

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

Research with Children

Effective 09/20/2007; Revised 01/02/2008, 10/14/2010, 09/16/2011

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Purpose:

To establish policy and procedures related to research with children.

Definitions:

1. Children: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
2. Assent: a child's affirmative agreement to participate. Failure to object (rather than the child's affirmative agreement) does not constitute assent.
3. Permission: the authorization by parent(s) or guardian(s).
4. Parent: a child's biological or adoptive parent.
5. Guardian: an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Policy:

Research involving children is permitted in the following instances if adequate provisions are made for soliciting the assent of the children and the permission of parents or guardians, as outlined below.

1. The IRB finds that no more than minimal risk to children is presented by an intervention or procedure.
2. The IRB finds that the study holds more than minimal risk but holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, if the IRB finds the risk is justified by the anticipated benefit to the subjects. The relation of the anticipated benefit to the risk must be at least as favorable to the subjects as that presented by available alternative approaches.

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3. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:
- the risk represents a minor increase over minimal risk;
 - the intervention or procedure presents experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder or condition; and

In rare instances, research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children may be proposed by a researcher. If the study is not funded by a federal agency, and the IRB finds and documents that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children then the IRB may approve it upon consultation with the vice president for institutional effectiveness. If the study is funded by a federal agency, and the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; it will be forwarded to the Secretary of Health and Human Services (DHHS) for further review.

For studies involving FDA- regulated products, clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children may proceed only if the IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and the Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine education, law) and following opportunity for public review and comment, determines either: (1) that the clinical investigation in fact satisfies the conditions noted above 1-3 or (2) that the following conditions are met: (a) the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (b) the clinical investigation will be conducted in accordance with sound ethical principles; and (c) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth below.

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Requirements for Parental/Guardian Permission and for Assent by Children

The IRB shall require that adequate provisions are made for soliciting the permission of each child's parents or guardians prior to the solicitation of the child. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater than minimal risk, or does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizing knowledge about the subject's disorder or condition, the IRB will require both parents' permission. Exceptions would include the following situations: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child. Permission by parents or guardians shall be documented in accordance with and to the extent required under the Informed Consent section of the IRB procedures manual.

There are a few circumstances where the IRB may grant a waiver of parental consent for participation of a child, when applicable law (state and local) has demonstrated that such a waiver would be acceptable:

- If the child is a victim of abuse or neglect and the study protects the child. If a guardian has been named, then the guardian's consent is required.
- Research on mature adolescents that involves minimal risk. The decision on who is a mature minor is made on a case-by-case basis. The IRB would in no circumstances consider a child younger than 16 to be a mature minor. The State of Florida does not permit research on children below the age of 18 without parental consent.
- In emergency situations, where life or health is threatened, when there is no acceptable treatment for a disease/disorder, and the study holds the prospect for benefit to the subject, and parents are not available to provide consent in a timely manner, then parental consent may be waived.

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the

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children is not a necessary condition for proceeding with the research.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Wards

Children who are wards of the state or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, or research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if such research is related to their status as wards, or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the IRB approves the research, it shall require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization.

References:

45 CFR 46.404
45 CFR 46.405
45 CFR 46.407
45 CFR 46.408
45 CFR 46.409
21 CFR 50, Subpart D

Procedures:

1. During the review of research, the IRB will determine and document the category of research that the proposed protocol falls under, and approve only those research studies permitted under the policies outlined above.
2. The IRB will ensure and document that appropriate informed consent/assent requirements are met.

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3. Investigators must describe in detail within the research protocol how informed consent procedures will occur. This includes a detailed description of how assent procedures will occur for children ages 7-17 as well as those children under the age of 7.

4. Investigators will develop consent and assent forms in keeping with the NSU-provided templates and models using the simplest possible language. For children under the age of 7 or who are deemed by the researcher unable to understand a written assent form, the researcher will submit a text version of a verbal assent process for these individuals.