Signature _____ **Date** _____



APPLICATION FOR APPROVAL OF FACILITIES LICENSED AS TISSUE BANKS

I here-by apply for approval of _____

NAME OF FACILITY

ADDRESS

To be licensed as a Tissue Bank Tissue Bank Title 22-Health, Chapter: 22-B3

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Signature

Date

LICENSE FEE: \$25.00: MAKE CHECK PAYABLE TO D.C. TREASURER

**RETURN TO: Michele Tallent, BS, MT
Health Services Program Specialist
Health Regulations and Licensing Administration
Health Care Facilities Division
899 North Capital Street NE, 2nd FL
Washington, DC 20002**

Please email once the payment has been mailed: Email: michele.tallent@dc.gov