

## GUIDELINES FOR TISSUE COLLECTION FOR RESEARCH AUTOPSY

1. Informed consent for the above tissue collection can be obtained by:
  - a. **Physicians** who have completed the CITI/Miami Human Subjects Research Educational Program,
  - b. **Nurses** who have completed the CITI/Miami Human Subjects Research Educational Program, and
  - c. **Study coordinators** who have completed the CITI/Miami Human Subjects Research Educational Program.
  
2. Informed consent for the above tissue collection can be given by the:
  - a. **Surviving spouse** unless legally divorced, legally separated or pending a court order for the same. In SC, the partner in common law marriage or living together situation is considered next of kin. If the deceased was never married, was divorced or if surviving spouse has been legally declared incompetent then,
  - b. **Adult children** (over 18), if none then,
  - c. **Adult grandchildren** (over 18), if none then,
  - d. **Parents**, if none, then,
  - e. **Adult brothers and sisters** (over 18), if none then,
  - f. **All grandparents**, if none then,
  - g. **All adult aunts and uncles** (over 18), if none then,
  - h. **All adult cousins** (over 18).
  
3. All tissue collected using these standard tissue collection consents will be sent to the MUSC Tissue Bank.
  
4. The appropriately completed informed consent will accompany the tissue sample to the Tissue Bank; if the informed consent does not accompany the tissue, the tissue sample will be destroyed.
  
5. No tissue will be released from the Tissue Bank for research purposes without written IRB approval.

Addressograph  
Or Patient Name / Hospital Number

## **MEDICAL UNIVERSITY OF SOUTH CAROLINA**

### **CONSENT TO RESEARCH**

#### **AUTOPSY TISSUE COLLECTION STANDARD CONSENT**

##### **PURPOSE AND BACKGROUND:**

You are being asked to allow tissue removed during autopsy to be used in future research to learn more about diagnosing, treating and curing disease.

##### **PROCEDURE:**

You are being asked to give permission to allow tissue removed during autopsy of the deceased to be stored indefinitely in the Medical University of South Carolina Tissue Bank. This tissue will be stored with the deceased's name, medical record number, diseases, age, gender and ethnic group. When you give permission for this tissue to be stored and used for research, you are also giving permission for researchers to review the deceased's medical record for information about the deceased's health and to study this tissue with this information. This tissue will not be used for research unless the research study is reviewed and approved by the Medical University of South Carolina Institutional Review Board (IRB) for Human Research. This Board is required by Federal law to protect the rights and welfare of people who volunteer to participate in research. This tissue might be given to researchers outside of the Medical University of South Carolina for research projects. If this is done, the deceased's name will not be released with the tissue; a code will be attached so other researchers will not know the person's name.

##### **DURATION:**

The tissue will be stored indefinitely.

**RISKS/DISCOMFORTS:**

The tissue that will be used for research is tissue that would normally be discarded. If you give your permission, the tissue you donate may be used for genetic research. 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. There are several things you need to know before allowing this tissue to be stored and studied.

1. In addition to the deceased's name, other information will be connected to the tissue sample. For instance, information about race, ethnicity, gender, medical history, and so forth might be available to investigators studying the tissue. Such information is important for scientific reasons and sometimes for public health. It is possible that genetic information might come to be associated with the deceased's racial or ethnic group.
2. Genetic information about the deceased will often apply (in one degree or another) to family members. It is not the University's policy to provide genetic information about the deceased to family members.
3. You have the right to refuse to allow this tissue to be studied or saved for future research studies. You may withdraw this participation 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.
4. South Carolina law mandates that genetic information obtained from any tests or from this research be kept confidential. Results of the research will not be given to you. To help protect privacy, these reports will not be put in the deceased's health record. 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 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 (IRB) and then we must take all steps to protect your identity.
5. Genetic research raises difficult questions about informing you 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. A process called "genetic counseling" is often appropriate in such cases; you should ask your doctor about this if you have any questions.

6. 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.
7. These are the best-known risks and challenges of genetic research. There might be other risks we do not know about yet.

**BENEFITS:**

The research that is done with this tissue probably will not help you. It might help others in the future.

**COSTS:**

There will be no cost to you for donating this tissue for research.

**COMPENSATION:**

You will not be paid for allowing this tissue to be used in research. This tissue will not be sold to researchers. It is possible that this donated tissue will help to develop new products in the future. There are no plans to share any potential financial gain with you.

**ALTERNATIVE:**

You do not have to allow this excess tissue to be used for research. An autopsy can be performed without agreeing to store tissue for research.

**MAKING YOUR CHOICE:**

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". No matter what you decide, it will not affect whether or not an autopsy is done. If you have any questions, please talk with the person asking for your consent or call the Institutional Review Board (IRB) for Human Research at 843-792-4148.

1. The deceased's tissue may be stored and used in research including genetic research to learn about, prevent, treat and cure health problems, for example, cancer, diabetes, heart disease and Alzheimer's disease.

Yes

No

2. I may be contacted in the future by someone from the Medical University of South Carolina to ask me to take part in research that may develop from the stored tissue.

Yes

No

3. The deceased's tissue may be stored and used in research including genetic research to learn about, prevent, treat and cure health problems, for example, cancer, diabetes,

heart disease and Alzheimer's disease without any personal identifiers. I understand that because the tissue will be anonymous I cannot request that it be withdrawn from the Tissue Bank at a later date.

Yes

No

Research conducted with these tissues may result in publication, but neither the deceased nor the family of the deceased will be identified. Information that is obtained concerning this research that can be identified with the deceased or family of the deceased will remain confidential to the extent possible within State and Federal law. The investigators associated with this study and the MUSC Institutional Review Board (IRB) for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

I have been given a chance to ask questions about this research. These questions have been answered to my satisfaction. I have been given a copy of this form for my records.

Please sign below after you circle your answers above.

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Authorizing Tissue Donation

\_\_\_\_\_  
Relationship to Deceased

\_\_\_\_\_  
Printed Name of Person Authorizing Tissue Donation

\_\_\_\_\_  
Date

Approved by the MUSC Institutional Review Board (IRB) for Human Research (IRB): 2/28/02