

# REGULATORY

**Bulletins (/current-bulletins)**

**Standards (/standards)**

**Government Advocacy Correspondence (/government-advocacy-correspondence)**

**Regulatory (/regulatory)**

**Guidance Documents (/guidance-documents)**

**State Statutes (/state-statutes)**

Tissue processing in the United States is governed by mandatory requirements enforced by federal and state regulatory authorities.

The authorization of the gift of tissues is governed by the Uniform Anatomical Gift Act in conjunction with state statutes.

Tissue banks in the United States are governed by the National Organ and Tissue Transplant Act (NOTA), which dictates that organs and/or tissues cannot be bought or sold. The law does allow for reimbursement of costs associated with the recovery, processing and storing of tissue and for the development of tissue processing technologies. These activities can include research, screening and testing, and unique sterilization processes with the goal to increase the safety and efficacy of donated tissue for recipients.

In the United States, all transplant tissue banks must be registered with the FDA and are inspected routinely for compliance to federal regulations. Tissue provided by AATB accredited tissue banks are required to comply with FDA, AATB Standards, and all state and local regulations.

**FIND AN ACCREDITED TISSUE ESTABLISHMENT**

(/accredited-  
bank-  
search)

---

# TISSUE SAFETY

Tissue transplantation has an impressive safety record. Transmission of infectious diseases through allografts is prevented through careful donor screening, including extremely sensitive laboratory testing, and tissue processing.

Human tissue products are inherently biocompatible, meaning they can be incorporated into a human body more easily and with fewer complications than many analogous synthetic products or those of animal origin (xenografts).

Every medical procedure, including the use of tissue for transplant, comes with risks and benefits. The AATB encourages any patient considering a tissue transplant to discuss the risks and benefits of the procedure with their physician.

**SEARCH FDA'S HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION** (<https://www.accessdata.fda.gov/hctdb/>)

---

# TISSUE TRACKING

Both FDA regulation and AATB's Standards require tracking tissue from the moment of recovery through all handling and distribution to the consignee, which is the entity that accepts the final delivery of the allografts.

FDA regulation does not require the consignee to track the tissue to final disposition, including use in a patient. This makes it critical for healthcare facilities to have systems to read bar codes containing unique identifiers, tracking allografts to the patient.

AATB's Standards require that members have a protocol in place to provide methods for the consignee to provide follow-up data collection (e.g., tissue trace card to complete and return) on the recipient. However, although critical, completion by end users is voluntary.

AATB does not regulate tissue internationally. It is regulated by the FDA.

---

# EXTERNAL REGULATORY ORGANIZATIONS

**US HEALTH & HUMAN SERVICES (HHS)** (<https://www.hhs.gov/>)

**US FOOD & DRUG ADMINISTRATION (FDA)** (<https://www.fda.gov/>)

**CENTER FOR BIOLOGICS EVALUATION & RESEARCH (CBER)** (<https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-offices-divisions>)

**CENTERS FOR DISEASE CONTROL & PREVENTION (CDC)** (<https://www.cdc.gov/>)

**CENTER FOR DEVICES & RADIOLOGICAL HEALTH (CDRH)** (<https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health>)

**EUROPEAN COMMISSION** ([https://ec.europa.eu/commission/index\\_en](https://ec.europa.eu/commission/index_en))

**WORLD HEALTH ORGANIZATION (WHO)** (<http://www.who.int/>)

**HEALTH CANADA** (<https://www.canada.ca/en/health-canada.html>)

**Over 120 tissue banks around the world are committed to the quality and safety of donated human tissue.**

**(/ACCREDITED-BANK-SEARCH)  
FIND AN ACCREDITED ESTABLISHMENT**

**AMERICAN ASSOCIATION OF TISSUE BANKS (/)**

8200 Greensboro Drive  
Suite 404  
McLean, VA 22102

Phone: 703.229.1020



**OF DONATE LIFE  
AMERICA**

*Donate Life is a registered trademark  
of Donate Life America.*

(<https://www.donatelife.net/>  
)

## **Join AATB**

[Accreditation \(/accreditation\)](#)

[Individual Membership \(/individual-membership\)](#)

[Affiliate Membership \(/affiliate-membership\)](#)

## **Standards & Regulatory**

[Bulletins \(/current-bulletins\)](#)

[Standards \(/standards\)](#)

[Government Advocacy Correspondence \(/government-advocacy-correspondence\)](#)

[Regulatory \(/regulatory\)](#)

[Guidance Documents \(/guidance-documents\)](#)

[State Statutes \(/state-statutes\)](#)

## **Education**

[Certification \(/certified-tissue-bank-specialist\)](#)

[Online Learning \(/online-learning\)](#)

[In-Person Programming \(/person-programming\)](#)

## **AATB**

[About Us \(/about\)](#)

[Why Tissue? \(/why-tissue\)](#)

[News + Announcements \(/news\)](#)

[Contact \(/contact\)](#)

[NewsBrief \(https://www.naylornetwork.com/aatb-newsbrief/signup.asp\)](https://www.naylornetwork.com/aatb-newsbrief/signup.asp)

[Careers \(https://jobcenter.aatb.org/\)](https://jobcenter.aatb.org/)

[Portal Login \(https://aatbnetwork.force.com/aatb/s/login/\)](https://aatbnetwork.force.com/aatb/s/login/)

