

# STANDARD OPERATING POLICY AND PROCEDURE

**SUBJECT:** Informed Consent Implementation For the SCI Tissue Bank

**Policy Number:** 401.1

**Policy Date:** 9/23/08

**Amendment Date:** N/A

**Revision Date:** 9-30-2010

## 1. INTRODUCTION AND PURPOSE

The ethical conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that all federal and state regulations have been met through the language of the informed consent document, and that informed consent itself has been properly obtained from the subject or the subject's legal representative. Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for appropriately obtaining and documenting the subject's informed consent for the SCI Tissue Bank.

## 2. SCOPE

This SOP applies to the activities involved in obtaining informed consent from research subjects who participate in the SCI Tissue Bank conducted at this investigative site. This SOP only applies to obtaining consent under general requirements or routine circumstances. Please see the SOP for Informed Consent Development and Implementation for specialized procedures for obtaining informed consent from subjects who do not speak English and from children.

## 3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.25	Elements of informed consent
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
	FDA Internal Compliance Program Guidance Manual, 1994; 7348.811: Clinical Investigators

<p>FDA Information Sheets, October, 1998</p> <p>May 9 1997</p> <p>Public Law 110-233, 122 Stat. 881</p>	<p>Frequently Asked Questions, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator, The Belmont Report and Declaration of Helsinki International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline</p> <p>The Genetic Information Nondiscrimination Act of 2008</p>
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#### 4. REFERENCES TO OTHER APPLICABLE SOPs

102	Responsibilities of the Research Team
302	Interactions with the Institutional Review Board
303	Regulatory Files and Subject Records
401	Informed Consent Development and Implementation
403	Subject Management While on Study
404	Adverse Event Reporting

#### 5. ATTACHMENTS

- A. SCI Tissue Bank Informed Consent Notification and Checklist
- B. Guidelines for Obtaining Informed Consent
- C. Assents for Special Populations (Children and Cognitively Impaired) Form

#### 6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in obtaining informed consent for the SCI Tissue Bank from research subjects. This includes the following:

- Principal investigator
- Sub-investigator/ Associated Study Personnel
- Clinic nurse/coordinator

#### 7. DEFINITIONS

The following definitions from the International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline apply to this SOP.

**Confidentiality:** Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

**Impartial witness:** A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

**Informed consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

**Institutional Review Board (IRB):** An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

**Legally acceptable representative:** An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

**Vulnerable subjects:** Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

## 7.1 ADDITIONAL DEFINITIONS

**Biorepository/ Tissue Bank:** A building, room, or container where biospecimens are stored, either for clinical or research purposes. A biorepository can be a formal organization or an informal collection of materials in a scientist's freezer.

## 8. PROCESS OVERVIEW

- A. Obtaining written consent from the subject (or the legal representative)
- B. Documenting the informed consent process

- C. Exceptions from general requirements for informed consent
  - 1) Consent of children
  - 2) Consent of cognitively impaired

## 9. PROCEDURES

### A. Obtaining written consent from the subject (or the legal representative)

<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>Ensure that the most recent version of the IRB-approved consent form is used. The patient must always be approached prior to the date of surgery. If possible, approach the patient at the time surgery is scheduled to allow for sufficient time for the consent process.</p> <p>In a location that provides privacy, review the informed consent form with the subject by discussing all of the elements: provide an overview of the study, explain its purpose, procedures, risks and benefits, alternatives, research-related procedures, etc. (Attachment B, Guidelines for Obtaining Informed Consent).</p> <p>Allow the subject time to read the document and ask questions. If appropriate, subjects are encouraged to take the consent with them for review and the consenting process completed upon their return to clinic. Encourage input from family members and other care providers, if appropriate.</p> <p>If the subject is unable to give written informed consent, provide the above information to the subject's close relative (as per local law) or the legal guardian.</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic Nurse</li> <li>• Interpreter</li> </ul>	<p>If the subject does not speak English, ensure that the above procedure is implemented in the subject's language, using a qualified interpreter. Ensure that both the subject and an impartial witness sign and date the informed <u>consent document that has been translated into the language of the subject and approved by the IRB</u>. A qualified interpreter (not a relative of the patient) must be present for all informed consent discussions.</p>

## B. Documenting the informed consent process

<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>After consenting to participate in the clinical study, ensure that the subject signs and dates the document. An acceptable representative of the Associated Study Personnel (Listed on the last page of the consent) must sign and date the document.</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>Provide a copy of the informed consent form document to the subject (or the legal representative).</p> <p>Note in the subject's records the date (and time) of informed consent, indicating that consent was obtained prior to initiation of any screening procedures or study-related activities. Note the name of the protocol.</p> <p>The original signed document must be kept on file by the research office. Forward the original to the SCI Clinical Research Office at Mail Code 9677. Fax a copy of the consent to the Tissue Bank Technician at 545-6823. A copy must be placed in the patient's official clinic and hospital chart.</p>

## C. Exceptions from general requirements for informed consent

### 1) Consent of Special Populations

<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>Consult with the IRB regarding state and local laws for the consent of minors and the cognitively impaired.</p> <p>If the subject is considered to be a legal minor or cognitively impaired, obtain consent from one or both parents, or legally authorized representative.</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>Follow all procedures for obtaining and documenting the informed consent process as outlined above.</p> <p>Provide a copy of the informed consent form to the parent(s) or legally authorized representative(s).</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Subinvestigator</li> <li>• Clinic nurse/coordinator</li> </ul>	<p>Consult with the IRB regarding their requirements for the assent of minors and the cognitively impaired.</p> <p>Develop a form to be used by children or the cognitively impaired for their verbal or written consent for their participation in the study that describes the risks and benefits in age-appropriate language (Attachment C, Assent of Children and cognitively Impaired Form).</p>

- PI
- Subinvestigator
- Clinic nurse/coordinator

Follow all procedures for obtaining and documenting the informed consent process outlined above.

Provide a copy of the informed consent document and assent (if applicable) to the child and parent(s) or legally authorized representative(s).

**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 style="text-align: center;"><a href="http://">http://</a> _____</p> <p style="text-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>		

(3) I have checked to be sure that the <b>patient has answered and initialed the question on page 5 of the ICF</b> document.		
(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 <b>NOTE: ICF must be received by the Tissue Bank Technician prior to 2:00 pm on the day before surgery.</b>		
(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

## **Attachment B**

### **GUIDELINES for OBTAINING INFORMED CONSENT**

- Informed consent must be obtained from each subject (or the subject's legally authorized representative) before the subject can take part in the Tissue Bank.
- Informed consent must be obtained from each subject prior to initiating any requirements of the study protocol, including data and sample collection.
- The investigator must give the subject sufficient opportunity to consider whether or not to participate in the Tissue Bank. The investigator/ clinic nurse cannot coerce or use undue influence to get a subject to participate.
- Non-English speaking subjects must have the information presented in a language that they understand. If non-English speaking subjects will be enrolled, the informed consent should be translated into the appropriate language.
- Each subject must be given a signed copy of the consent document for his or her reference.
- The original signed informed consent should be kept in the Clinical Research office in the appropriate Tissue Bank file. A copy should be in the subject's medical record, including the hospital medical record.

Attachment C

**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) 545-7602 • Fax: (217) 545-7873**

**ASSENT FORM**

**For Children between the ages of 5-11**

**I have read the consent form and/or the consent form has been read to me in the presence of my parent(s). The research study has been explained to me and I understand what is involved in my participation. I had the chance to ask questions. I request that my guardian/parent(s) agree to my participation and sign the consent form.**

_____	_____
Assenting Participant	Date
_____	_____
Parent/Guardian**	Date
_____	_____
Parent/Guardian**	Date
_____	_____
Investigator/Authorized Study Personnel	Date

***\*\*By signing, I am verifying that a thorough verbal consent was delivered to the participant.***

The proposed participant's assent has not been secured for the following reason(s):

\_\_\_\_\_  
\_\_\_\_\_

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**Instruction for the Investigator:** *Regardless if the participant is able to sign the assent portion of this form or not, the person obtaining the assent must ensure that the participant has been adequately informed of what is involved in the study and that participation is wholly voluntary. This must be explained in an appropriate language level to be certain the participant understands fully and an informed decision has been made. Unless the medical condition of the participant is such that they cannot reasonably be consulted, an assent must be secured. If the age and maturity level of the participant prohibits the participant from fully understanding the study, parent/guardian signature on this form must still be obtained. If there is reason that assent cannot be obtained, the facts and circumstances leading to such waiver of assent must be documented in the study file and on this form in the space provided above.*

*If the assenting declines participation in the study, the parents or legally authorized representative cannot force the under-aged individual to participate. Also, mere failure to object should not be construed as assent.*

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### ASSENT FORM

#### **For Children between the ages of 12-17**

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

Morris Cooper, a scientist working with Southern Illinois University School of Medicine, has asked me to find out if you would be willing to be in a study that collects blood and tissue from children and adults who are being treated at Southern Illinois University Healthcare.

We are asking you to be in this study because we need blood and tissue from both healthy and sick people so that we can study how to help others who are sick or how to keep them from getting sick. Your blood and tissue will be collected now but may not be used immediately. It will be placed in a freezer until a scientist makes a request for tissue and blood that matches your characteristics, such as age and gender.

If you agree to be in this study, you will have some blood and tissue removed from your body. If you are going into the hospital, the blood and tissue will be taken while you are asleep and you won't be able to feel it. If you are at a doctor's office the tissue will be taken from part of your body that is asleep or numb. You may be awake when the blood is taken through a needle, which may hurt.

The tissue that is being removed is being taken because it is tissue that is making you sick or you no longer need it to be healthy. This will happen even if you are not in the study. The study would like to have some of this tissue for experiments before they throw it away. The blood and tissue will stay frozen and only be used as researchers request it for experiments they are hoping to complete.

We are also asking your parents about your participation in the study to see if they are agreeable to your donating your tissue and blood. Please talk about this with your

parents to decide if you want to be in this study. Even if your parents say “yes” to your being in the study, you can still decide not to be in the study.

IF YOU DO NOT WANT TO BE IN THE STUDY YOU DO NOT HAVE TO. No one will be upset or mad at you if you say NO. You can also change your mind later and stop being a part of this study without anyone being mad at you. We will take just as good care of you even if you decide not to be in the study.

You can ask me questions about the study now or if you decide you have a question later you can call Dr. Cooper at 217-545-8462.

**I have read the consent form and/or the consent form has been read to me in the presence of my parent(s). The research study has been explained to me and I understand what is involved in my participation. I had the chance to ask questions. If I have more questions, I know whom to call. I request that my guardian/parent(s) agree to my participation and sign the consent form. I will receive a copy of this signed assent form.**

\_\_\_\_\_  
Assenting Participant  
Date

\_\_\_\_\_  
Parent/Guardian\*\*  
Date

\_\_\_\_\_  
Parent/Guardian\*\*  
Date

\_\_\_\_\_  
Investigator/Authorized Study Personnel  
Date

***\*\*By signing, I am verifying that a thorough verbal consent was delivered to the participant.***

The proposed participant’s assent has not been secured for the following reason(s):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Instructions for the investigator:** *The investigator or other authorized study personnel should direct the discussion during the consent process to the parent(s) and the child. The discussion should be based on the consent template and be conveyed in an age appropriate language level. The participant should be adequately informed of what will be done, the risks associated with participation, the benefits, compensation (if any), assurance of confidentiality, and that participation is wholly voluntary. Unless the medical condition of the participant is such that they cannot reasonably be consulted, an assent must be secured. If there is reason that assent cannot be obtained, the facts and circumstances leading to such waiver of assent must be documented on this form in the space provided above and in the study file.*

*If the assenting declines participation in the study, the parents or legally authorized representative cannot force the under-aged individual to participate. Also, mere failure to object should not be construed as assent*

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### **ASSENT FORM**

#### **For the Cognitively Impaired**

(Note: This study document has not been approved by the IRB and only represents sample language. If you have a cognitively impaired patient please contact the Tissue Bank Director prior to enrolling in this study. )

**The research study has been explained to me and I understand what is involved in my participation. I had the chance to ask questions. If I have more questions, I know whom to call. I request that my legally authorized representative or power of attorney agree to my participation and sign the consent form. I will receive a copy of this signed assent form.**

_____	_____
Assenting Participant	Date
_____	_____
Legally authorized representative or power of attorney**	Date
_____	_____
Investigator	Date

***\*\*By signing, I am verifying that a thorough verbal consent was delivered to the participant.***

The proposed participant's assent has not been secured for the following reason(s):

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**Instructions for the investigator:** *The person obtaining the assent must ensure that the participant is in an adequate condition to provide an informed assent, and has the ability to understand what is involved in their participation in the study in order to make an informed decision. If the capability of the participant is so limited that they cannot reasonably be consulted due to medical condition or mental capacity, an assent need not be secured, however the facts and circumstances leading to such waiver of assent must be documented on this form in the space provided above as well as in the participants study file.*

*If the assenting declines participation in the study, the power of attorney or legally authorized representative cannot force the cognitively impaired individual to participate. Also, mere failure to object should not be construed as assent.*