

Background

The text below was prepared as a template for an addendum to next-of-kin authorization forms used to seek permission from family members for donation of their deceased loved one's tissues to the Genotype-Tissue Expression (GTEx) project. The template describes key elements of the GTEx project including the general research purpose, risks, benefits and confidentiality procedures. Due to differences in workflow and recruitment strategies, the concepts included in the addendum were implemented differently across biospecimen source sites collecting tissues for GTEx. Some sites chose to integrate concepts from the template directly into their existing next-of-kin authorization form. Other sites opted to adapt the template to serve as a separate addendum to their standard next-of-kin authorization form. All sites had the authorization/addendum forms reviewed by their institutional review board. In addition, the GTEx staff reviewed all final documents prior to implementation to ensure all essential concepts were included.

Addendum Seeking Permission for Family Member Participation in a National Institutes of Health (NIH) Research Project

We are asking for your permission for your family member to be part of a NIH research study.

This project will help scientists understand how normal human bodies work. This will help them find causes for diseases like cancer, high blood pressure, Alzheimer's, and many others.

This project will collect and study tissue samples and health information from many people. Tissue samples are small amounts of human skin, organs, blood or other material. Scientists will use the samples and information to study how genes affect human health. Genes are instruction manuals for our bodies. Genes carry information about traits that run in families, like brown eyes or blue eyes. Some tissue samples may be treated so that they grow forever and can be studied for many years.

We will label your family member's samples and information using code numbers. The National Cancer Institute (NCI) will store the tissues and information. The NCI is part of the NIH. Scientists will not know names, addresses, social security numbers, or any other information that identifies your family. The coded samples and data will be saved for many years. Scientists from around the world will use the samples and information for many kinds of medical research.

This research will not directly benefit your family. There is no cost to participate. Your family will not be paid for the tissues or health information. The tissue samples and health information will be used only for medical research. Nothing will be sold for profit. Research using your family member's samples or information could lead to new tests, drugs, or other products. If this happens, your family will not share in any profits.

We believe that the risks of participation are low. But, we cannot guess all future risks. There is a small risk that someone could find out your family member's genetic and health information. If this happens, there is a small risk that blood relatives could be identified. We will do our best to keep this from happening. In addition, there are State laws and a Federal law, the Genetic Information Non-

discrimination Act, that help protect your family from being treated unfairly because of their genes. It is up to you whether or not to donate your family member's tissue. Saying no will not affect your family member's care. You can change your mind and later withdraw your family member's samples, genetic data, or health information from this project by calling or writing to us (**provide details here, or below**). In this case, remaining samples will be destroyed. But, you cannot stop samples and information from being used in studies that have already started. Test results from studies that used your family member's samples and information will not be destroyed.

Research results from your samples and information will not be given back to you. You can learn about the kinds of research that use these samples and information by visiting several NIH web sites, including <http://www.genome.gov/27543767> and <http://biospecimens.cancer.gov/default.asp>

If you have questions about this research, please contact _____.