

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-19
Effective Date: September 4, 2007

POLICY TITLE:

DOCUMENTATION OF INFORMED CONSENT

POLICY:

Informed consent shall be documented in writing by the use of a written consent form approved by the IRB. The IRB may approve a waiver from the requirement for *written* consent if the research meets the criteria for waiver of written consent defined in the federal regulations. Informed consent shall be signed and dated at the time of consent by the researcher obtaining consent and by the research participant or the participant's legally authorized representative. A copy of the signed and dated written consent form shall be given to the research participant or the participant's legally authorized representative. A copy of the signed and dated consent form is retained in the researchers' file. A copy of the signed and dated consent form is retained in the participant's medical record, if the research procedure or intervention is offering medical care, treatment, or diagnosis to the participant.

PROCEDURE:

- 19.1 The written consent form must contain the information required under federal regulations for obtaining informed consent, including:
- A. A statement that the proposed treatment/study involves research, an explanation of the purposes 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 which are experimental [45 CFR 46.116(a)(1) and 21 CFR 50.25(a)(1)];
 - B. A description of any reasonably unforeseeable risks or discomforts to the subject [45 CFR 46.116(a)(2) and 21 CFR 50.25 (a)(2)];
 - C. A description of any benefits to the subject or to others which may reasonably be expected from the research [45 CFR 46.116(a)(3) and 21 CFR 50.25(a)(3)];

- D. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject [45 CFR 46.116(a)(4) and 21 CFR 50.25(a)(4)];
- E. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [45 CFR 46.116(a)(5)] and, if applicable, noting the possibility that the FDA may inspect the records [21 CFR 50.25(a)(5)];
- F. For research involving more than minimal risk, an explanation as to whether any compensation 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 [45 CFR 46.116(a)(6) and 21 CFR 50.25(a)(6)];
- G. An explanation of whom to contact for answers to pertinent questions about the research or subjects' rights, as well as whom to contact in the event of a research-related injury to the subject [45 CFR 46.116(a)(7) and 21 CFR 50.25(a)(7)];
- 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 [45 CFR 46.116(a)(8) and 21 CFR 50.25(a)(8)].

19.2 Additionally, the written consent form shall contain the following information when such information is applicable to the research project:

- 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 [45 CFR 46.116(b)(1) and 21 CFR 50.25(b)(1)];
- B. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent [45 CFR 46.116(b)(2) and 21 CFR 50.25(b)(2)];
- C. Any additional costs to the subject that may result from participation in the research [45 CFR 46.116(b)(3) and 21 CFR 50.25(b)(3)];
- D. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject [45 CFR 46.116(b)(4) and 21 CFR 50.25(b)(4)];
- 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 [45 CFR 46.116(b)(5) and 21 CFR 50.25(b)(5)];
- F. The approximate number of subjects involved in the study [45 CFR 46.116(b)(6) and 21 CFR 50.25(b)(6)].

19.3 Children's IRB requires the following information to be included in the written consent form:

- A. Heading:
- i. "Children's Hospital and Regional Medical Center", "Consent Form". For research studies with multiple consent and assent forms, the heading shall indicate for which group the form is intended;
 - ii. Title of the study;
 - iii. Names and contact information of:
 1. Principal Investigator;
 2. All research team members involved in the consent/assent process; and
 3. At least one designated research team member who possesses enough knowledge to answer subject questions about the research (can be same individual that is listed for other reasons).
 - iv. 24-Hour Emergency Telephone Number, when applicable. An emergency telephone number is applicable to research that involves a potential for research related injuries when the participant is outside of a medical setting.
- B. Payment or incentives to take part;
- C. Disclosures of any financial interests of research team members.
- D. Participant statement to include:
- i. The participant or their legally authorized representative has had the study explained to them;
 - ii. The participant or their legally authorized representative has had opportunity to ask questions and knows they can ask questions at any time;
 - iii. The participant or their legally authorized representative voluntarily agrees to take part.
- E. Signature and Date Lines for:
- i. Person obtaining consent (must be listed on the consent form);
 - ii. Person giving consent (participant; legally authorized representative);
 - iii. When appropriate, witness or advocate. Witness signatures are required when informed consent is being obtained with the use of an interpreter. Witness signature may be required by the IRB if the oral consent process is being conducted by telephone. An advocate signature would be required when the IRB requires the use of an advocate to act in the best interests of the research participant.
- F. Copies to: Research Participant and/or Parent; Researchers' file; Medical Record (if appropriate). When research is providing patient care or management, a copy of the consent form goes in the medical

record.

- 19.4 In most all cases, the consent form shall be a written consent document that embodies the elements of informed consent. This form may be read to the participant and/or the participant's legally authorized representative. The investigator must give the subject or representative adequate opportunity to read the document and ask questions before signing. [45 CFR 46.117(b)(1) and 21 CFR 50.27(b)(1)];
- 19.5 In rare cases, the investigator may use a short form written consent document stating that the elements of informed consent have been presented orally to the participant or legal representative in the presence of a witness. The short form is to be signed by the participant or representative; the witness shall sign the short form along with a copy of the written summary of what is to be said to the participant or representative. This written summary will be approved by the IRB. A copy of the summary and short form will be provided to the subject or representative [45 CFR 46.117 (b)(2) and 21 CFR 50.27(b)(2)].

The use of a short form consent document is used most frequently in situations where the researcher wants to enroll participants with limited or no English language skills. See IRB Policy 21.

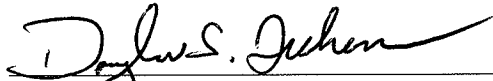
- 19.6 The IRB may waive the requirement for the investigator to obtain signed, written consent from some or all research participants or their legally authorized representative if it finds:
- A. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each participant will be asked if they want documentation linking the participant to the research, and the participants wishes will govern [45 CFR 46.117(c)(1)]; or
 - B. The research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context [45 CFR 46.117(c)(2) and 21 CFR 56.109 (c)(1)]. The IRB may require the investigator in such cases to provide the research participant or their legally authorized representative a written statement (information sheet) regarding the research [45 CFR 46.117(c) and 21 CFR 56.109 (d)]
- 19.7 Consent forms are to be written in a language understandable to the participant or their legally authorized representative. [45 CFR 46.116 21 CFR 50.20] Based on literacy statistics for the U.S. population the IRB requires that consent forms be written at an 8th grade or lower reading level. Consent forms for persons with limited or no English language skills must be

translated into a language understandable to the participant and/or their legally authorized representative. See IRB policy 21 on Consent Requirements for Language Minorities.

19.8 Research participants or their legally authorized representative must sign and date the written consent form after the researchers have provided the information (oral and written) needed to make an informed decision about participation in the research and given sufficient opportunity to consider their decision. The signature and dates on the consent form should document that the participant or their legal representative signed and dated the consent form after the elements of informed consent were presented to them by the researchers.

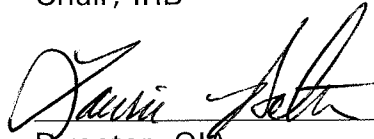
Submitting Committee: Institutional Review Board

Approved by:

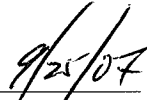


Chair, IRB

Date



Director, OIA



Date