Background

The text below was prepared by caHUB as a template for an addendum to self-authorization forms to seek permission for donation of an individual's tissues to the Genotype-Tissue Expression (GTEx) project following death. 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 sef-authorization form. Other sites opted to adapt the template to serve as a separate addendum to their standard self-authorization form. All sites had the authorization/addendum forms reviewed by their institutional review board. In addition, caHUB staff reviewed all final documents prior to implementation to ensure all essential concepts were included.

Addendum Seeking Your Permission
for Participation in a National Institutes of Health Research Project

We are asking you to be part of a National Institutes of Health 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 samples and information using a code number. The National Cancer Institute (NCI) cancer Human Biobank (caHUB) 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 you. 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 you or your family. There is no cost to participate. You 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 samples or information could lead to new tests, drugs, or other products. If this happens, you will not share in any profits.

We believe that the risks of participation are low. But, we can not guess all future risks. There is a small risk that someone could find out your genetic and health information. If this happens, there is a small risk that you or your family 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 you from being treated unfairly because of your genes.

It is up to you whether or not to donate your tissue. Saying no will not affect your care. You can change your mind and later withdraw your 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 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 nd http://cahub.cancer.gov.

If you have questions about this research, please contact_____.