

SOP: IC 701 Version No: Effective Date: 01/01/07	GENERAL REQUIREMENTS AND DOCUMENTATION	Supercedes Document Dated:
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1. POLICY

Informed consent must be legally effective and prospectively obtained informed consent.

Except as described in SOP IC 702, no Investigator may involve a human being as a research subject unless he or she has obtained legally effective informed consent of the subject or the subject's legally authorized representative. Consent shall be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative.

Specific Policies

1.1 The Consent Form

- A. A written consent document that embodies the elements of informed consent described in 21 CFR 50.25 and 45 CFR 46.116(a). This form may be read to the subject or the subject's legally authorized representative, but, in any event, the Investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. The subject must also be given a copy of the signed form.
- B. A "short form" written consent document is not used at Sparrow Health System.

1.2 Required Elements of Informed Consent

- A. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- B. A description of any reasonably foreseeable risks or discomforts to the subject.
- C. A description of any benefits to the subject or to others that may reasonably be expected from the research.
- D. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- E. A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records.
- F. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Required language at Sparrow Health System is included in the Guidelines and Basic Elements document (Form IC 701-A).
- G. An explanation of whom to contact for answers to pertinent questions about

the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

- H. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

1.3 Additional Elements

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.
- B. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
- C. Any additional costs to the subject that may result from participation in the research.
- D. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- E. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
- F. The approximate number of subjects involved in the study.

1.4 Other Requirements

- A. Second person: The language of the consent document should be in the second person style so the consent form conveys a dialogue with information being provided and that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style.
- B. Language should be simple: The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should not include complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology in parenthesis immediately following the first use of the term. The reading level of the consent form, excluding technical and scientific terminology, shall be equivalent to that of an 8th grade level of education unless the population involved in the study as a group differs from this grade level.
The use of the word "understand" in informed consent documents is discouraged. Subjects simply agree to participate following a detailed explanation of the study and its potential risks.
- C. Exculpatory language: Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights, or releases or appears to release the Investigator, the Sponsor, or the Sparrow Health System from liability for negligence.
- D. Confidentiality: Informed consent documents 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.

- E. FDA-regulated test articles: For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

1.5 Documentation of Informed Consent

Each subject or his/her legally authorized representative must sign and date a copy of the current IRB-approved consent form prior to enrollment or any participation in any phase of the study, unless the requirement is waived by the IRB. The subject must also be given a copy of the signed document.

The IRB may approve procedures for documentation of informed consent that involve (a) a written consent form signed by the subject; or (b) in limited circumstances, waiver of signed written consent form. Each of these options is described in detail below. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews. Generally, only option (a) will be appropriate.

- 1.5.1 Written consent form signed by subject or legally authorized representative. In most circumstances, the IRB should require that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. The Investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be given to the person signing the form.
- 1.5.2 The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent (see above).
- 1.5.3 Subjects who do not understand English should be presented with an informed consent document written in a language understandable to them. See SOP RR 401, section 1.6.3.
- 1.5.4 If a witness signature line is included on the informed consent, the witness signature line must include a description of what is being witnessed. Examples of the description may include, but are not limited to: a statement that the witness is observing the entire consent process, or a statement that the witness is only observing the study participant's signing of the informed consent form.

1.6 Observation and Monitoring of the Informed Consent Process

- 1.6.1 The IRB foresees circumstances that may arise under which the IRB may want to observe the consent process. For example, at the time of initial protocol review, the Board may determine that although the risk/benefit determination allows for consenting of potentially cognitively impaired adults, additional safeguards may be instituted to protect the rights and welfare of subjects. In this situation, the IRB may delegate the administration or observation of the consent process to a qualified third party.

1.7 Cognitively Impaired Subjects

Studies involving subjects who are decisionally impaired may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders). Additionally, the IRB should consider whether, and when, it should require a reassessment of decision-making capacity.

1.8 Waiver of Documentation

The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;

Note: When the IRB waives the requirement for documentation under this condition, each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the Investigator to provide subjects with a written statement regarding the research.

1.9 Use of Facsimile or Mail to Document Informed Consent

In emergent circumstances, an Investigator may use a process that allows the informed consent document to be delivered by mail or facsimile to the potential subjects or the potential subject's legally authorized representative and conduct the consent interview by telephone when the subject or legally authorized representative can read the consent document as it is discussed. If the investigator wishes to use such a procedure for non-emergent studies, full IRB approval will be required. All other applicable conditions for documentation of informed consent must also be met when using this procedure. In some kinds of survey research, the IRB may approve phone consent prior to a phone survey. Interviewee must be informed that they may stop the interview at any time. Interviewer must document such consent.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

IRB Administrator is responsible for initially reviewing all incoming informed consent documents and for communicating with Investigators to bring documents into compliance.

IRB or IRB Chairperson (or designee) is responsible for final determination of all incoming informed consent documents and for communicating with Investigators to bring documents into compliance.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50

45 CFR 46.116, 46.117

FDA Information Sheets, 1998

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

- RR 402-A Protocol Review Worksheet – Primary Reviewer(s)
- IC 701-A Informed Consent Checklist – Primary Reviewer(s)
- IC 701-B Informed Consent – Guidelines and Basic Elements
- IC 701-C Informed Consent Template
- IC 701-D Glossary of Medical to Lay Terms

7. PROCESS OVERVIEW

Informed consent must be legally effective and prospectively obtained. Except as described in SOP IC 702, no Investigator may involve a human being as a research subject unless he or she has obtained legally effective informed consent of the subject or the subject's legally authorized representative. Consent shall be sought only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Review proposed ICFs upon receipt of study, and confirm that all required elements are present.	Guidelines and Basic Elements
<i>IRB</i>	Conduct final review of the informed consent form. If elements are found missing, return consent document to Investigator with request for revision and suggested language (where appropriate).	Informed Consent Document Template