

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: INFORMED CONSENT FOR CLINICAL TRIALS
STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS
EFFECTIVE: 1/98; 11/03; 04/04

POLICY: The informed consent document shall comply with the requirements of Federal regulations found in 21 CFR part 50, 45 CFR 46.116, and meet the requirements set forth by the DMH IRB.

No investigator may involve a human being as a subject in research conducted under the auspices of Decatur Memorial Hospital and the Institutional Review Board without first obtaining the legally effective informed consent of the subject or the subject's legally authorized representative.

IMPLEMENTATION:

General Requirements

- 1) An investigator or clinical research associate shall seek informed consent only under circumstances that provide the prospective subject or subject representative sufficient opportunity to consider whether or not to participate and eliminate the possibility of coercion or undue influence.
 - a) Subjects should not be required to certify completeness of disclosure (e.g., "this study has been fully explained to me, or, "I fully understand the study.") They may certify that they understand the statement in the consent document and are satisfied with the explanation provided during the informed consent process.
 - b) There shall be no claims of effectiveness, explicitly or implicitly, that may unduly influence potential subjects.
 - c) If subjects are paid for participation, the schedule of all payments must be presented to the IRB at the time of initial review and outlined in the informed consent document. Payment should accrue as the study progresses and should not be contingent upon completion of the entire study. Payment of a small portion for completion of the study is acceptable providing that such incentive is not coercive.
- 2) The information that is given to the subject or the subject's legally authorized representative must be in language understandable to the subject or the subject's representative.
 - a) Technical and scientific terms must be adequately explained or replaced with common terms.
 - b) If it is anticipated that the subject population will include non-English speaking people or the informed consent interviews will be conducted in a language other than English, a translated informed consent document is required and must be submitted at the initial protocol review or prior to that subjects consent.
 - c) Oral translation may be utilized if a non-English speaking subject is unexpectedly encountered. A "short-form" written informed consent document in a language the subject understands should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally.
 - d) If a person speaks and understand English but does not read and write, the informed consent document may be read to them and obtained by "making their mark" on the informed consent document. There must be an impartial witness to attest to the adequacy of the informed consent process and to the subject's voluntary agreement.
 - e) If medical records are not available in English, the patient is responsible for a certified medical translator unless the researcher is bilingual.
- 3) The informed consent process and the research may be observed by an IRB voting member or a third party appointed by the IRB chairperson.

Elements of Informed Consent

- 1) The IRB has developed standard language and format to be used in portions of all informed consent documents. Where changes are needed from the standard paragraphs or format, the investigator must explain the reasons for the changes with the initial submission to the IRB. The proposed informed consent must be on DMH approved letterhead and must contain all of the following requirements:
 - a) A statement that the study involves research, an explanation of the purpose(s) of the research, how many people will take part in the study, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - i) Any procedures relating solely to research (e.g. randomization and placebo control) should be explained to the subjects.
 - ii) Informed consent documents for studies of investigational articles should contain a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety. In studies that also evaluate the effectiveness of the test article, informed consent documents should include that purpose but not contain claims of effectiveness.
 - b) A description of any reasonably foreseeable risk or discomfort to the subject.
 - i) Risks of procedures relating solely to research should be explained in the consent document. The tests required in the protocol which carry significant risk of morbidity/mortality should be explained and adverse effects not minimized.
 - c) A description of any benefit(s) to the subject or to others which may be reasonably expected from the research.
 - i) Description of benefit(s) should be clear and not overstated.
 - ii) If no direct benefit(s) is (are) anticipated, that should be stated.
 - iii) If benefit(s) to "others" are different than those normally expected to result from conducting research, and may be relevant to the subject's decision to participate, they should be disclosed in the informed consent document.
 - d) Disclosures of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - i) Informed consent documents should briefly and sufficiently explain any pertinent alternatives to entering the study.
 - e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and the possibility that the Food and Drug Administration may inspect the records.
 - i) If any other entity, such as the sponsor of the study or drug manufacturer has access to the study records, the informed consent document must contain that information.
 - f) For research involving more than minimal risk, an explanation as to whether compensation and medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
 - g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's 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.
- 2) When appropriate, one or more of the following elements of information shall also be included in the informed consent document:

- a) A statement that a 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.
 - i) if measures to prevent pregnancy should be taken while in a study,
 - ii) the availability of counseling resources
- b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - i) An unexplained statement that the investigator and/or sponsor may withdraw subjects at any time does not adequately inform the subject of anticipated circumstances for such withdrawal.
 - ii) A statement that the investigator may withdraw a subject if he/she does not follow study procedures is not appropriate. A subject may be informed that he/she may be withdrawn if he/she does not follow the instruction given to them by the investigator.
- 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 the 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 to be involved in the study.

Exceptions

- 1) An informed consent procedure may be approved which does not include, or which alters, some or all of the elements of informed consent set forth above, or waives the requirement to obtain informed consent provided the IRB finds and documents that:
 - a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (1) public benefit of service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs.
 - b) The research could not be practicably carried out without a waiver or alteration.
- 2) The IRB may approve an informed consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waives the requirement to obtain informed consent provided that it finds and documents that:
 - a) The research involves no more than minimal risk to the subjects.
 - b) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - c) The research could not practicably be carried out without the waiver or alteration.
 - d) Whenever appropriate, the subject will be provided with additional pertinent information after participation.

DOCUMENTATION:

Documentation of Informed Consent

- 1.) Except as provided in number four of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or subject's legally authorized representative and one of the following combinations:
 - a) the investigator and clinical research associate
 - b) the investigator and witness
 - c) two clinical research associates
 - d) clinical research associate and a witness
 A copy shall be given to the subject or subject's legally authorized representative signing the form.
- 2.) The signature on the informed consent document must be dated to permit verification that the consent was obtained prior to the subject's participation in the study. The subject or the subject's legally authorized representative must initial each page of the informed consent document.

- 3.) Except as provided in number four of this section, the informed consent document may be either of the following:
 - a) A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This document may be read to the subject or the subject's legally authorized representative. The investigator or clinical research associate shall give the subject or the representative adequate opportunity to read and ask questions before it is signed.
 - b) A short form written document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary. A copy of the summary shall be given to the subject or the subject's representative, in addition to a copy of the short form.
- 4.) Waiver of the requirement for the investigator to obtain a signed informed consent document for some or all subjects may be granted if the IRB determines that:
 - a) The only record linking the subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
 - b) The research presents no more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of the research context.
- 5) In cases in which the documentation requirement is waived, the IRB may elect to require the investigator to provide subjects with a written statement regarding the research. If so, the investigator will be notified at the time of the waiver of informed consent documentation. The waiver of informed consent documentation does not waive or alter any element of the informed consent process.

APPLICABLE TO: IRB MEMBERS & INVESTIGATORS

APPROVED BY:

President and CEO