Instructions for Assent Templates

Under the federal regulations (45 CFR 46) for human subjects research, informed consent must be sought from each prospective subject or the subject’s legally authorized representative (usually the parent or legal guardian) and the informed consent must be appropriately documented as outlined in section 46.117 of the regulations. The concept of obtaining consent and documenting consent are listed as separate requirements because there are times where it is appropriate in the research to waive or alter the consent process, or waive the requirement of documentation of consent (obtaining a written signature on a form). When you waive the documentation of consent, this means that the consent process and all the information required under the regulations to be part of the consent process are still presented and discussed with the subject, but the researcher does not obtain a signature on the consent or Parent/Legal Guardian Permission form.

The term consent is used generally in Subpart A of the regulations (45 CFR 46.116) to refer to adult consent, parent/legal guardian permission, and assent. In Subpart D of the regulations, Additional Protections for Children Involved as Subjects in Research, the principle of consent is broken down further into parental permission and assent. In Subpart D the following terms are introduced and defined:

(a) **Children** are 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.
(b) **Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
(c) **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.
(d) **Parent** means a child's biological or adoptive parent.
(e) **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

DePaul Policy indicates that for children age 6 and under assent is not required. In general, verbal assent is obtained for children ages 7-10 and written assent is obtained for children ages 11-13, and ages 14-17. DePaul has three assent templates for the differing age groups to accommodate the differences in maturity, reading ability, and comprehension ability in the differing age groups. The IRB needs to understand the age groups of the children being targeted for enrollment and have an understanding of their maturity level and psychological state in order to make the best determination regarding the assent process which is appropriate for a specific research protocol and whether that assent process should be verbal or written. For additional guidance on the assent process, refer to the OHRP website: [http://answers.hhs.gov/ohrp/categories/1570](http://answers.hhs.gov/ohrp/categories/1570)

There are times that assent for children may be waived. Under 45 CFR 46.408 (a): *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 children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A*
It is important to remember that obtaining assent, much like obtaining consent, is a process and not about obtaining a signature on a form. The assent process involves the presentation and discussion of the content of the assent by the investigator to the child, the investigator addressing the child’s questions or concerns, the investigator assessing the child’s understanding of the information, and then finally obtaining the child’s assent or agreement to be in the study either verbally or in writing.

Under the federal regulations (45 CFR 46), when possible, the required basic elements of consent that must be included in the assent document or process are:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additionally, the federal regulations detail optional consent elements that should be included in the assent document, when applicable to the research or depending upon the comprehension level or age of the children being recruited for the research.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

Investigators should complete the appropriate assent template when children are to be included in the research. Keep in mind that what is a child is defined by local or state law, so if the research is conducted in another state or country the age at which a child is considered to be an adult may differ from Illinois state law. Additionally, if the research plans to recruit children from a wide range of age groups, it is possible that one study may require more than one assent document/script.

When the template is completed, the investigator should ensure that all instructional text has been deleted, that all text is one size (size 12 font), that all text is black (except for any links or email addresses), and that there is a footer which contains the version date and the page numbers in and X of Y format. The assent document should be sent to the IRB as a stand-alone WORD document. KEEP IN MIND that the language level of the assent document should be tailored to the children that will be enrolled in the study, with special attention being paid to simplify language as much as possible.

When the assent document is approved, the IRB will complete the approval information in the upper right-hand corner, and will convert the document to a PDF. Investigators should use a copy of this actual document with the approval stamp present when obtaining written or verbal assent or when providing copies of approved assent documents or scripts to the child.

If you have any question about completing the assent template, please contact orp@depaul.edu or the Research Protections staff.