New York State Regulation of Tissue Banks

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Regulation History

Clinical Laboratory and Blood Banks  1965
Stem Cell Banks (general PH authority)  1988
Semen Banks  1989
Human Milk Banks  1990
Article 43-B, "Organ, Tissue and Body Parts Procurement and Storage"  1990
General Tissue Banking Standards  1991
Tissue-specific Technical Standards  1993
Guidelines for Collection, Processing, and Storage of Cord Blood Stem Cells  1997
PHL Article 43-B - "Organ, Tissue and Body Parts Procurement and Storage"

- Broad statutory authority to promulgate regulations
- New York State Transplant Council established
Features of New York Requirements

- Licensure
- Director/medical director requirements
- Medical advisory committee
- Application process
- General technical standards
- Tissue-specific standards
- Nontransplant anatomic banks
Focus of Standards

- Donor selection and testing
- Donor and recipient consent
- Records
- Labeling
- Processing
- Distribution
- Quality assurance
Exceptions to License Requirement

- Out-of-state banks distributing nontransplant anatomic parts to licensed banks in NY
- Use of prepared slides and/or human-derived cell lines in nontransplant research and education
- Federal government (e.g., VA hospitals)
- Uses of microbially inactivated tissue (e.g., dentists)
- Avascular eye tissue and HPCs shipped from out-of-state banks to licensed banks in NY
Part 52 - Tissue Banks and Nontransplant Anatomic Banks

Subparts 52-1, 52-2, 52-3 - administrative, licensure, and general technical requirements applicable to tissue banks operating in NY
Tissue-specific technical standards for tissues for clinical use
Part 52- Technical Standards

Subpart 52-11 (proposed) - Nontransplant anatomic banks

Includes tissue-specific technical standards for whole bodies, body segments, organs and tissues for research and/or education.
Hematopoietic Progenitor Cell Committee develops and monitors standards for collection, processing, storage, distribution, and clinical use of HPCs in NY
Technical requirements for HPC banks:

- Cord blood
- Peripheral blood stem cells
- Bone marrow
Licensure Categories

- Collection
- Processing
- Storage
- Transplantation
<table>
<thead>
<tr>
<th>Type of HPCs</th>
<th>Located in NY</th>
<th>Located Out-of-State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Marrow</td>
<td>27</td>
<td>2</td>
</tr>
<tr>
<td>Peripheral Blood</td>
<td>34</td>
<td>1</td>
</tr>
<tr>
<td>Cord Blood - Total</td>
<td>16</td>
<td>25</td>
</tr>
<tr>
<td>Community</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Patient-need</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Family storage</td>
<td>2</td>
<td>16</td>
</tr>
</tbody>
</table>
Administrative Requirements
(Other than HPC banks)

- Tissue Bank Director - appropriate education and tissue banking experience
- Medical Director - medical license in state of practice
- Medical Advisory Committee - 5 members with pertinent expertise, including infectious disease (and, for reproductive tissue banks, genetics)
Administrative Requirements (HPC banks)

Director/ Medical Director

- A physician licensed in state of practice with experience or training in clinical hematology/oncology (for processing-only may hold appropriate doctoral degree)
- Specific experience in collection of HPCs, including a minimum number of procedures

Medical Advisory Committee

- Expertise in infectious disease, hematology, oncology, histocompatibility, and/ or transfusion medicine
License Approval Process

- Review Application
  - Issue provisional license (1 year, renewable)
  - Conduct on-site survey
  - Issue Tissue Bank Evaluation Report
  - Review plan of correction
  - Issue full license (4 years, renewable)
Donor Assessment

- Complete health history evaluation
- Infectious disease testing
- Only required rejection is confirmed HIV (medical flexibility)
Banks may apply for special exemption from a specific standard in cases of medical emergency or special medical condition, or for unique methodology.
Maintaining Licensure

- Report errors and accidents
- Submit annual activities report
- File annual application renewal
- Report changes in director, medical director and owner and follow-up with new application
- Maintain compliance with applicable regulations
Applicable Guidelines

Guide for the Interpretation and Management of Tissue Donor Screening Test Results - April 1997

Common Deficiencies

- Inadequate consent processes
- Lack of infectious disease expertise in tissue banks. Failure to perform required testing
- Quality assurance deficiencies
- Unlicensed tissue banks
Challenges

- Family storage cord blood banks – erroneous assumption that the infant is not a donor subject to screening (mother)
- Role of OB as an agent of the cord blood bank
- Awareness of hospital administration
- Multiple facilities: cradle-to-grave tracking of tissues
- Rapidly progressing technology
- Media coverage of tissue bank incidents
Blood and Tissue Resources Program

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