

INFORMED CONSENT (Guidelines and Basic Elements)

GUIDELINES :

The following list does not exhaust the required elements of consent (see Basic Elements below), but highlights some matters of special concern emerging from recent discussions on the Federal level. *These guidelines and basic elements apply specifically to studies reviewed by the IRB.*

1. **Informed consent is a process, not just a form.** Information must be presented to enable persons to decide voluntarily whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons who may be willing to offer their bodies and experiences to assist investigators in research without promise or benefit.
2. The informed consent **document** provides a summary of the clinical study and the individual's rights as a participant. The document acts as a starting point for the necessary exchange of information between the investigator and the potential research participant. In addition, the consent form may be used as an information resource and reference for the participant throughout the research trial. The document is not a risk management tool for the investigator and/or the institution.
3. **The procedures used in obtaining informed consent should be designed to educate** the subject population in terms that can be easily understood. The consent form should be written in "lay language" (i.e., language able to be understood by the person or persons being asked to participate). Use of scientific or legal jargon is not appropriate. The active voice, simple declarative sentences personal pronouns, clear page layout, white space, and large fonts make documents easier to read. The consent form should be carefully designed to present to potential participants the information they need to make to make an informed choice about the research.
4. **Consent forms should be written in the second person.** The Office of Human Subjects Research (OHRP, formerly OPRR), National Institutes of Health (NIH), states that the use of the first person (e.g., "I will view seven videos," "I give permission to...") can be interpreted "as suggestive.... and can constitute coercive influence over a subject." The second person pronoun and/or other explanatory language (e.g., "You are being asked to participate in a study because...") is preferred because it is inherently more open and conversational with subjects.

5. **The use of the word "understand" in consent forms is discouraged.** Subjects simply agree to participate following a detailed explanation of the study and its potential risks.
6. **The consent form should not include exculpatory language** whereby the subject waives, or appears to waive, any of his/her legal rights, including any release of the institution or its agents.
7. Be sure to **discuss any participant incentives in your consent form.** The value of any gifts offered for participation must not pose a coercive influence on the subject's decision to participate.
8. Statements concerning confidentiality should include language equivalent to the following: **"Your privacy will be protected to the maximum extent allowable by law."** Since there are situations in which a researcher may be compelled to break the confidentiality of subjects (e.g., in response to a subpoena or at the request of the IRRC), no absolute guarantees to privacy are possible.
9. All consent forms should **include the researcher's contact information and Sparrow Health System contact information.** It should be clearly marked that participants may contact the researcher in the event that they want to discuss any questions about the research or research related injuries. Additionally, the consent form should plainly state that if participants have questions regarding their role and rights as a subject of research, they may contact Sparrow Health System separately from the Principal Investigator. The Sparrow Health System contact information is:

George S. Abela, MD, Chairperson
Institutional Research Review Committee
Phone: (517) 364-2150
10. **You must retain copies of signed consent forms** for at least three (3) years past the completion of your research activities.
11. A **header** (identifying the study) and a **footer** (providing space for the subject's initials and a date) must be added to each page of the consent form.

BASIC ELEMENTS:

The consent form **should include**, but need not be restricted to, the following statements or concepts:

ITEM DESCRIPTION

THE PURPOSES, RISKS, AND BENEFITS OF THE RESEARCH	
1. Summary explanation of research	State that the study involves research, say why the participant is being invited into the study ("You are being asked to take part in this study because. . ."), give a brief summary of the research, and state the purpose of the research in clear language.
2. How subjects will be entered into the study	Say how many subjects will participate in the study, how they will be selected for the various arms of the study (where applicable), what randomization means (where applicable), and whether or not the doctor will know which drugs or treatment the patient will receive.
3. Study procedures	Describe the procedures to be undergone by the subject in the study. Clearly identify which of these procedures is experimental and which is part of the standard therapy. Indicate the amount of time the subject will be in the study. In complicated protocols it is very helpful to have a chart to lay out the procedures.
4. Risks and side effects	List the discomforts and risks that will or may result from participation in the study. Include not the only the risks from individual drugs and treatments but the overall effect of the combined drugs or treatments. If there is a risk to an unborn or nursing child, these risks should be addressed in this section. <i>Qualitative and numerical descriptors need to be included with each category of risk. Examples of common definitions include:</i> <i><u>Likely</u> (occurs in more than 25% of people – more than 25 out of 100 people)</i> <i><u>Common</u> (occurs in 10-25% of people – 10 to 25 out of 100 people)</i> <i><u>Infrequent</u> (occurs in 1-10% of people – 1 to 10 out of 100 people)</i> <i><u>Rare</u> (occurs in less than 1% of people – less than 1 out of 100)</i> <i>Note: If the level of specificity is not feasible, explain why in the application form.</i>
5. Alternative Treatments	Describe alternative treatments available to the patient, indicating where appropriate which treatments are currently the standard of care for the patient's problem. Where appropriate tell the patient that no additional treatment is also an option. Include the risks and benefits for the alternative treatments.

6. Benefits	State the potential benefits of the study to the patient, where appropriate, and to others who may benefit from the research.
RIGHTS OF THE PARTICIPANT	
7. Voluntary Participation	State that the participation of the subject is voluntary. The patient may choose to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which the patient is otherwise entitled.
8. New Information	Where applicable, the consent form should indicate to the participant that any new information that bears on the risks and/or benefits of the study will be made available to the participant.
9. Confidentiality or anonymity	State the procedures for and degree to which information about the subject will be held confidential, including a statement indicating known exceptions to the promise of confidentiality. For example, drug or medical device study consent forms should carry notice that the FDA, study sponsor and IRRC may inspect all records, including subject records. Consent forms should indicate that confidentiality can only be protected to the maximum extent allowable by law.
10. Treatment of physical injury to the subject(s)	<p>Specify that if an injury occurs as a direct result of the research study, emergency medical care required to treat the injury will be provided by. . . (indicate the payee). The statement should also specify whether reimbursement will be sought from the subject's insurance company for the emergency care and any other medical expenses incurred as a result of the injury.</p> <p>The following injury clauses have been provided as suggested language to incorporate in the informed consent form (select only the appropriate clause):</p> <p>1. No costs will be paid</p> <p>If you are injured as a result of your participation in this research project, Sparrow Hospital will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The Hospital's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact <i>[insert Principal Investigator's name and phone number]</i> with any questions to report an injury.</p>

	<p>2. Third party will pay If you are injured as a result of your participation in this research project, Sparrow Hospital will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. Any costs that are not covered or in excess of what are paid by your insurance, including deductibles, shall be paid by <i>[name of payee]</i>. The Hospital's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact <i>[insert Principal Investigator's name and phone number]</i> with any questions or to report an injury.</p> <p><i>Option #3 would be used only if the research study is funded by the Department of Defense.</i></p> <p><u>3. The Following Language is to be Used for Use for Contracts with the Army or Where Army Personnel are Involved:</u> If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.</p>
<p>11. Contact person(s) for subjects</p>	<p>Indicate whom the subject should contact regarding any questions or concerns that may be raised by participating in the study (name and phone number of principal investigator or designee).</p> <p>This section should also include the name and phone number of the Sparrow Health System's Institutional Research Review Committee Chairperson, George S. Abela, MD (517-364-2150) for questions about participants' rights as human subjects of research.</p>
<p>OTHER ISSUES</p>	
<p>12. Termination of the study by the investigator or doctor</p>	<p>Indicate the circumstances under which the investigator or patient's doctor may terminate the study without the consent of the patient.</p>
<p>13. Possible economic costs to subjects</p>	<p>In the case that there are likely to be additional costs to the subject, investigators must incorporate a statement specifying the nature of these costs in their consent</p>

	<p>forms. A statement should be included to the effect that either:</p> <p>The participation of the subject in this research project will not involve any additional costs to the subject or the subject's health care insurer.</p> <p><u>OR</u></p> <p>The participation of the subject in this research will necessitate additional procedures (indicate procedures, e.g., obtaining medical tests and examinations). The costs may be covered by the subject's insurance. [Where applicable: Those costs not covered by the insurance will be provided by research funds.] The subject will remain responsible for the insurance deductible and co-pays.</p> <p><u>OR</u></p> <p>The participation of the subject in the research project may involve additional costs to the subject (specifying the additional procedures, tests, etc. that occasion the costs). The subject's health insurance will not cover all of the additional costs. An estimate of total costs is \$_____. If actual costs exceed the estimate, the subject will remain responsible for the costs.</p>
<p>14. The signature of the subject specifying the consent</p>	<p>The signature acknowledges that the subject:</p> <ul style="list-style-type: none"> • Has voluntarily decided to participate in the study; and • Has received a full copy of the consent form. <p>Special provisions apply in the case of cognitively impaired persons. For a discussion of these provisions, please contact the IRRC office (517) 364-2150.</p>
<p>15. Minor subjects</p>	<p>If the subject is a minor, provisions should be made for obtaining parent or guardian's informed consent (signature) and the minor's assent. A signed statement of assent must be obtained if the patient is 13-17 years old. Minor subjects ages 7-12 years of age must assent to be in the study (see IC 703-A – Requirements and IC 703-B – Informed Consent Document Template: Assent)</p>
<p>16. Investigator's statement and signature</p>	<p>A signed statement by the investigator acknowledging they have fully explained the study (in all aspects) to the patient or his representative before the patient was consented.</p>

IRRC Approved Revisions: 10/08/01; 1/27/03; 04/11/05; 11/14/05; 2/13/06
Approved: Institutional Research Review Committee, 05/07/01