

**SCI TISSUE BANK INFORMED CONSENT NOTIFICATION
AND CHECKLIST**

Protocol Number: 08-112

Protocol title: **Simmons Cancer Institute at Southern Illinois University School of
Medicine Tissue Bank Protocol**

Patient Name: _____ **SIU Medical Record Number:** _____

Date of Surgery: _____ **Time:** _____ **Type of Surgery:** _____

Hospital: _____ **MRN:** _____

Surgeon: _____ **Surgery Center of Hospital:** _____

Place Patient Sticker Here

(a) The following is a checklist of the items needed to complete the Tissue Bank Consenting Process which are **required** by the Tissue Bank to be conducted as part of the Tissue Bank informed consent process:

	Yes	No
<p>(1) I have used the most current version of the Informed Consent (ICF) and HIPAA Authorization Documents found on the Tissue Bank Website.</p> <p>(One way to verify this is to determine if today's date is within the stamped date range found on the signature page of the Informed Consent Document.)</p> <p align="center">http://www.siu.edu/~scicenter</p> <p align="center">SIU Website → Research → Cancer Research → Tissue Bank Facility → Forms → Current ICF and HIPAA Authorization</p>		
<p>(2) I have thoroughly reviewed the ICF and HIPAA Authorization with the patient or their legally authorized representative.</p>		
<p>(3) I have checked to be sure that the patient has answered and initialed the question on page 5 of the ICF document.</p>		

(4) The patient has signed the ICF Document and dated it.		
(5) The patient has signed and dated the HIPAA Authorization Document.		
(6) An Authorized physician has signed and dated the ICF Document. Authorized personnel are listed at the end of the ICF Document.		
(7) I have provided the patient a signed copy of the ICF and HIPAA Authorization documents.		
(8) I have faxed a copy of the ICF, HIPAA Authorization, and this checklist to the Tissue Bank Technician. Tissue Bank Technician Fax No: 545-1398 NOTE: ICF must be received by the Tissue Bank Technician prior to 2:00 pm on the day before surgery.		
(9) I have placed a copy of the ICF and HIPAA Authorization in the patient's SIU chart. If clinic's keep a separate working chart, an additional copy may be placed there.		
(10) I have placed a copy of the ICF and HIPAA Authorization in the patient's Hospital chart. (This could be sent over with the hospital orders.)		
(11) I have documented in the patient's SIU medical record that they have been consented for the SCI Tissue Bank, SCRIHS Protocol No. 08-112. (Stickers can be provided for this)		
(12) I have sent the original ICF and HIPAA Authorization, and this checklist to the SCI Clinical Research Office Mail Code 9677. An alternative is to have Tissue Bank Personnel pick the originals up on a regular basis at the clinic.		
(13) If the patient was younger than 18, I have had a parent sign the ICF and HIPAA Authorization and the child sign an Assent Form.		

Person Explaining the Consent and
Completing the checklist

Date

Springfield Committee for Research Involving Human Subjects

**INFORMED CONSENT FORM FOR
TISSUE BANKING**

You are being asked to be a participant of a Tissue Bank. The main goal of a Tissue Bank is to collect biological specimens (tissue, hair, saliva, etc.) for use by researchers to gain knowledge about human disease states that may help other people in the future.

If you agree to participate in this Tissue Bank, you will be asked to sign this informed consent document. Informed consent is a written agreement that you, or your authorized representative, sign indicating willingness to participate in this Tissue Bank. This informative document will tell you about the purpose, risks, and benefits of the Tissue Bank. You should consent only after you have been given all the necessary information and have had enough time to decide whether you wish to participate. Your signature on this form is voluntary and does not waive any of your legal rights or make any institutions or persons involved in this Tissue Bank any less responsible for your well-being.

TITLE:

Simmons Cancer Institute at Southern Illinois University School of Medicine Tissue Bank Protocol

WHAT IS A TISSUE BANK?

A Tissue Bank is a building, room, or container where biological specimens are stored, either for clinical or research purposes. A tissue bank can be a formal organization or an informal collection of materials in a scientist's freezer.

The Tissue Bank at the Simmons Cancer Institute is a formal organized program for banking and collecting tissue for future research use.

WHAT IS THE PURPOSE OF A TISSUE BANK?

Studies performed using blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research performed using specimens can also be helpful for the development of new tests to identify diseases or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Some of the possible goals of the research involving human specimens might include determining whether a particular gene (material that is passed from parents to child that determines the makeup of the body) is associated with a certain type of disease. Sometimes researchers collect and store many specimens together and use them for different types of research or share them with other scientists; this is called a tissue bank.

We are requesting your permission to donate some of your blood, tissue or body fluids for future research. The samples that will be stored in the tissue bank are left over from specimens that were taken, or will be taken, as part of your routine medical care.

WHO IS RESPONSIBLE FOR COLLECTING THESE SPECIMENS AND DATA FOR THE TISSUE BANK?

Morris Cooper, Ph.D.
Tissue Bank Director
Simmons Cancer Institute
(217) 545-8462

HOW LONG WILL I BE IN THE TISSUE BANK?

Your personal involvement will only be during the collection of the sample. Samples will include tissue and blood. These samples are usually collected during an already scheduled surgery, laboratory procedure or clinic visit. Once the sample has been obtained, it will then be stored indefinitely with your personal data for use in future research studies, unless you decide to withdraw the sample and data from the tissue bank.

WHAT ARE BIOLOGICAL SPECIMENS?

A human biological specimen is any material derived from a human subject—such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids—whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.

HOW WILL MY SPECIMENS BE COLLECTED AND WHAT WILL HAPPEN TO MY SAMPLES?

You are scheduled to have a surgical procedure (an operation), a blood test, or some other procedure in which you would provide a tissue sample (biopsy). During the surgical procedure it may be necessary for your doctor to remove some body tissue to conduct tests to diagnose or treat your condition. It is common for there to be left over tissue after the necessary tests are completed. No additional tissue will be removed—only tissue that would normally be discarded after the necessary tests are performed. The purpose of the Tissue Bank is to preserve this left over tissue for future research. The collection and storage of the left over tissue will not affect the outcome of your tests or your operation.

At the same time, you will be asked to donate about 4 teaspoons of blood. In order to minimize your distress and discomfort, blood will be obtained during a blood test needed for diagnosis or treatment purposes or when an intravenous line (a tube placed into the vein, usually in the arm) is placed as part of your normal care.

The following information will be collected at the time of your procedure:

- Age and date of birth
- Gender
- Race
- Tissue site (for example breast or lung)
- Disease diagnosis if applicable (for example metastatic breast cancer) and associated staging
- Your type of surgery or procedure and the surgeon that performed it
- Pathological report of data about your tissue (cancer or non cancer and other tissue characteristics)
- Date of your surgery
- Past Treatments you may have undergone (for example chemotherapy or radiation)

We may collect and save information from your medical records, such as personal and family histories of disease, lifestyle factors (activity level, smoking status, etc.), results of physical examinations, diagnosis, diagnostic tests, treatments, hospitalizations, and follow-up information. We may access this information as long as your records are available at SIU School of Medicine.

WHAT WILL HAPPEN TO THE SPECIMENS

We do not know if any of your tissue or samples and your associated information will be used. If the samples are used they might be used for research about cancer, heart disease, diabetes, or other diseases. The purpose of collecting and storing your particular sample is to make it readily available for future research. The specific experiments that your tissues or samples will be used for are not yet known, nor are the identities of the persons conducting the research or the facility in which the research will be carried out.

Once your tissue or sample is sent to the Tissue Bank, there are several possible ways in which it may be stored. These include freezing it, growing it in laboratory animals, and immortalizing the sample in culture (Your sample is made up of cells, which are the building blocks of all living things. Some cells can be grown in a special nutrient enriched solution indefinitely.).

The research performed on your samples will not affect your care and no information will be added to your medical record or reported to you or your physician. Research made possible through donated tissue and other samples may lead to a better understanding of the causes, prevention, and cure of diseases. Your tissue or sample may be helpful for research regardless of your current state of health.

WHAT ARE THE RISKS OF PARTICIPATING IN THE TISSUE BANK?

Donation of your tissue, blood, etc. does not involve any additional risks or discomfort beyond what is already required for diagnosis or treatment. Your care, including any procedures, will not be affected in any way by donating your tissue, blood or other samples; nor will your care be affected if you decide NOT to donate.

The unintentional release of your private information is your greatest potential risk. Your tissue, blood, or other samples will not be labeled with your name or other identification that would allow you to be identified and the Tissue Bank will not release any information to a researcher (unless authorized by you) that could be linked to you or allow your tissue, blood or samples to be identified.

Your donated tissue or blood may be used for genetic (also called DNA research), RNA, proteins and metabolite research. Blood contains genes, RNA, proteins and metabolites. Genes (DNA) provide the blueprints for the many processes which occur in the body, including those for the proteins produced and for traits such as eye color. This blueprint is copied into a new molecule called RNA. RNA is then used as the message to make proteins. Proteins are needed for body function and structure; examples of proteins are hormones, enzymes and antibiotics. Metabolites are produced by the action of proteins or the break-down of food, drugs and naturally occurring substances.

Everyone's genes are a little different. Information about these differences among people can help researchers understand more about diseases and how to best use drugs to treat them. Differences in RNA, protein or metabolite patterns among people can also help researchers understand how different people respond to drugs.

If your tissue or blood is used in genetic research there are unknown risks to you due to the identification of such genes. Potential risks may include paternity determinations (who fathered a child), loss of social acceptance, or employment or insurance discrimination (for example: denial of insurance or difficulty finding employment.) These risks may also extend to your family members that share your genes (biological sibling or child). Unless special approval is granted, your name will not be released with your tissue. The results of these tests will also not be released to you. Your information will be treated as confidential and practices to prevent the misuse of your information (identifiable or not) are in place.

In rare circumstances, it is possible that a researcher may believe that it is important to identify an individual, for reasons that are not now foreseen or predicted. In order for the researcher to get this information about you, ~~the researcher would need to obtain specific approval from the Springfield Committee for Research Involving~~ Human Subjects Institutional Review Board (IRB) and obtain a new consent from you, unless the need for consent was waived by the IRB.

OPTIONAL RELEASE OF IDENTIFYING INFORMATION

If, as a result of a research study, the researcher believes that it is important to obtain information that identifies you, would you allow us to release your name and information to the researchers who have obtained adequate approval through a separate IRB protocol?

YES

NO

INITIAL HERE

ARE THERE ANY BENEFITS TO TAKING PART IN THE TISSUE BANK?

Your decision to donate tissue, blood or other samples is entirely voluntary.

The research that may be conducted with your tissue or other samples is not designed to provide direct benefit to you. You will not be notified of any results of the research conducted on your tissue, blood, or other samples. However, others may be helped through the knowledge gained about diseases or conditions and how to prevent or treat them.

WHAT OTHER OPTIONS ARE THERE?

You could choose not to participate.

If you decide not to participate you will receive your surgical procedure, laboratory tests, and routine standard care for diagnosis and treatment as discussed with your doctor.

ARE THERE ANY COSTS FOR TAKING PART IN THE TISSUE BANK

There is no cost to you for the collection or storage of your donated tissue, blood or other samples. Your medical expenses associated with your routine care will remain your responsibility.

WILL I RECEIVE PAYMENT FOR MY DONATION OF TISSUE, BLOOD, OR OTHER SAMPLES?

All tissue, blood, and additional samples will be considered a donation and no compensation is offered. You should be aware that new products might be developed and commercially sold as a result of research done on your samples. You should understand that you will receive no economic benefit from this.

WILL MY INFORMATION REMAIN CONFIDENTIAL?

Information from your medical records may be stored along with your specimens. Donation of tissue, blood or other samples to the Tissue Bank could result in the loss of privacy; however, information about you will be handled as confidentially as possible.

Any information obtained for the Tissue Bank that may identify you will remain confidential within the limits of the law or will be disclosed only with your permission and approval of the IRB. Researchers using your samples will not have direct access to your medical record, nor be able to link the information back to you. Should any publication or public presentation result from this research, your identity will not be revealed.

The specimens may be shared with researchers at this or other institutions. We will not release any information to a researcher (unless authorized by you) that could be linked to you or allow your specimens to be identified.

We will assign a code number to your specimen and any data that could identify you directly. The purpose of the code number is to protect your confidentiality. It is necessary to maintain a link between your specimen and your identifying information because many of our researchers study the effects of new cancer treatments on cancers that returned after an initial treatment(s). Only approved research personnel will have access to this information.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in the Tissue Bank is voluntary. Your care, including any procedures, will not be affected in any way by donating your specimens; nor will your care be affected if you decide NOT to donate.

If at any time you decide you no longer want your specimens used for research purposes, you may request to withdraw your specimens and data. However, you should understand that any research performed with your samples can not be withdrawn; only samples and data which have not been used can be removed. Declining to enter or leaving the Tissue Bank will not result in any penalty or loss of benefits to which you are entitled. You will still continue to receive the same good medical care.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You may contact the following persons to answer any inquiries you may have concerning the Tissue Bank and your rights as a participant, or to find out where to inquire about withdrawing your tissue, blood, or other samples from the Tissue Bank:

Morris Cooper, Ph.D.
(217) 545-8462

John E. Godwin, M.D., M.S.
(217) 545-5817

You also have the right to contact the tissue bank where your donated specimens and personal data are stored. The name, address, and phone number of the bank are given below:

Morris Cooper, Ph.D.
Tissue Bank Director
SIU School of Medicine
801 N. Rutledge
Springfield, IL 62794-9626
(217) 545-8462

For questions about your rights as a Tissue Bank participant, contact the Springfield Committee for Research Involving Human Subjects (which is a group of people who review protocols such as the Tissue Bank) to protect your rights at:

Southern Illinois University School of Medicine
801 North Rutledge
Springfield, IL 62702
Telephone number: (217) 545-7602

The Chairperson of this committee will review the matter with you.

DOCUMENTATION OF INFORMED CONSENT

AFTER SIGNATURES ARE OBTAINED FROM YOU AND AN AUTHORIZED PERSONNEL LISTED BELOW, A SIGNED COPY OF THIS CONSENT WILL BE GIVEN TO YOU.

You are voluntarily making a decision whether to participate in the Tissue Bank. Your signature means that you have read and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions throughout the Tissue Banking process, you should contact the Tissue Bank.

I agree to take part in the Tissue Bank.

Signature of Participant, Legal Guardian, or Power of Attorney

Date

Printed Name

I certify that all the elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in the Tissue Bank.

Signature of Authorized Personnel

Date

Printed Name

AUTHORIZED PERSONNEL CAPABLE OF OBTAINING INFORMED CONSENT FROM PARTICIPANTS

Principal Investigator: Morris Cooper, Ph.D.

Telephone Number: (217) 545-8462

THIS CONSENT IS
ONLY VALID BETWEEN
4/13/2011 TO 4/13/2012

Participating Physician(s) and Participating Health Care Personnel:

Thomas Tarter, M.D.	(217) 545-8860	Steven Hazelrigg, M.D.	(217) 545-8875
Theresa Boley, RN, MSN	(217) 545-5000	Mary McAsey, Ph.D.	(217) 545-4692
Elizabeth Peralta, M.D.	(217) 545-7230	James Malone, M.D.	(217) 545-5140
Gary Dunnington, M.D.	(217) 545-8880	John Torricelli	(217) 545-7698
Michael Neumeister, M.D.	(217) 545-7018	Jan Rakinic, M.D.	(217) 545-7230
William Pyle, M.D.	(217) 545-7600	K. Thomas Robbins, M.D.	(217) 545-3833
Krishna Rao, M.D., Ph.D.	(217) 545-7307	Stephen P. Stone, M.D.	(217) 545-3821
Lucinda S. Buescher, M.D.	(217) 545-3821	John Godwin, M.D.	(217) 545-7089
Imran Hassan, M.D.	(217) 545-7230	Robert Mochamuk, M.D	(217) 545-7089
Nicole Sommer, M.D.	(217) 545-6314	Aziz-Ur-Rehman Khan, M.D.	(217) 545-7089
Kathy Robinson, Ph.D.	(217) 545-1946		

Springfield Committee for Research Involving Human Subjects

Southern Illinois University School of Medicine • Memorial Medical Center • St. John's Hospital

801 North Rutledge Street • P.O. Box 19616 • Springfield, Illinois 62794-9616

Telephone: (217) 782-4549 • Fax: (217) 524-0786

Authorization To Use and Disclose Protected Health Information for Tissue Banking Purposes

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for the Tissue Bank and associated researchers to be able to use or disclose your protected health information for Tissue Banking and related research purposes in the study entitled **“Simmons Cancer Institute at Southern Illinois University School of Medicine Tissue Bank Protocol” (Protocol #08-112)**.

You authorize Morris Cooper, Ph.D. and the Tissue Banking staff to use and disclose your protected health information for the purposes described below. You also permit your doctors and other health care providers to disclose your protected health information for the purposes described below.

Your protected health information that may be used and disclosed includes:

- Demographic information or results of physical exams, blood tests, X-rays, and other diagnostic and medical procedures as well as medical history and follow-up (future) health information related to this hospitalization.

Limited information will be collected at the time of your surgery (such disease site, type of tissue, type and date of surgery, type and grade of cancer). If a researcher requests further information, additional information may be obtained from your medical record. There is not a specified time point in which this information may be requested or obtained.

- Collection of biological specimens and associated specimen information.

Your protected health information will be used for:

- The Simmons Cancer Institute Tissue Bank wants to use your health information as part of the Tissue Bank protocol listed above and described to you in the Informed Consent document. In particular, medical researchers who use the banked tissue can learn about various diseases by conducting research on biological samples collected from individuals with and without various diseases (called matched groups). This research can lead to generalized knowledge about various diseases and may lead to the development of new treatments for a disease.

The Tissue Bank may use and share your health information with:

- Southern Illinois University School of Medicine’s Institutional Review Board: The Springfield Committee for Research Involving Human Subjects (SCRIHS)
- Government representatives, when required by law
- Memorial Medical Center and St. John’s Hospital
- Southern Illinois University School of Medicine Surgery Clinics

Dr. Cooper and the Tissue Bank Staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law. Should the health information be disclosed by the Tissue Bank, to someone outside of the Tissue Bank, it may be subject to re-disclosure and may no longer be covered/protected by the federal privacy protections.

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You may not be allowed to participate in the Tissue Bank.

After signing the Authorization, you can change your mind and:

- Not let the Tissue Bank use or disclose your protected health information (revoke the Authorization). If you revoke this Authorization, the Tissue Bank may not release any protected health information about you and will destroy any unused specimens that you have donated to the bank.
- Research may still be performed on specimens and information already released to a scientist conducting research. Only specimens and data that have not been used can be removed from the bank.
- If you revoke the Authorization, you will send a written letter to: Morris Cooper, Department of Medical Microbiology, Immunology, and Cell Biology at Southern Illinois University School of Medicine, P.O.Box 19626, Springfield, IL 62794-9626 to inform the Tissue Bank of your decision.
- If you change your mind and withdraw the authorization, you may not be allowed to continue to participate in the Tissue Bank.

This Authorization does not have an expiration date.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights as a Tissue Bank participant, you should contact the Springfield Committee for Research Involving Human Subjects (SCRIHS) at:

**Southern Illinois University School of Medicine
801 North Rutledge
Springfield, IL 62702
Telephone number: (217) 545-7936**

You are the participant or are authorized to act on behalf of the participant. You have read this information, and you will receive a copy of this form after it is signed.

Signature of Tissue Bank participant or
*Tissue Bank participant's legal representative

Date

Printed name of Tissue Bank participant or
*Tissue Bank participant's legal representative

Representative's relationship to
Tissue Bank participant

*Please explain Representative's Relationship to Patient and include a description of Representative's Authority to act on behalf of Patient:

