

# CONSENT FOR GENETIC RESEARCH ON BIOLOGICAL SAMPLES

[ Unlinked, no recontact]

Research to identify genes that cause or contribute to a disease or trait is an increasingly important way to try to understand the role of genes in human disease. You have been given this consent form because the Medical University of South Carolina investigators want to include your tissue, cell or blood sample in a research project, or because they want to save such biological samples for future research. There are several things you should know before allowing your tissues, cells or blood to be studied or to be stored.

Once the sample is taken, it will be separated or “unlinked” from your name or any other type of identifier which could be traced to you. This will protect your confidentiality and anonymity; it will also have other consequences:

1. Suppose the investigators discover that your tissue sample carries a gene for a disease. Because the sample does not have an identifier linked to you, they will not be able to provide you or any family member with this information. In other words, because the tissue sample does not have an identifier linked to you, information about it cannot be communicated to you or any relative.
2. Even though your name will not be connected to the tissue or blood sample, other information about you might still be connected. For instance, information about your race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your racial or ethnic group.
3. When your name is removed from these samples it will be impossible for you to withdraw these samples from any future research project. This is because the samples will not have any identifiers linked to you and it will not be possible to find your sample to withdraw it.
4. If you are concerned about a potential genetic disorder, you and your doctor might choose to test specifically for it. This would require additional blood or tissue samples and would not be part of this research project. You should discuss this option with your doctor or genetic counselor.
5. The presence of a genetic marker does not necessarily mean that an individual will develop a disease. Informing people of all such markers independently of medical need can cause unnecessary anxiety. On the

other hand, the absence of a marker does not mean that someone will not get the disease. Genetic diseases appear as a result of a complex mixture of hereditary, environmental, behavioral and other factors. These are the best-known risks and challenges of genetic research. There might be other risks we do not know about yet.

It is important that you talk to your doctor, nurse or genetic counselor if you have questions or concerns about the research study.