



IRB Standard Operating Procedures		
SOP#: 005 Revision#:	Title: Assent and Parental Permission	Effective Date: October 12, 2018
Approved By:	Institutional Review Board	Approval Date: October 12, 2018

PURPOSE

To set forth the requirements for obtaining child assent and parental permission in studies with children as research subjects.

DEFINITIONS

Assent - a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

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.

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

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

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

Parent - a child's biological or adoptive parent.

Written, or in writing - writing on a tangible medium (e.g., paper) or in an electronic format (definition for purposes of this part).

POLICY

Assent

Assent: agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent is typically paired with parental permission from a parent or guardian, and together they comprise the informed consent to participate.

Children (minors) are a vulnerable research population and, as such, require additional protections when they are potential research subjects. Subpart D of both 45 CFR 46 (DHHS), and 21 CFR 50 (FDA) require certain additional protections for children involved as subjects in research. The requirements of Subpart D apply to all non-exempt research involving children conducted under the auspices of Northeastern Illinois University. The regulations require that adequate provisions be made for soliciting the assent of all children involved in research, when the children are capable of providing assent. In determining whether children are capable of assenting, the ages, maturity and psychological state of the children should be taken into account.

In general, children should be given developmentally appropriate information about a research study in a language and manner that is understandable to them, given their age, maturity, and cognitive abilities.

- **For children under the age of 7:** Typically, minors under 7 years old should provide oral assent. The oral assent script should be conversational and stated in such a way that is understandable and age-appropriate. **The script or study records must document that assent was obtained.** Assent should be obtained along with the consent of a parent or guardian.
- **For children aged 7-11 years:** This age group should be fully informed about the research, using language appropriate to their age and maturity, and either written or oral assent should be obtained from those deemed capable of making a meaningful decision. Assent should be obtained along with the consent of a parent or guardian.
- **For children aged 12-17 years:** Children in this age group should be fully informed about the research and written assent should be obtained. The Informed Consent Form used for adults should be adapted, with age-appropriate language, to serve as a written and signed assent for participants ages 12-17. The information provided to the subject should be appropriate to the individual's age, maturity and developmental abilities. Assent must be obtained along with the consent of a parent or guardian.

If a child is capable of assent and the Institutional Review Board (IRB) requires that assent be sought, it must be obtained before the child can participate in the research activity. Thus, if the child dissents from participating in research, even if his or her parents or guardian have granted permission, the child's decision prevails.

When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research is no longer regulated by the requirements of [45 CFR part 46.408](#) regarding parental or guardian permission and subject

assent. The investigators should seek and obtain the legally effective informed consent, as described in [45 CFR 46.116](#), for the now-adult subject for any ongoing interactions or interventions with the subjects. However, the IRB could approve a waiver of informed consent under [45 CFR 46.116\(d\)](#), if the IRB finds and documents that the required conditions are met.

Waiver of Assent

The IRB is responsible for deciding whether child assent is required in proposed research activities. Child assent is required, except in the following three circumstances described at 45 CFR 46.408(a):

- the capability of some or all of the children is so limited that they cannot reasonably be consulted;
- the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
- the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d).

Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under certain circumstances in accord with 45 CFR 46.116 and 45 CFR 46.408(a).

Parental Permission

Sections 408(b) and 55(b) of Subpart D require that adequate provisions be made for soliciting the permission of parents or guardian of each child involved in a research study. All of the requirements concerning informed consent apply to obtaining parental permission and the appropriate elements of consent must be included in a written parental permission document.

If research will be performed in the schools, it may be possible to send information home to parents that allow them to opt out. Then the teens may assent for their own participation provided their parent has not opted out.

The IRB requires the investigator to make a compelling and persuasive argument for why parental permission is not a necessary condition for proceeding with the research.

Waiver of Parental Permission

The IRB may waive the requirement for obtaining parental permission as permitted under 45 CFR 46.116 and [45 CFR 46.408\(c\)](#) when it is not a reasonable requirement to protect subjects. This waiver may apply to minimal risk research, such as surveys, interviews or focus groups.

Waiver of Documented (Signed) Parental Permission

The IRB may waive the requirements to obtain documented (signed) parent/guardian permission under the same conditions that apply to waiving signed consent from adult subjects as permitted in 45 CFR 46.117.

Wards

- Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 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 research is approved under paragraph (a) of this section, the IRB shall 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 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. This includes ensuring that to the extent possible, the child understands what will be required of him or her during the research, and that if capable, the child provides his or her assent to participate.

The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

RESPONSIBILITIES

- The IRB is responsible for reviewing the proposed assent and parental permission document(s) to ensure that all applicable federal and NEIU requirements are met.
- Investigators may only enroll subjects using assent/permission forms, which have been approved by the IRB unless the IRB grants a waiver from the requirement for informed consent or documentation.

PROCEDURES

- The principle investigator (PI) submits an IRB application which includes a proposed assent and parental permission procedure and written forms prior to initiation of research.
- The IRB application must indicate which study personnel will participate in the assent and parental permission procedure or individuals the PI will authorize to obtain assent and permission on his/her behalf.
- The NEIU IRB provides **assent and parental permission templates**, available on the IRB website. Investigators should use the templates unless the IRB grants exemption or a waiver.
- The IRB will assess the PI's description of the assent and parental permission process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject or subject's legally authorized representative; be in language understandable to the subject; be obtained under circumstances that allow

the subject to adequately consider whether or not to participate; be obtained under circumstances that minimize coercion or undue influence; does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence).

- The IRB is responsible for reviewing the proposed assent and parental permission document(s) to ensure that all applicable federal and NEIU requirements are met.
- Investigators may only enroll subjects using assent/permission forms, which have been approved by the IRB unless the IRB grants a waiver from the requirement for informed consent or documentation.

REGULATIONS

[45 CFR 46.408](#)

[45 CFR 46.116](#)

[45 CFR 46.117](#)

[21 CFR 50.55](#)

[HHS Research with Children FAQs](#)

AUTHOR REFERENCE

NEIU IRB

[George Mason University IRB SOP “Informed Consent, Assent, Parental Permission, and Documentation”](#)

[The University of Chicago Social & Behavioral Sciences IRB Manual](#)

Contact Information

Please direct questions or concerns about this policy to:

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Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.