

**Issuing Department:** Human Subjects Protection Program (HSPP)  
**Policy Number:** 2011-006.3  
**Policy Title:** Additional Protections for Certain Populations: Children

### ***Purpose***

The purpose of this policy is to set forth the requirements of the HSPP for review and approval by the Institutional Review Board of non-exempt research intending to involve children as subjects.

### ***Definitions***

See Policy 2011-007.0 for definitions of the following terms:

Assent	Guardian	Parent
Permission	Risk, Minimal	Children
Ward	Research	Clinical Investigation

### ***Policy***

For purposes of this policy the term research is to be interpreted as either research as defined by DHHS or clinical investigation as defined by the FDA.

Research proposing to involve children may qualify for exemption if the research falls into one of the federally-approved categories defined in 45 CFR 46. The only exemption also applicable to FDA regulated studies is the exemption regarding taste and food quality evaluation and consumer acceptance studies as also noted in 21 CFR 56. The exemption noted in 45 CFR 46 for research involving survey or interview procedures or observations of public behavior does not apply to research involving children unless the research involves only the observation of public behavior and the investigator(s) does not participate in the activities being observed.

The additional protections for children apply to all non-exempt research that is federally funded and non-exempt research that involves an intervention or interaction with a child regardless of funding source. Studies proposing to involve children may qualify for expedited review if the study falls into one or more of the federally-approved expedited categories published in the guidance in the Federal Register. The DHSP, in consultation with the IRB Chairs, may develop additional categories of research that are deemed minimal risk and eligible for expedited review providing the research is not federally funded or supported. The assigned IRB reviewer will make the final determination regarding approval status and categories.

When the additional protections apply, the IRB may approve research involving children if the IRB finds that the research satisfies the conditions of all applicable sections noted below.

#### **No More than Minimal Risk:**

For research not involving greater than minimal risk the IRB must find and document:

- that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
  - when parental permission is to be obtained, the IRB may find that the permission of one parent or guardian is sufficient.

**Greater than Minimal Risk / Prospect of Direct Benefit:**

For research in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subjects well-being the IRB must find and document that:

- the risk is justified by the anticipated benefit to the subjects;
- the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches; and
- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
  - when parental permission is to be obtained, the IRB may find that the permission of one parent or guardian is sufficient.

Use of a placebo, or routine monitoring for safety, is not considered to provide direct benefit to subjects.

**Greater than Minimal Risk / No Direct Benefit:**

For 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 the IRB must find and document that:

- the risk represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to subjects 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 subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition; and
- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
  - when parental permission is to be obtained, both parents/guardians must give their permission unless one is deceased, unknown, incompetent or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child.

**Not Otherwise Approvable:**

For research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children the IRB must find and document:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and
- for studies funded or supported by DHHS, the Secretary, or for studies subject to FDA oversight the Commissioner, after consultations with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either that the research in fact satisfies one of the set of conditions described above, or the following:
  - the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children;
  - the research will be conducted in accordance with sound ethical principles; and

- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

**Assent:**

The IRB must 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. The judgment may be made for all children to be involved in research under a particular protocol, or for each child. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Assent is not a necessary condition for proceeding with the research 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 IRB may also waive the assent requirement. Likewise, the dissent of the child, though normally respected and honored, may be overruled by the child's parents at the discretion of the IRB. In such situations the IRB will consider the present health status of the child, the child's wishes and the level of discomfort and risk to which the child will be exposed.

**Permission:**

In accordance with and to the extent that consent is required under regulation, the IRB shall determine that adequate provisions are in place for soliciting the permission of each child's parents or guardian.

In addition to the provisions for waiver of consent contained in DHHS regulations, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subject (e.g., neglected or abused children) it may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity status and condition. This is not applicable to FDA regulated studies.

Permission by parents or guardians shall be documented in accordance with and to the extent required by regulations. FDA regulated studies do not qualify for the exception to the requirement to document consent.

**Wards:**

Children who are wards of the state or other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, or research that is not approvable under a defined regulatory category but that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children only if the research is 1) related to their status as wards, or 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved, the IRB will require 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 be the advocate for more than one child. The individual acting as the advocate shall have 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 (except as the advocate or IRB member) with the research, the investigators, or the guardian organization

### ***Procedure***

See policy 2011-006.0 – Additional Protections for Certain Populations: General

In addition, when research is conducted outside of Connecticut, and review and approval by a local IRB or its equivalent is not required, the investigator must consult with legal counsel as to who is considered a child, and if applicable legally authorized representative or guardian, in the jurisdiction where the research is to be conducted and submit documentation of legal counsel's opinion.

The procedures outlined below are general and may be altered by the IRB depending on the nature of a specific study and the mental and physical status of the children involved.

- If the subject is 12 years of age or older, the child signs and dates an assent signature line on the consent form and a parent or guardian also signs the consent form. No separate assent statement is required.
- If the child is between 7-12 years of age, and the study is a therapeutic trial the child does not have to sign and the parents sign the consent form.
- If the child is between 7-12 years of age and the study is not a therapeutic trial, the parents or guardians sign the consent form and the subject signs an assent statement that is either included at the end of the consent form after the signature lines or as a separate document.
- If the child is less than 7 years of age, the parent or guardian signs the consent form, the subject signs nothing. No assent statement is required.

### ***Related Policies***

2011-006.0 – Additional Protections for Certain Populations - General

2011-007.0 – Definitions Applied to Policies

2011-008.0 – Informed Consent Form

2011-008.2 – Informed Consent - Waivers and Alterations

2011-008.3 – Informed Consent - Assent

2011-008.5 – Informed Consent - Providing and Obtaining Informed Consent

2011-009.2 – Institutional Review Board – Exemptions

2011-009.3 – Institutional Review Board – Expedited Reviews

2011-009.5 – Institutional Review Board – Review by Convened Board

### ***Basis***

45 CFR 46

21 CFR 50

### ***Document Attributes***

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**Reviewed and Approved By:**

***Richard H. Simon***

**Richard Simon, MD**

**Director Human Subjects Protection Program**

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**Date**