Sample Consent Document 5: *Authorization for Tissue Donation in National Institutes of Health Research Project*

This document was used for the recruitment of organ and tissue donors for authorization of tissue use for research at the time of organ procurement. It includes an addendum describing a secondary genome-sequencing project.

Important note: This consent document was developed for the GTEx Project. It is not provided as guidance or as a template promoted by NHGRI, but as a reference to inform investigators and IRBs considering these issues. It is important to tailor consent documents for each individual study.

Authorization for Tissue Donation in National Institutes of Health Research Project

Thank you again for your generous gift of life. This authorization discusses another opportunity for donation. The project is acquiring tissue from generous donors to help scientists and doctors from around the world understand how genes work. As you probably know, genes carry the information that is passed from parent to child that affects such things as eye color or susceptibility to disease. The goal of the project is to help scientists understand exactly how genes affect health. This could potentially help in the development of medical tests and cures for many diseases such as cancer, heart disease and diabetes in the future.

I will provide information to you before asking for your authorization to recover the gifts of tissues for this important research. Please ask if there are things you do not understand.

- □ This project was established to do two things: first, it is a BIOBANK. A biobank is a facility that stores donated tissues from many people so that it can be used in medical research studies. Second, the donated tissue will be analyzed for their genetic information. This will be put into a DNA DATABASE that will be made available to researchers.
- □ Scientists will use the tissue to examine each donor's complete genetic makeup. This information along with information from the donor's medical record will all be stored in a DNA database on the Internet. Qualified scientists and companies from around the world will be able to use the tissue and information in the DNA database for many kinds of medical research. A limited portion of this database will be made available publically on the Internet.
- □ Brain tissue is important to the study of many diseases like Alzheimer's, Parkinson's and Autism, and if allowed, the entire brain will be recovered. In other areas of the body only very small amounts of tissue, about the size of 8 stacked quarters, will be collected.
- □ Some tissues may be treated so that it grows forever and can be studied for many years. The tissue may be stored indefinitely and cells from the tissue can also be transformed into different kinds of cells. For example, skin cells could be transformed into nerve cells.
- □ There is a chance that the donor and the blood relatives of the donor could be identified. The project will make every effort possible to keep this from happening. The donor's name and other things like address and medical record numbers will be removed from the database and the labeling of the tissues. No researchers using the tissues or database will know the identity of the donors as the information and tissues will be labeled only with a code number.
- □ You can change your mind and withdraw the tissue or health information from the study by calling [*Institution*] at [*Contact #*] and referencing [*title of project*]. In this case, any tissue remaining in the biobank will be destroyed and never used again. Health information and genetic data will be removed from the database and never distributed further. However, you cannot stop samples and information from being used that have already been sent to researchers.
- □ Families will not be given results of any testing done using the donor's samples. We will send you a brochure about the project, which includes websites designed specifically for the public and for people who donated to this important research.
- □ We would also like to collect additional samples of tissue for use in other important research projects that are not connected to this particular project. Donated tissues may be stored indefinitely and these projects will vary in purpose. For instance, there is a possibility that some of the donated tissue may be used for genetic research, treated to grow forever, and be transformed into different types of cells that could be used to make medical products. However, you will not be informed about what types of research projects the tissues are used for or about what happens to the tissue after it is collected. Only small amounts of additional tissue would be collected.

For telephonic authorization, please have NOK verbalize the following:

I, _____, being the _____ and next-of-kin of _____,
(print name of next-of-kin) *(relationship)* *(print name of donor)*
authorize [*Institution*] for the donation of samples of the tissue types and associated connective tissues indicated below? Please state yes or no to each.

Brain(Tissue Donor only) □Yes □No	Salivary gland □Yes □No	Stomach □Yes □No	Liver □Yes □No
Skin □Yes □No	Endocrine tissue □Yes □No	Large intestine □Yes □No	Reproductive tissue □Yes □No
Adipose(fat) □Yes □No	Heart tissue □Yes □No	Pancreas □Yes □No	Blood □Yes □No
Muscle □Yes □No	Mammary tissue □Yes □No	Spleen □Yes □No	Lymph node □Yes □No
Blood vessel □Yes □No	Lung □Yes □No	Kidney □Yes □No	
Neurological tissue □Yes □No	Esophagus □Yes □No	Bladder □Yes □No	

Please specify limitations: _____

Do you have any questions about the information I just read?_____

_____ _____
(Signature of Next-of-Kin) *(Signature of Witness #1)*

_____ _____
(Print name of Next-of-Kin) *date/time* *(Print name of Witness #1)* *date/time*

_____ _____
(Street Address) *(Signature of Witness #2, Hospital Representative)*

_____ _____
(City/State/Zip) *(Print name of Witness #2, Hospital Representative)* *date/time*

❑ **Check box if telephonic authorization obtained[1].**

1. If telephonic authorization obtained: (i) print name(s) of Next-of-Kin and any witness(es) and (ii) note date and time of authorization.

Addendum to [*primary project*] Authorization form for the [*secondary project*]

In addition to this project, there is another project called XXXX - that we are partnering with. Like this project, XXXX analyzes donated tissues for their complete genetic information. The purpose of XXXX is to learn how all of the parts of the DNA work.

XXXX differs from this project in these ways:

- All tissues collected for XXXX will be sent to researchers within a few weeks after collection, and once this happens, there will be no way for you to withdraw from the study.
- In XXXX, the only information connected to the data will be limited and general, such as gender, age, and cause of death.
- All information in XXXX – including the genetic data - will be shared freely in open access databases on the Internet. Although only experts will know how to interpret this information, anyone will be able to access it, and there is a chance that somebody could use it to connect your family member with the information generated from the donated samples. If that happened, the information could potentially be used to discriminate against you or your family members.

The discoveries that scientists can make by using these donated tissues will be highly valuable for understanding human health and disease. However, we cannot always foresee the results of research, and this means that new risks may come up in the future that we cannot predict now.

1. If telephonic authorization obtained: (i) print name(s) of Next-of-Kin and any witness(es) and (ii) note date and time of authorization.