**Assent of a Minor Form and Process Preparation**

In accordance with 45 CFR 46.402(b), assent is defined as a child’s affirmative agreement to participate in research. The child must actively show his or her willingness to participate in the research rather than just complying with directions to participate and not resisting in any way. Mere failure to object, absent affirmative agreement, should not be construed as assent. Assent is obtained from each child who participates in research unless they are not capable of understanding what is being asked of them.

The purposes of assent are:

* information exchange between the research team and the child
* enhances decision making process between the parents and the child
* granting child ability to exercise dissent

When creating the process, the following components must be considered: ages, maturity, psychological state of the children involved and the nature of the proposed research.

**Assent Process Protocol Description**

Investigators have a legal and ethical obligation to ensure that prospective subjects/subjects’ representatives have sufficient knowledge and comprehension of the elements of process and the study. To allow the IRB to make the determination that prospective subjects will be adequately informed of the research, the protocol must describe the following elements:

***Process of Assent***

Describe who will obtain assent, how the assent process will be structured, and what will be done to ensure the process is conducive to rational and thoughtful decision making by the child/subject. Describe the use of additional tools that will be used to assist children in understanding the research (e.g.: plush toys, pictures, dolls, etc). Describe how children will be made to feel comfortable. Describe how questions will be answered. If necessary to use ‘Auditor/Witness’ and/or translator, these roles would be described in this section.

***Subject Capacity***

Describe the age of the children, their ability to provide assent and how their individual capacity to understand will be assessed in this project. If it is expected that some or all of the children will not have capacity to understand the research, justification for why the children will not have capacity and therefore will not be able to provide assent must be included.

Determination of a child’s ability to assent should be based on the following components:

1. the nature of the proposed research
2. age
3. maturity level
4. psychological capability

For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity limits their ability to fully comprehend the nature of the research project but who are still capable of being consulted about participation, it may be appropriate to focus on conveying an accurate picture of what the participation in the research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort.

As stated in 45 CFR 46 Subpart D; when the IRB determines that assent is required, it shall also determine whether and how assent must be documented in the study. The IRB relies on the information provided by the researcher when making this determination.

***Subject/Representative Comprehension***

Describe how it will be determined that the subject understood the information presented. This section should clearly document that the investigator has an adequate plan in place to assure an acceptable level of comprehension before assent is obtained. This section should also include a specific plan to assess comprehension during assent (the subject’s agreement).

***Documentation of Assent***

The PI is responsible for ensuring that assent is obtained and documented for all subjects, when appropriate. If not already addressed in item two above (Process of Assent) specifically describe how assent will be documented and how/where documentation will be stored.

**The Assent Process**

The National Cancer Institute suggests like the informed consent process, the assent process is intended to be an ongoing, interactive conversation between the research team and the child or young adult. The process is not about getting the young person "to sign on the dotted line"; rather, it is about making sure they understand the study and what it means to participate. By engaging young people in understanding the research project, health care providers and young patients may become "partners" in the project. Children are likely to feel more in control and more involved in the trial as a result.

The assent process should reflect a reasonable effort to enable a child to understand, to the degree they are capable, what their participation in research would involve. More than one method for obtaining assent may be used when participants represent a wide range of ages. Verbal assent is appropriate for children who are younger then the age of 7.

For children approximately age seven and older, assent is sought either verbally or in a simple form written at the second or third grade reading level. Children 14 and older may understand the language presented in the consent form for parents. If so, they may sign the consent form along with the parent or guardian.

Template assent forms for children ages 7-17 are available on the IRB website.

**Tips for Preparing an Assent Form Document and Process**

1. Keep language simple.
2. Use larger type and pictures for younger age groups such as 7-11 years. Try to limit to one page, if possible.
3. Ensure the information in the form matches what will be verbally exchanged with the child during the assent process.
4. Ensure study procedures that are not part of the child's regular care are highlighted.
5. Any information that can affect a child's decision to take part should be included, e.g., stating that the study involves approaching the child's teacher about how the individual acts in school, or inviting playmates to take part in the study.
6. Take your time. The consent process may take more than one visit to complete. Ensure all questions are addressed that are asked and encourage the child to ask questions.
7. Involve the family in the process. Ensure the child is comfortable as much as he or she can be in the situation.
8. Think outside the box when creating the assent process. A video tape of procedures to be completed or a power point may assist the child in understanding more of what is happening. The use of dolls or plush toys may assist in explaining procedures.
9. Explain technical and scientific terms in common terms, taking into account the child’s reading level and level of understanding.
10. Although not prohibited by regulations, use of the wording, "I understand..." in assent documents may be inappropriate as many prospective subjects will not "understand" the scientific and medical significance of all the statements. Second person writing style helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject agreement, i.e., the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension.
11. Federal Regulations state that 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 the waiver of consent regulations.

**Some Additional Thoughts**

In case where a child may lack the capacity to assent to participate, assent may be waived for that child. This type of waiver may be used on a case by case basis when the researcher believes that the age, maturity level, and psychological state of the particular child would not yield adequate assent. This should be used sparingly and when possible in consultation with the IRB. The researcher should always report such instances to the IRB immediately following the consent/assent process.

Researchers should note however, that since assent of minor is based upon the basic ethical principle -respect for persons -the researcher may not ask for assent only from compliant subjects or depend solely on parental permission. If assent is requested of and not granted by a child, the child's refusal to participate in the research is binding.

**Parental Permission**

Unless parental permission can be waived, adequate provisions must be made for soliciting the permission of the parent(s) or legal guardian(s). The regulations define “permission” as the “agreement of parent(s) or guardian to the participation of their child or ward in research.” The term “parent” means a “child's biological or adoptive parent.” The term “guardian” means “an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

The Protocol must outline the study team’s plan to obtain parental permission from either one or both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Generally, permission should be obtained from both parents before a child is enrolled in research. However, the IRB may find that the permission of one parent is sufficient.

**Waiver of Parental Permission**

The IRB may waive the requirement for obtaining consent from a parent or legal guardian for research if both of the following are true: the research meets the provisions for waiver in 45 CFR 46.116 (f) or the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). For such studies, an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver cannot be inconsistent with Federal State or local law. In these types of research, the children who are the research subjects should be given the full opportunity for informed consent as if they are adults, or the Principal Investigator should propose alternative procedures for protecting the rights and interests of children asked to participate.

A waiver of for obtaining parental consent (permission) may be approved by the IRB if the following evidence is provided:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable

biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

1. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.