

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):
Physician Attestation	Signature: _____ Date: _____		
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: _____	

Although the information contained in this informed consent template is intended to be current and complete, each health care facility should modify the template to suit its own particular purposes to reflect all applicable local, state and federal laws and regulations, as well as internal policies, and evolving best practices. AABB expressly disclaims any liability for any loss which may arise from use of this template.