

## **GUIDELINES FOR HUMAN BIOLOGICAL MATERIAL COLLECTION FOR RESEARCH**

1. Informed consent for collection of human biological material (tissue, blood, body fluids) may 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. <http://www.musc.edu/CITI>
2. Informed consent for human biological material collection may be given by the:
  - a. Adult participant (over 18),
  - b. Parents (over 18) for child (less than 18), or
  - c. Court appointed guardian for child (less than 18) or adult without decision capacity
3. A notation will be made in the medical record that the patient has been consented for donation of Human Biological Materials and include the date of this consent.
4. All material collected using this standard human biological material collection consent will be sent to the MUSC Hollings Cancer Center Tissue Biorepository.
5. The appropriately completed informed consent will accompany the human biological material sample to the Tissue Bank. For samples obtained within one year of informed consent, the patient stamp plate and a copy of the medical record notation indicating date of consent will accompany the specimen. If either the informed consent or notation of such consent does not accompany the material, the sample will be destroyed.
6. No material will be released from the Tissue Bank for research purposes without written IRB approval.



Patient Name: \_\_\_\_\_ MRN: \_\_\_\_\_

Date of Surgery: \_\_\_\_\_ Surgeon: \_\_\_\_\_

Tumor Primary Site: \_\_\_\_\_

Surgical Site Designation: \_\_\_\_\_ Subsite: \_\_\_\_\_

Preoperative Diagnosis: \_\_\_\_\_

Clinical TNM Stage: \_\_\_\_\_

Ischemia time (*time at loss of arterial blood supply*): \_\_\_\_\_

Prior chemotherapy:                      YES                      NO

Prior radiation therapy:                      YES                      NO

Smoking status:                      NEVER                      PRIOR                      ACTIVE

Additional data pertinent to research (risk factors, tumor markers, viral positivity, demographic info, etc)

**MEDICAL UNIVERSITY OF SOUTH CAROLINA  
CONSENT TO BE A RESEARCH SUBJECT**

**STANDARD CONSENT FOR COLLECTION OF HUMAN BIOLOGICAL MATERIAL**

**PURPOSE AND BACKGROUND:**

You are being asked to donate your human biological material (blood, body fluids, tissue) to be used in future research to learn more about preventing, diagnosing, and treating disease.

**PROCEDURE:**

You are being asked to give permission to store your tissue, blood or body fluid ('material') indefinitely in the Medical University of South Carolina HCC Tissue Biorepository. This will not in any way affect the use of your material for diagnostic or treatment purposes. If tissue is being donated, this tissue will only be collected at the time of your scheduled surgery or other procedure.

You should know that you are agreeing to donation of materials for up to one year from the date of signature. If you prefer that this be a one-time only donation, you will be given that option. This material will be stored with your name, medical record number, diseases, age, gender, and ethnic group. When you give permission for this material to be stored and used for research, you are also giving permission for researchers to review your medical record for information about your health and to study this material 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 for Human Research.

This material might be given to researchers outside of the Medical University of South Carolina for research projects. If this is done, your name will not be released with the material; a code will be attached so other researchers will not know the material belongs to you.

**DURATION:**

Your material will be stored indefinitely and you may be contacted in the future and asked questions about your health.

**RISKS/DISCOMFORTS:**

The risks of blood drawing include temporary discomfort from the needle stick, bruising, infection or clot in the vein.

The risks for collecting tissue at the time of your scheduled procedure are the same as for the procedure itself. These have been discussed with you by your care provider, and include bleeding, infection, and injuring surrounding tissues.

If you give your permission, the material you donate may be used for genetic research. Research to identify genes that cause or contribute to a disease or traits is an increasingly important way to try to understand the role of genes in human disease.

A cell line may be created from your material. A cell line is a material sample that continues to reproduce itself. A cell line provides an unlimited supply of your DNA for future research studies. There are several things you need to know before allowing your material to be stored and studied:

1. In addition to your name, other information about you will be connected to your material sample. For instance, information about race, ethnicity, gender, your medical history, and so forth might be available to investigators studying your material. Such information is important for scientific reasons and sometimes for the public health. It is possible that genetic information might come to be associated with your racial or ethnic group.
2. Genetic information about you will often apply (in one degree or another) to family members. It is not the University's policy to provide genetic information about you to your family members.
3. You have the right to refuse to allow your material to be studied or saved for future research studies. You (or your next-of-kin at the time of your death) may withdraw your participation at any time and remove any samples that contain identifiers from research use after the date of your withdrawal.
4. South Carolina law mandates that your genetic information obtained from any tests or from this research be kept confidential. Results of the research will not be given to you or your doctor. To help protect your privacy, these reports will not be put in your 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 your genetic information with anyone except in a few narrow circumstances. One of these times is a research project of this type, approved by the Institutional Review Board. We will take all steps to protect your identity.
5. 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.
6. If you are concerned about a potential genetic disorder, you and your doctor might choose to test specifically for it. This would require additional material samples and would not be part of this research project. You should discuss this option with your doctor or genetic counselor.

These are the best known risks and challenges of genetic research. There might be other risks we don't know about yet.

**BENEFITS:**

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

**COSTS:**

There will be no cost to you for donating your material to research.

**COMPENSATION:**

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

**ALTERNATIVES:**

Version 10/29/2009

You do not have to allow your material to be used for research. Your care will not be influenced by your decision.

### **STUDENT PARTICIPATION:**

Your participation or discontinuation will not constitute an element of your academic performance nor will it be part of your academic record at this institution.

### **EMPLOYEE PARTICIPATION:**

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be part of your personnel record at this institution.

## **AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES**

HIPAA is a federal law that requires the protection of health information that can identify you. Protected Health Information (PHI) includes information that pertains to your past, present or future physical and mental health conditions, or the provision of health care.

### **WHAT IS THE PURPOSE OF USING OR DISCLOSING YOUR PROTECTED HEALTH INFORMATION?**

You are being asked to donate your material to be used to learn more about preventing, diagnosing, treating, and curing disease. You are also being asked to give permission for researchers who use your material for research to review all of your medical records. Researchers need to link material studied to health and medical histories to understand disease.

### **WHAT PROTECTED HEALTH INFORMATION WILL BE USED OR DISCLOSED?**

Your medical and health records will be reviewed and researchers may need to discuss your health information with your treating physicians. Researchers may also generate new information about you as a result of the future research procedures. The information that will be used or disclosed to others may include your entire medical record. You understand this information may include reference to the following: 1) psychiatric/psychological care, 2) sexual assault, 3) alcohol abuse, 4) drug abuse, and 5) results of tests for all infectious diseases including AIDS/HIV.

### **WHO WILL DISCLOSE YOUR PROTECTED HEALTH INFORMATION?**

The researchers and staff of the Medical University of South Carolina who are involved in research studies using your material will disclose your medical/health information for their studies.

### **WHO WILL RECEIVE YOUR PROTECTED HEALTH INFORMATION?**

Your protected health information may be used or shared with others outside of MUSC for purposes directly related to the research done on your donated material. Once this information leaves MUSC, we cannot guarantee that it will be protected. If this is done, no information which links the material to you will be shared with others outside of MUSC. Your protected health information may be shared with the following:

- Sponsors of future research studies or their agents such as data repositories or contract research organizations.
- Medical centers/institutions/investigators outside of MUSC participating in future research studies including Data Safety and Monitoring Boards.
- Federal/state/MUSC agencies/committees that have authority over the research such as:
- MUSC Institutional Review Board (IRB) that oversees human research
- Department of Health and Human Service (DHHS)
- Food and Drug Administration (FDA)

- National Institutes of Health (NIH)
- Office of Human Research Protections (OHRP).

**DO YOU HAVE TO GIVE PERMISSION FOR USE OF YOUR PROTECTED HEALTH INFORMATION?**

You do not have to give permission for your health information to be used and shared. If you choose not to give permission, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. You will not be allowed to donate your material for future research.

**IF YOU GIVE PERMISSION, CAN YOU CHANGE YOUR MIND?**

You have the right to withdraw your authorization to allow MUSC to use or share your protected health information collected for future research studies. Protected Health Information that has already been used or disclosed cannot be withdrawn. Once your permission is withdrawn and you no longer want your material used for research, no more protected health information will be collected. If you want to withdraw your permission, you must do so in writing to the MUSC HCC Tissue Biorepository. The address is:

Angen Liu, MD, PhD, Director  
Hollings Cancer Center - Tissue Biorepository  
86 Jonathan Lucas Street, HCC-351  
Charleston, SC 29425

If you withdraw your authorization, your remaining material will be destroyed. You have been given a copy of your institution's Privacy Notice. If you have questions or concerns about your privacy rights, you should contact MUSC's Privacy Officer at (843) 792- 0021.

