

CONSENT FOR GENETIC RESEARCH ON BIOLOGICAL SAMPLES **[Linked, potential 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.

1. Your tissue, cell or blood sample will be stored under your name or some other type of identifier which could be linked to you. Sometimes these samples are shared for research purposes with other investigators at other research sites. If this is done, the other investigators would not know your name.
2. In addition to your name, other information about you might be connected to your blood or tissue sample. For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your tissue or blood. Such information is important for scientific reasons and sometimes for public health. It is possible that genetic information might come to be associated with your racial or ethnic group.
3. Genetic information about you will often apply (in one degree or another) to family members. It is not generally the University's policy to provide genetic information about you to your family members. However, certain studies, called *pedigree studies*, share such information among family members. For this and related research you will be asked if you are willing to share your genetic information with your family members.
4. You have the right to refuse to allow your tissue or blood to be studied or saved for future research studies. You may withdraw from this study at any time and remove any samples that contain identifiers from research use after the date of your withdrawal. This means that while the University might retain the identified samples-the law often requires this-they would not be used for research.
5. South Carolina law, mandates that your genetic information obtained from any tests or from this research, be kept confidential. Our state law prohibits any insurer using this information in a discriminatory manner against you or any member of your family in issuing or renewing insurance coverage for you or your family. Our state law further prohibits our sharing your genetic information with anyone except in a few narrow circumstances, one of these being a research project of this type, approved by the Institutional Review Board and then we must take all steps to protect your identity. You will still be responsible for paying for health care, however. The Medical University of South Carolina will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.
6. Genetic research raises difficult questions about informing you and other subjects of any results, or of future results. Some people feel anxious about the possibility of having a defective gene that would place them or their children at risk. Some people want to know what is found out about them; others do not. The risks of knowing include anxiety and other psychological distress. The risks of not knowing what is found include not being aware if there is treatment for the problem being studied. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. If there is a medical reason to seek specific information from you, your doctor will tell you this. A process called *genetic*

counseling@is often appropriate in such cases; you should ask your doctor or nurse about this if you have any questions.

Investigators in this study may try to recontact you in the future to find out about your health. If you are recontacted and want to know what the investigators have learned about your samples, you should understand that the following are the kinds of things the investigators or your health team might tell you:

- a) Information is too sketchy to give you particular details, but you will receive a newsletter informing you about the results of the project.
- b) You carry a gene for a particular disease that can be treated.
- c) You can carry a gene for a particular disease for which there is no current treatment. This news might cause severe anxiety or other psychological distress, depending on the severity of the disease.
- d) You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene. It can be very difficult to decide whether to share such information with relatives. Genetic counselors can help sort out the various options in such a case.

Also, for any future research, we may contact you with a new consent form giving you additional information.

- 7. 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.
- 8. 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.