

**Federal law requires tissue establishments “screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.” (Title 21 Code of Federal Regulations, Part 1271, Subpart D)**

### ***Al Higginbotham's Story***

**Back in 1995, Al Higginbotham was entertaining clients on a hunting trip in Alabama when a tree collapsed, crushing his spine. He couldn't move and was in horrible pain. Five vertebrae were damaged in the accident, requiring extensive surgery. He was told he wouldn't walk again. He went home to learn a new life as a paraplegic fully confined to a wheelchair. A good friend suggested a bone transplant surgery that may relieve the pain and perhaps enable him to walk. By January of 1996, after that surgery, he was out of the chair, using a walker. He now uses hand canes to walk and has hiked the Grinnell Glacier in Montana.**

Courtesy of the American Association of Tissue Banks

### **Additional Information**

Check out these links for more information about HCT/P transplantation.

American Association of Tissue Banks:  
[www.aatb.org/](http://www.aatb.org/)

CDC Frequently Asked Questions:  
[www.cdc.gov/transplantsafety/questions\\_answers.html](http://www.cdc.gov/transplantsafety/questions_answers.html)

Donate Life America:  
[www.donatelife.net/](http://www.donatelife.net/)

Donate Life Florida:  
[www.donatelifeflorida.org/](http://www.donatelifeflorida.org/)

FDA—Tissue and Tissue Products:  
[www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm](http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm)



# **Human Tissue Transplantation**

**The risks and benefits of human cell, tissue, and cellular- and tissue-based product (HCT/P) transplants**



## HCT/P Transplantation Safety Support

Improvements in donor screening, serologic testing, reporting and investigating suspected donor-derived disease transmission have improved tissue safety. The risk of acquiring an infection from tissue transplant is thought to be very low. However, the risk for transmission of infectious pathogens (such as viruses, bacteria, fungi and protozoa/parasites) remains and requires continued vigilance. For this reason, donor screening includes processes such as interviews, medical record reviews, questionnaires, and laboratory testing. In Florida, non-profit federally designated organ procurement organizations and tissue banks, which include tissue processors, donor recovery centers, and tissue distribution centers, work together to facilitate the donor testing, screening, and processing of HCT/Ps. Once screened, these entities take additional steps to rid tissue of pathogens that might be present on or within the tissue.

Multiple organizations play a role in organ and tissue safety. The Centers for Disease Control and Prevention (CDC) provides expertise and assistance in investigating potential transmission of infections from HCT/P. The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research is a government agency

that regulates human tissue, including ocular tissue, for transplantation. In Florida, the Department of Health (DOH) coordinates with the CDC on any potential disease transmission and the Agency for Health Care Administration works with the FDA to regulate HCT/P.

### Informed Patients

Prior to any transplantation procedure, it is important patients understand the:

- ◆ Type of HCT/P they are receiving
- ◆ Risks and benefits associated with HCT/P transplantation
- ◆ HCT/P tracking, should there be an issue (i.e. name of manufacturer, unique tissue identification number)
- ◆ Generosity of the person who donated the tissue

There are hundreds of thousands of HCT/P transplants in the United States annually, and the use of allografts (surgically transplanting tissue from one person to another) is diverse and growing. Transplanted tissue can include bone, ligaments, ocular tissue, skin, veins, arteries, or heart valves. The safety of transplanted tissue is determined by donor testing and screening, as well as specific processing steps to reduce, inactivate, or remove any bacteria and viruses. Aseptic processes at a minimum meet federal guidance and international standards for safety and can prevent cross-contamination. Terminal sterilization processes provide the highest safety assurance for live human tissue

such as birth tissue. Federal guidance requires any written claim that a processing method has inactivated a virus or prevented disease or bacterial contamination must be based on a validation study. Some tissues, such as corneas, blood vessels, heart valves, and fresh tissue grafts are damaged by most traditional processing techniques and cannot be sterilized, but all must still meet federal guidance for safety. Patients should be sure to discuss their specific procedures and potential risks with their physicians.

### The American Association of Tissue Banks (AATB)

The AATB *Standards for Tissue Banking* support the provision of safe tissue of high quality intended for transplantation. The American Academy of Orthopedic Surgeons recommends using tissue grafts from an AATB-accredited tissue bank to provide uniform levels of safety and quality.