

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

**SUBJECT: Human Research Review Board - HRRB-
Informed Consent**

POLICY

I. Purpose:

- A. To ensure that Children's Hospital of Wisconsin's (CHW) prospective subjects or their legally authorized representative understand the nature of the research and can knowledgeable and voluntarily decide whether or not to participate.
- B. Additionally, to describe when one or both parents' permission is required and when parental permission can be waived.

II. Policy:

A. Definitions

- 1. Assent: Assent is a child's affirmative agreement to participate in research. Failure to object, by itself, does not constitute assent.
- 2. Children: Persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. In Wisconsin, the legal age of consent is 18 years of age.
- 3. Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- 4. Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in a research study. Under Wisconsin law, a Legally Authorized Representative may be the parent, guardian or legal custodian of a minor, the person vested with supervision of a child under state law, the guardian of a person adjudged incompetent, as defined under state law, the personal representative or spouse of a deceased subject, or any person authorized in writing by the subject or a health care agent designated by the subject as a principal under state law if the subject has been found to be incapacitated under state law except as limited by the power of attorney for health care instrument.

5. Parent: A child's biological or adoptive parent.

B. Elements of Informed Consent:

1. Required Elements of Informed Consent

- a. Statement that the study involves research.
- b. Explanation of what the study is designed to discover or establish.
- c. Description in lay language of all procedures, their frequency, and identification of any drugs, devices or procedures used in the study that are investigational or experimental.
- d. Expected duration of the subject's participation.
- e. Description of the discomforts, inconveniences, and other risks to be reasonably expected and indication of incidence of occurrence.
- f. Description of any benefits reasonably to be expected (Note: Direct payment or other forms of remuneration are not considered benefits of participation in a research study).
- g. Description of alternative procedures that might be advantageous and disclosure of any standard treatment being withheld.
- h. Amount or nature of the compensation subjects will receive, if any.
- i. For research involving greater than minimal risk, an explanation as to whether any compensation or any medical treatments are available if the subject is injured and, if so, what they consist of or where further information may be obtained.
- j. Confidentiality statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and any exceptions.
- k. Statement that participation is voluntary and the subject has the right to withdraw from the study at any time without affecting future medical care at CHW.
- l. Principal investigator's and/or co-investigator's name and phone number for questions regarding the study and a contact in the event of a research-related injury.
- m. Statement to contact the Human Research Review Board (HRRB) and the phone number to call for any questions about rights as a research subject.
- n. The expiration date and the date the HRRB approved the informed consent document.

2. Additional Elements of Informed Consent, Where Applicable:
 - a. Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if applicable) that are currently unforeseeable.
 - b. Statement about providing the subject with significant new findings which develop during the course of the research that may relate to continued willingness to participate.
 - c. Description of anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
 - d. Explanation of any additional costs to the subject that may result from participation in the study.
 - e. Description of the consequences of a subject's decision to withdraw from the research study and the procedures for terminating participation.
 - f. Identification of the approximate number of subjects involved in the study.
 - g. Statement that the subject will not receive any compensation if products derived from his or her tissues that are collected as part of participation in the research study are developed and successfully marketed.
 - h. Disclosure of the investigator's financial or other interests that may affect the investigator's professional judgment.

C. Waiver of Informed Consent

1. The Human Research Review Board (HRRB) may approve a consent procedure which does not include some or all of the elements of basic informed consent (as stated above) or waive the requirement for informed consent entirely if the HRRB finds and documents the conditions listed in a. through d. below. Waiver of informed consent applies in limited circumstances (e.g., medical record reviews). Note: Informed consent cannot be waived for research involving FDA-regulated products (i.e., drugs, biologics and devices) except in emergency situations in accordance with HRRB policy (see "HRRB Emergency Use of a Test Article" and "HRRB Planned Emergency Use" policies).
 - 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; and
 - d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
2. If the HRRB has approved a waiver of informed consent for a study, it does not necessarily mean that the study will also qualify for a waiver of HIPAA authorization (refer to “HIPAA- Use and Disclosure of Protected Health Information for Research Purposes” policy).

D. Process for Obtaining Informed Consent

1. The investigator must conduct the consent interview unless he or she delegates his or her responsibility for conducting the informed consent interview to another individual who is both knowledgeable about the research study and under the investigator’s direct supervision. However, state law requires the physician-investigator, himself or herself, to inform the subject about the availability of all alternate, viable medical modes of treatment and about the benefits and the risks of these treatments.
2. Before informed consent may be obtained, the investigator, or person designated by the investigator, in accordance with State law, must provide the prospective subject or the Legally Authorized Representative (LAR) ample time and opportunity to inquire about details of the study and to decide whether or not to participate.
3. Examples of giving the subject sufficient opportunity to review information about the study would include:
 - a. Discussing the issues with prospective subjects on more than one occasion.
 - b. Allowing a period of time between giving the information and requesting a signature on the consent form. During this waiting period, prospective subjects should be encouraged to discuss their possible participation with family members, friends or trusted advisors.

E. Documentation of Informed Consent

1. Informed consent shall be documented with the use of a written informed consent form approved by the HRRB and signed and dated, in the individual’s own handwriting by:
 - a. The subject or the subject’s LAR.
 - b. The person obtaining consent or facilitating the consent process.
 - c. The investigator if not the same individual referred to in (b) above.
 - d. An impartial witness, if specifically required by the HRRB.

2. If required by the HRRB, an impartial witness must be present during the entire consent process and sign the informed consent form. A witness's signature does more than attest to the witnessing of the subject's signature, it attests to the occurrence of the consent process.
3. The consent form may be either of the following, however generally, researchers should use the "Long Form" as stated in (a) below:
 - a. Long Form Written Consent Document: A written consent document that embodies all of the required elements of informed consent and additional elements, if applicable, as delineated above in section B. A copy of the signed informed consent document shall be given to the person signing the form (subject or their LAR).
 - b. Short Form Written Consent Document: A written document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR. This should only be used in certain circumstances, for example, illiterate or blind research subjects. When this method is used:
 - i. The HRRB, or HRRB Chair under expedited review, shall have approved a written summary of what is to be said to the subject or the LAR;
 - ii. There shall be a witness to the oral presentation;
 - iii. The witness shall sign both the short form and a copy of the summary;
 - iv. The subject or the LAR needs to sign the short form consent only;
 - v. The person actually obtaining consent shall sign a copy of the summary;
 - vi. Both a copy of the summary and the short form shall be given to the subject or subject's LAR.
4. For research not regulated by the Food and Drug Administration (FDA), the HRRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - a. That the only record linking the subject and the research would be the 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; or

- b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the HRRB may require the investigator to provide subjects with a written statement regarding the research.

- 5. The informed consent process and related circumstances, including the time the informed consent was obtained, shall be documented in the patient's medical record unless it may be an increased risk (harm) to the subject. No research procedures, including any screening activities may be performed until after informed consent has been obtained and documented.
- 6. A copy of the signed informed consent and assent form, if applicable, shall be placed in the subject's medical record, and a copy shall be given to the parent/guardian.
- 7. Only the most recent HRRB approved informed consent form, date stamped with an expiration date, may be used to obtain consent from prospective subjects.
- 8. Any changes or revisions to an approved version of the informed consent must be HRRB approved prior to use. (See "HRRB Research Revisions and Amendments" policy for more information)

F. Permission of Parents to Participate in Research

- 1. In general, permission should be obtained from both parents before a child is enrolled in a study. However, the HRRB may find that the permission of one parent is sufficient if the research to be conducted falls under one of the following two categories:
 - a. Research involving no greater than minimal risk to children; or
 - b. Research involving greater than minimal risk but presenting with the prospect of direct benefit to individual subjects.
- 2. Permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if the research to be conducted falls under one of the following two categories:
 - a. Research involving more than minimal risk to children with no prospect of direct benefit for the individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition; or
 - b. Research that is not otherwise approvable but which represents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

3. For studies not regulated by the FDA, the HRRB may waive the parental consent requirements if it determines that the research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects and is not inconsistent with Federal or State law (e.g., neglected or abused children). An appropriate mechanism for protecting the children who will participate as subjects in the research must be substituted. Note: Parental or guardian permission must be obtained for any study regulated by the FDA (e.g., drug and device studies).

PROCEDURE

- A. Upon receipt of the initial study application, the HRRB coordinator will review the proposed informed consent form to determine if all of the CHW HRRB mandated requirements are included. The coordinator will communicate with the investigator or his/her designee to resolve any issues regarding incomplete informed consent forms in advance of the HRRB meeting date.
- B. A "Request for Waiver of Informed Consent" form must be completed for waivers of informed consent, alternations or waivers of some of the basic elements of informed consent (described in II.C. above) or waiver of the requirement to document consent (described in II.E.4. above).
 1. For waivers of informed consent or alterations of elements of informed consent, the investigator or his/her designee must clearly describe why:
 - a. The research involves no more than minimal risk to the subject;
 - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - c. The research cannot practicably be carried out without the waiver or alteration.
 2. For waiver of the requirement to document consent, the investigator or his/her designee must clearly explain:
 - a. That the only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality. Further, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
- C. The HRRB, or HRRB Chair or designee, if the study qualifies for expedited review, will review the proposed informed consent form (or request for waiver) in a manner consistent with the population under study and communicate required revisions to the informed consent form (or its decision with regard to waiver) in writing to the investigator.
- D. The HRRB will also make a determination as to whether required revisions to the informed consent form, if any, are substantial or minor in nature. (See "HRRB Research Revisions and Amendments" policy for more details.)

Approved by the Medical Executive Committee 10/02/2006

Jon E. Vice, President CHHS, Inc.

References:

- A. 45 CFR 46.116, 46.117
- B. 21 CFR 50.25, 50.27

Documentation (Documents & Forms):

- A. HRRB Registration Form
- B. Request for Waiver of Informed Consent