

# Informed Consent Form for Human Tissue Implants

1. A. \_\_\_\_\_ (patient name), or  
B. (name of one of the representative below) \_\_\_\_\_ as:  
☐ Parent ☐ Representative ☐ Guardian  
acting on this patient's behalf have been advised through discussions with Dr. \_\_\_\_\_ that I (or the patient named above if signed by a representative) may have human tissue implanted during my surgical procedure.

The donor tissue will be provided by \_\_\_\_\_ (the name of the tissue bank).

I have been informed that the following human tissue(s) may be implanted during my or the surgery:

- ☐ Tendon ☐ Sclera ☐ Skin  
☐ Bone ☐ Cornea ☐ Other: \_\_\_\_\_

2. I acknowledge that my doctor's explanation included a description of the procedure, the reasonable benefits and potential risks of the surgical procedure with human tissue implant(s). The following are some, but not all potential risks that I have been told can occur;  
☐ Transmission of infectious disease (bacterial/fungal/viral)  
☐ Graft failure  
☐ Other: \_\_\_\_\_ (opportunity for surgeon to explain any additional risk specific to the graft)
3. I have also been told what may happen if I decide not to have this surgery. I have been informed of reasonable medical alternatives, if any, and their common foreseeable risks and benefits. These alternatives include, but are not limited to:  
☐ Pain management with medication  
☐ Physical therapy  
☐ Other: \_\_\_\_\_
4. I have been informed that the human tissue(s) used is/are a gift for which the donor or donor's family received no compensation.
5. I understand that the risks of infection associated with receiving human tissue(s) have been reduced at least by required infectious disease tests and careful donor selection. I understand that all human tissue intended for transplantation are from donors who test negative for:
- Human immunodeficiency virus, type 1 (HIV-1) and type 2 (HIV-2)
  - Nucleic acid test for HIV-1
  - Hepatitis B surface antigen (HBsAg)
  - Total antibodies to hepatitis B core antigen (anti-HBc)
  - Antibodies to the hepatitis C virus (anti-HCV)
  - Nucleic acid test for HCV
  - Syphilis
- In addition, I understand that all donor tissue used for implantation at \_\_\_\_\_ (the name of your institution) are acquired from tissue banks accredited by the American Association of Tissue Banks or from eye banks accredited by the Eye Bank Association of America and registered with the United States Food and Drug Administration.
6. While the precautions taken by my surgeon and the testing and screening of the donor and donor tissue generally prevent complications associated with tissue implants, I understand that I may still be subject to ill effects as a result of receiving donor tissue.
7. I understand that this form documents that I have had a conversation with my physician and that he/she has provided me with an explanation of the most common complications, consequences and reasonable alternatives of receiving human tissue.
8. I acknowledge that I have had the opportunity to ask all questions of my physician with regard to this treatment and that they have been answered to my satisfaction.

## Patient Affirmation

I am also acknowledging that I am satisfied with the explanation I have been given about my need for human tissue. I fully understand what I am now signing of my own free will.

## Witness to

**Affirmation:** Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Patient (or parent, guardian

or Representative): Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Physician Attestation

I, Dr. \_\_\_\_\_, attest that this patient has been informed about the common foreseeable risks and benefits of human tissue as well as its reasonable alternative(s), if any. Further questions the patient has asked with regard to this treatment have been answered to his/her apparent satisfaction.

**Surgeon:** Signature: \_\_\_\_\_

Date: \_\_\_\_\_