

Children's
Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-13
Effective Date: June 20, 2005

POLICY TITLE:

INFORMED CONSENT

POLICY:

Respect for persons requires that prospective research participants and/or their legally authorized representative, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them [Belmont Report]. Participants and/or their legally authorized representative must be provided information about the nature of the research and based on comprehension of that information knowledgeably and voluntarily decide whether or not to participate. Investigators shall seek consent under circumstances that provide the prospective participant sufficient opportunity to carefully consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the prospective participant must be in language understandable to the participant or their legally authorized representative and may not include any exculpatory language. [45 CFR 46.116 and 21 CFR 50.20]

PROCEDURE:

- 13.1 The federal regulations [45 CFR 46.116(a) and 21 CFR 50.25] require that certain information be provided to each research participant or legally authorized representative 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 subjects' rights, and 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)].
- 13.2 When appropriate, one or more of the following elements of information shall also be provided to each research participant [45 CFR 46.116(b) and 21 CFR 50.25(b)]:
- 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)].

- 13.3 Children's IRB requires the following additional information to be provided during the informed consent process:
- A. Payment or incentives to take part;
 - B. Disclosures of any financial interests of research team members.
- 13.4 During the informed consent process (oral and written) there can be no use of exculpatory language through which the research participant or their legal representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. [45 CFR 46. 116 and 21 CFR 50.20]
- 13.5 Informed consent requires that the information be presented in a language understandable to the participant [45 CFR 46. 116 and 21 CFR 50.20]. Based on U.S. adult literacy data the IRB requires that the language used, both oral and written, be presented at an 8th grade reading level or lower. This also requires that when participants or their legal representatives have limited or no English language skills that the consent process (oral and written) be in a language understandable to them. See IRB Policy 21.
- 13.6 In order for consent to be informed, researchers are responsible for ascertaining that the research participant or their legally authorized representative has comprehended the information presented. The researchers' obligation to ascertain comprehension increases when the risks of the research are more serious. [Belmont Report] Methods for ascertaining comprehension shall vary and take into account research participants' circumstances and abilities (e.g., maturity, intelligence, language skills). Possible methods include asking participants to describe key points of the research in their own words, asking questions to ascertain comprehension of key points, reviewing key points that are known to be difficult for participants to comprehend, or developing written or oral tests to ascertain comprehension.
- 13.7 Consent is valid only if voluntarily given. Researchers must obtain informed consent under circumstances that minimize the possibility of coercion or undue influence. [45 CFR 46. 11 and 21 CFR 50.20]
- 13.8 Whenever possible, the IRB will request that a qualified member of the research team who does not have a relationship of authority with the participant or their legally authorized representative, obtain consent. When the researchers obtaining consent have a relationship of authority with the participant and there is no other member of their research team qualified to obtain consent, the researchers shall describe for the IRB the steps they will take to minimize the possibility of coercion and undue influence. The IRB must be satisfied that adequate provisions are in place to reduce coercion

and undue influence.

- 13.9 In determining who is qualified to obtain informed consent the IRB shall consider the person's knowledge of the specifics of the research and the condition or disorder being studied and the person's knowledge of the general requirements for informed consent. The research team member obtaining consent shall be qualified by training and education to present the required elements of consent and answer the questions of the research participant. For research involving medical care, treatment or diagnosis, the IRB will require that the person obtaining consent be a trained and licensed health care professional, e.g., nurse, physician. The research team member obtaining consent shall have completed human subjects protections training (IRB Policy 17) and be knowledgeable about the general requirements for informed consent.
- 13.10 Informed consent requires that researchers allow participants sufficient opportunity to consider whether or not to participate [45 CFR 46.116 and 21 CFR 50.20]. In addition, informed consent requires that researchers allow sufficient time to present the information to the prospective participants and answer their questions.
- 13.11 The IRB shall take into consideration, when relevant, timing issues when approaching prospective participants regarding participation in the research project. Timing considerations must be weighed carefully in situations that increase the vulnerability of research participants. Examples of situations that increase the vulnerability of research participants and their legally authorized representatives include newly diagnosed patients, patients diagnosed with a terminal illness, patients in a critical care situation, patients in an emergency situation, or parents, siblings or other family members of a recently deceased child.
- 13.12 Federal regulations permit modifications to the required elements of informed consent and, under certain circumstances, informed consent may be waived [45 CFR 46.116 (c) and (d)]. The FDA regulations allow for exceptions to the general requirements for informed consent involving an FDA regulated test article in a life threatening situation where informed consent is deemed infeasible [21 CFR 50.23 (a) (b) (c)]. The requirements surrounding waiver or modification of consent are described in IRB Policy 18.
- 13.13 In most instances, the informed consent process shall be 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 requirements for documentation of informed consent are outlined in IRB Policy 19.

