

GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS

1. INTRODUCTION

The ethical principle of respect for persons requires that subjects be given the opportunity to choose what shall and shall not happen to them. Valid informed consent requires (1) Disclosure of relevant information to prospective subjects about the research; (2) their comprehension of the information, and (3) their voluntary agreement, free of coercion and undue influence, to research participation.

Ideally, informed decision-making by research subjects is a process that generally includes discussion of the research study with the Principal Investigator (PI), and others as appropriate, and signing the written informed consent document. Depending on the nature, type and duration of the research, ongoing discussion with and education of subjects about the study may continue long after the informed consent document is signed.

A goal of the NIH is to assure that all written informed consent documents are complete and clearly written so as to promote informed decision-making by subjects participating in its research activities. This information sheet provides guidance to NIH clinical researchers and IRBs on the procedures and requirements for informed consent to research participation and the content and format of written consent documents.

2. REQUIREMENTS FOR INFORMED CONSENT

A. GENERAL PROCEDURES

Unless otherwise waived by the Committee, research investigators should obtain valid informed consent from all research subjects (or their legally authorized representatives) that participate in their research studies. Generally, after the Principal Investigator has explained the research study to the subject, the subject's informed consent is documented by signing the protocol's written consent document, which the Committee must have previously reviewed and approved. Sample consent documents with acceptable language are included in this packet. The subject is given a copy of the signed document for his or her records. In cases where subject accrual occurs elsewhere, signed consent documents are retained according to the policies of the institution where the research is conducted.

B. GENERAL PRINCIPLES

Unless otherwise authorized by an IRB, research investigators are responsible for ensuring that informed consent shall:

- Be obtained in writing from the subject or the subject's legally authorized representative;
- Be understandable to the subject or her/his representative. Suggestions for writing consent documents are provided below.
- Be obtained in circumstances that are not coercive and that offer the subject (or her/his representative) sufficient opportunity to decide whether she/he should participate. The consent document should not contain language that implies or suggests that the subject (or her/his representative) give up any legal rights or releases research investigators or the University from liability for negligence.

C. BASIC ELEMENTS FOR WRITTEN INFORMED CONSENT DOCUMENTS

Unless otherwise authorized by the Committee, research investigators must provide the following information to each subject in writing:

- A statement that the study involves research;
- An explanation of the purpose of the research and the expected duration of the subject's participation;
- A description of the procedures to be followed and identification of any procedures that are experimental;
- A description of any foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject;

A statement describing to what extent records will be kept confidential, including a description of who may have access to research records;

- For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if research subjects are injured; where further information may be obtained, and whom to contact in the event of a research-related injury.
- An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights (include the Clinical Center's Patient Representative and telephone number); and
- A statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled. *

D. ADDITIONAL ELEMENTS

- When appropriate, and required by the Committee one or more of the following elements of information will also be provided to each research subject:
- If the subject is or may become pregnant, a statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus;
- A description of circumstances in which the subject's participation may be terminated by the investigator without the subject's consent;
- Any costs to the subject that may result from participation in the research;

- What will happen if the subject decides to withdraw from the research and how withdrawal will be handled;
- A statement that the Principal Investigator will notify subjects of any significant new findings developed during the course of the study that may affect them and influence their willingness to continue participation;
- The approximate number of subjects involved in the study;
 - When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study.

E. WAIVER OR ALTERATION OF THE REQUIRED ELEMENTS OF INFORMED CONSENT

In certain circumstances prescribed by the Federal Regulations (45 CFR 46), an IRB may waive the requirement to obtain informed consent, or may approve a consent process which does not include or alters some or all of the elements in (c) above.

3. SUGGESTIONS FOR WRITING INFORMED CONSENT DOCUMENTS

When an investigator writes or reviews a research consent document, she/he should ask the following questions:

Question 1: Is it written at a reading level understandable to research subjects?

(a) A general rule of thumb is that consent documents should be written so that they are understandable to people who have not graduated from high school (Generally considered an eighth-grade reading level). The reading level of a document is more difficult if it contains long sentences, words with more than two syllables, and continuous run-on text.

(b) Therefore, if possible use words with fewer than three syllables; use non-scientific/non-medical words; use short sentences, and break the text up into short sections.

Question 2: Is the document formatted well? Does it have headings that break the text into short sections?

Question 3: Does the document contain the basic elements for informed consent and are they presented in a clear, easy-to-understand way?

Question 4: Can the document be shortened without compromising clarity or other requirements?

Usually, before a person agrees to take part in a research study, he/she not only reads a written consent document but also discusses the study with a researcher. A suggestion when writing consent documents is to assume that prospective subjects will not talk to a researcher (or research nurse) at all about the study, and that all their information will come entirely from the consent document. If this approach is used the document is more likely to be clear, complete, devoid of medical/scientific terminology and able to "stand alone."