



ASSENT OF CHILDREN TO PARTICIPATE IN CLINICAL RESEARCH

Clinical Research Policy/Procedure	
Approved: March 2008	Next Review: March 2011

Purpose

To safeguard the rights and welfare of children participating in clinical research.

Responsible Persons

The Principal Investigator (PI) is ultimately responsible for ensuring that a child is not involved in research without the assent of children and the permission of the children's legally authorized representative(s), as required by the IRB. Investigators and Research Coordination Staff may also participate in obtaining the assent of children and the permission of parent(s)/guardians.

Definitions

Assent means a child's affirmative agreement to participate in research.

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted.

Guardian means an individual who is authorized under applicable law to consent on behalf of a child to general medical care.

IRB or Institutional Review Board is a group of individuals designated by an institution to review, to approve the initiation of, and to conduct periodic review of research, in order to assure the protection of the rights, safety and welfare of human subjects participating in the research.

Legally Authorized Representative means 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 the research.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s)/guardian to the participation of their child/ward in research.

Policy

Federal regulations governing clinical research require investigators to obtain the legally effective informed consent of a subject or the subject's legally authorized representative before involving the subject in research. However, pursuant to applicable law, children are generally incapable of providing legally effective consent to participate in research. Accordingly, when children are proposed to be included in research, federal regulations require the permission of the children's parent(s)/guardians (i.e., legally authorized representatives) as well as the assent of the children if deemed appropriate by the IRB reviewing the research.

When a proposed research project involves children as research subjects, among other determination, the reviewing IRB determines whether adequate provisions have been made for soliciting the assent of the children (when in the judgment of the IRB the children are capable of providing assent). Federal regulations grant IRBs the authority to require or waive assent for all children involved in a research project or for each child as the IRB deems appropriate. In making assent determinations, the IRB considers the age, maturity, and psychological state of the children, as well as the nature of the research. When the IRB determines that assent is required, the IRB has the discretion to determine if it is appropriate in a manner, if any, of documenting child assent.

When a proposed research project involves children as research subjects, the reviewing IRB also determines whether adequate provisions have been made for soliciting the permission of each of the children's parent(s) or guardians. For research governed by the Department of Health and Human Services (DHHS) regulations, the IRB maintains the authority to require or waive permission, for one or both parents or guardians. For research governed by the U.S. Food and Drug Administration regulations, the IRB may not waive permission requirements. When the IRB determines that permission is required, the IRB also determines whether and how permission must be documented.

The IRB provides notice to investigators of its assent and permission determinations via its initial approval document (i.e., Certificate of Approval). The IRB maintains the authority to observe or have a third party observe the assent/permission process and the research.

Procedure

- Under Washington state law, persons under the age of eighteen (18) (i.e., minors) are deemed **not** to have attained the age of majority to make decisions in regard to their own body (e.g., medical treatment). See RCW 26.28.010 and 26.28.015. Thus, in general, minors should be considered "children" for the purposes of participating in clinical research.

However—under specific circumstances—Washington state law grants minors the authority to consent to certain medical procedures. In such circumstances, minors can legally consent to their own medical treatment and should not be considered "children" for the purposes of participating in clinical research. For more information regarding the circumstances where minors can consent to medical treatment (and clinical research involving such medical procedures) in Washington State, refer to **Administrative Policy: INFORMED CONSENT FOR MEDICAL TREATMENT**.

2. When a PI is informed by the IRB that the assent of children participating in the research is required:
 - a. The PI must ensure that the affirmative agreement of the child to participate in the research is obtained as directed by the IRB. Assents should be obtained in a non-coercive manner and setting.
 - The child must actively demonstrate his or her willingness to participate in the research. A child's passive acquiescence or failure to object may not be construed as assent.
 - b. The PI must ensure that assent of children is documented as determined by the IRB (e.g., use of a written assent form). In all cases, the act of obtaining child assent must be recorded in sourced documentation.

3. When a PI is informed by the IRB that parental/guardian permission is required before a child may participate in the research:
 - a. The PI must ensure that the permission of the parent(s)/guardian for their child's participation in the research is obtained as directed by the IRB.
 - b. The PI must ensure that parental/guardian permission is documented as determined by the IRB. In all cases, the act of obtaining parental/guardian permission must be recorded in sourced documentation.
 - When a written permission document is required by the IRB, the PI must ensure that the Clinical Research Policy/Procedure: INFORMED CONSENT FOR PARTICIPATING IN CLINICAL RESEARCH is followed.

4. Where both the assent of children and parental/guardian permission are required, disagreement between a child and his/her parent(s)/guardians about participating in the research disqualifies the child from being a subject in the research. For example, if a child dissents from participating in research, even if his/her parents have granted permission, the child's decision prevails.

Forms

N/A

Supplemental Information

- Administrative Policy: INFORMED CONSENT FOR MEDICAL TREATMENT
- Clinical Research Policy/Procedure: INFORMED CONSENT FOR PARTICIPATING IN CLINICAL RESEARCH

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Regulatory Requirement

21CFR§§50.3,50.51–50.55.
45CFR§§46.401–46.408.

References

“Frequently Asked Questions”, Information Sheets Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors, U.S. Food and Drug Administration (1998).

“OHRP Research Involving Children Frequently Asked Questions”, Office for Human Research Protections at www.hhs.gov/ohrp/researchfaq.html (December 5, 2007).

Addendum

N/A

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