

GCP Requirements: Informed Consent

8/8/08

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Informed Consent Form

- ◆ Information given to subject “shall be in a language that is understandable...”
- ◆ Guidelines for writing Informed Consent Form
 - Use short sentences and paragraphs
 - Use one or two syllable words, if possible
 - Avoid scientific or medical jargon; define scientific or medical terms in lay language
 - Write in the second person “you”
 - Verbs should be in the active voice
 - Be concise

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Basic Element 1

◆ Describe the overall research process

- Statement that the study involves research
 - The word “research” or “experiment” should be used not “study” or “trial”
- Purpose of the research, e.g. evaluation of new drug
 - If an investigational article is being used – include statement that the trial includes an evaluation of safety and/or effectiveness of the investigational article
 - If trial is to evaluate effectiveness – no claims of effectiveness
 - If trial is to evaluate safety - no claims about safety

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Basic Element 1 continued

- Expected duration of subject's participation
 - Number of days, number of visits, overnight stay in hospital, hospitalization, etc.
- Description of procedures that will be followed
 - Number of needle-sticks or other discomforts
 - Verify procedures with protocol
 - Recommend including a time and events chart
- Identification of procedures which are experimental
 - Explain terms - placebo, randomization, etc
 - Include procedures required for study purposes

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Basic Element 2

- ◆ Describe the reasonably foreseeable risks, harms (including social harms or financial harm), discomforts and/or inconveniences associated with the research
 - Include description of risks attributable to test article and a description of risks attributable to other procedures
 - Explain discomforts e.g., number of needle-sticks

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Basic Element 3

- ✦ Describe any benefits that the subject may reasonable expect from the research
 - May be none to subject but benefit to society
 - Compensation is NOT a benefit
 - Don't overstate benefits by implying a cure or favorable medical outcome can be expected

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Basic Element 4

◆ Describe alternatives to participating in the research study

- Explain full range of alternative options available

Examples:

- The same medication may be available at the local clinic
 - Supportive care with no further medication
 - Alternative marketed product available
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- Any clear advantage or disadvantages of alternatives should be listed

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Basic Element 5

◆ Confidentiality of Records

➤ Inform subjects of extent to which their records will be kept confidential

- For FDA regulated research – subjects should be informed that FDA may inspect records including individual medical records
- Don't state or imply that FDA needs permission from subject for access - no option of keeping records from being reviewed by FDA
- Explain who else may have access to records, e.g. monitors, auditors, IRB/IEC

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Basic Element 6

- ◆ **For research – related injury that could occur in greater than minimal risk studies**
 - Explanation as to whether any compensation is available if injury occurs, and what it consists of, or whom to contact for more information
 - Explanation as to whether any medical treatments are available if injury occurs, and what it consists of, or whom to contact for more information

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Basic Element 7

◆ Consists of three components:

- Identification of persons to be contacted to answer questions about research
 - Usually investigator
- Identification of persons to be contacted to answer questions about research subjects' rights
 - Usually IRB office
- Identification of persons to be contacted to answer questions in the event of research-related injury
 - Can be investigator

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Basic Element 8

- ◆ A statement that **participation is voluntary**
- ◆ A statement that **refusal to participate** will involve no penalty or loss of any benefits to which the subject is otherwise entitled
- ◆ A statement that subject may **discontinue participation** without penalty or loss of any benefits to which the subject is otherwise entitled

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◆ Compensation

- Amount, if any, to be stated
- State schedule of payment (if any); should be prorated
- Should not be so large as to be coercive

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Additional (not optional) elements to be included when appropriate:

- ◆ A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if pregnant) which are currently unforeseeable

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Additional (not optional) elements to be included when appropriate:

- ✦ **A statement about anticipated circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent**
 - Not sufficient to state "your doctor will explain the possibilities to you" or "if deemed appropriate"
 - Appropriate to state "your participation will be ended if tests show that you are not responding to drug"

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Additional (not optional) elements to be included when appropriate:

- ◆ Any additional costs to the subject that may result from participation in the research
 - These may include cost of administering the drug, costs of tests or procedures
 - Subjects should not be charged for investigational drugs unless the study is under a treatment protocol

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Additional (not optional) elements to be included when appropriate:

- ◆ Consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject
 - The subject should be warned if sudden withdrawal from an investigational drug might adversely affect their health

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Additional (not optional) elements to be included when appropriate:

- ✦ A statement that new significant findings that may influence a subject's willingness to participate will be provided to the subject
 - Only use this statement if there is a procedure in place or an intent to promptly inform subjects of new developments
 - Inappropriate to use this statement if the clinical trial involves only one dose of investigational drug and no time for new findings to develop during subject's scheduled exposure

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Additional (not optional) elements to be included when appropriate:

- ✦ **Approximate number of subjects involved in the study**

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Documentation of Informed Consent

- ✦ Informed consent must be documented - written informed consent form that has been approved by IRB
- ✦ Signed by subject or subject's legally authorized representative
- ✦ Subject or representative - adequate time to read the consent form before signing it

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Documentation of Informed Consent

- ✦ The written informed consent form may be read to subject or subject's legally authorized representative
- ✦ Copy of the informed consent form to be given to the person signing the form

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Documentation of Informed Consent

Short form written consent document

- ◆ This document to state that required elements of consent presented orally to subject or their representative
- ◆ When this method used – must have witness to oral presentation
- ◆ IRB/IEC approves written summary
- ◆ Only short form signed by subject or representative
- ◆ Witness signs short form and summary
- ◆ Person obtaining consent signs copy of summary

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Assent of Children

- ◆ Assent of children should be obtained whenever possible
- ◆ IRB/IEC determines whether children are capable of assenting
 - Age
 - Maturity
 - Psychological state
- ◆ If IRB/IEC determines that consent is required, must specify how assent is documented
- ◆ Consent of child's parents or guardians also required
 - Both parents or guardians?

45 CFR46 Subpart D