

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: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>

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.

The elements of assent are based upon the required elements of consent outlined in the Federal regulations. However, the age and maturity level of the child may affect which elements are within a particular assent document. For example, it is not likely that a child age 7 will understand the concept of the commercialization of their tissue or financial conflict of interest of the researcher. The revised regulations at 45 CFR 46, which became effective January 21, 2019, indicate the following six General Requirements for Informed Consent in section 46.116 (a):

- (1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- (2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
 - **Coercion** occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will get a lower grade in a class or lose their job standing if he or she does not participate in the research.
 - **Undue influence**, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, the investigator offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized and research participation remains voluntary.
- (3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- (5) Except for broad consent obtained in accordance with paragraph (d) of this section (116):
 - (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
 - (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- (6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or

releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- Examples of exculpatory language:
 1. By agreeing to this use, you should understand that you will give up all claims to personal benefit from commercial or other use of these substances.
 2. I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
 3. I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.
- Examples of acceptable language:
 1. Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
 2. The products developed from this research may have commercial value. There are no plans to provide financial compensation to you should this occur.
 3. By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
 4. DePaul University and the hospital where some of the research is conducted are not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you were injured as a result of the research you should contact: [\[insert name and contact information for the investigator.\]](#)
 5. DePaul University and the hospital where some of the research is conducted make no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you were injured as a result of the research you should contact: [\[insert name and contact information for the investigator.\]](#)

Under the revised federal regulations (45 CFR 46.116 (b)) the nine required basic elements of consent that must be included in the consent 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;
- (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;
- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (i) A statement that the identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additionally, the federal regulations (45 CFR 46.116 (c)) detail nine additional elements of consent that should be included, when appropriate to 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) that are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject;
- (6) The approximate number of subjects involved in the study;

- (7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

For research which requires expedited or full review, investigators should create a research-specific assent document using the DePaul assent template provided on the forms and templates section of the IRB website. The investigator should review the optional elements of consent listed above to ensure that they are included in the final document, if they are applicable to the specific research protocol and age appropriate for the child. The assent template for older children includes all the elements and indicates whether a particular section is required or optional based upon the research design. Please note that although the regulations include the subject number in the additional elements, the DePaul IRB requires the presence of this information in all consent documents.

Investigators should complete the appropriate assent template when children are to be included in the research. Keep in mind, who is a child (a minor) 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. The templates for younger children are simplified further to make them understandable to the suggested age range. The age ranges are not written in stone and if study is fairly simple, it is possible to use one assent document for multiple age ranges.

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 Office of Research Services, Research Protections staff.