Guidelines for Research Involving Children/Minors

Researchers planning to involve children/minors as subjects in a research study need to take into account special considerations. The UNH Institutional Review Board (IRB) for the Protection of Human Subjects in Research developed these guidelines to assist researchers planning such studies.

The UNH IRB uses terms throughout these guidelines as follows:

- **Child/Minor**: Individuals who have not attained the age of majority (18 in New Hampshire and most states) in the jurisdiction where the research will take place. (Throughout these guidelines, “child” also denotes “minor” or “ward.”)

- **Parental/Guardian Consent**: Consent (permission) of parent(s)/guardian(s) to the participation of their child/ward in a research study. (Throughout these guidelines, “parent” also denotes “guardian.”)

- **"Passive" Parental Consent**: A “passive” parental consent procedure (sometimes called an “opt out” procedure) typically involves distributing a letter to the children's parents describing the study and instructing them to return the form only if they do not want their child to participate.

- **Assent**: “A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent” [45 CFR 46.402(b)].

- **Consent**: The agreement of an individual over 18 years of age to participate in a research study.

- **Minimal Risk**: “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily living or during the performance of routine physical or psychological examinations or tests” [45 CFR 46.102(i)].

**Best Practices for Researchers:**

**A. Parental Consent**

1. Consent for involvement of a child in a research study is a two-stage process. The first stage is seeking the consent of the parent(s): see C3 regarding whether one or both parents must consent. Unless waived by the IRB, parents must provide written consent to allow their child to participate in a research study; that means that unless waived by the IRB, researchers must obtain and retain for each child involved in a study a signed parental consent form. Parental consent must be obtained for a child to participate in a study before a researcher may approach the child to solicit the child’s assent (stage two); if a researcher has not obtained parental consent for a specific child, unless waived by the IRB, the researcher may not approach that child to obtain assent.

2. Researchers must obtain parental consent for the involvement in research studies of any UNH students who are under 18 years of age, or request from the IRB a waiver of documentation of parental consent (see section B on passive consent), or a waiver of parental consent.

3. Federal regulations require (or permit the IRB to require) a researcher to obtain the consent of both* parents for the participation of their child for the following:
a. If the research presents more than minimal risk and offers no prospect of direct benefit to child subjects.
b. For any proposed study where the IRB determines that consent of both parents is necessary as an additional protection for child subjects. The IRB makes this determination on a case-by-case basis, and may make this decision even in cases where the permission of both parents is not required by regulation. The IRB will notify the researcher whenever it determines that permission must be obtained from both parents/guardians for a study.

Where the IRB has required obtaining the consent of both parents, if one parent does not give his/her consent, or fails to sign and return the consent form, the researcher may not involve the child in the study.

*Exception: Consent of one parent is sufficient if the other parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the care and custody of the minor child.

4. In studies where the IRB has not required obtaining the consent of both parents, if one parent objects to the involvement of the child in the study, the researcher may not involve the child in the study, even if the other parent has given consent.

5. A parental consent form must contain the same elements as a typical consent form (see here for consent form templates) and be addressed to the parent(s). The wording of the parental consent document should be appropriate to the typical educational background of the research population.

6. The IRB may approve a waiver of parental consent if it finds the following:
   a. The research involves no more than minimal risk to the subjects;
   b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   c. The research could not practicably be carried out without the waiver or alteration; and
   d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Further, there may be certain situations in which obtaining parental consent is not in the best interest of a child. For example, a study of the effectiveness of an existing smoking cessation program in a high school, where parents are not aware of their child’s involvement in the program (and do not know that their children smoke). In such cases, the IRB may waive the requirement for parental consent, provided that the waiver is consistent with federal, state, or local law and other adequate protections are in place to protect the rights and welfare of the children. Such decisions are made on a case-by-case basis, and protections would be study-specific.

7. Researchers working in educational settings should ensure that parents know that participation in a research study is separate from any instruction, and that refusal to allow their child to participate, or withdrawing their child from participation, will affect neither their child’s participation in standard (non-experimental) educational activities, nor their child’s grade or class standing.

8. For certain studies involving more than minimal risk and where children are wards of the state, the IRB may only approve the involvement of children if the research is:
   a. Related to their status as wards; or
   b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

For these studies, the IRB will require the 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 study, and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the researchers, or the guardian organization [45 CFR 46.409(b)].

B. “Passive” Parental Consent

1. A passive parental consent procedure (sometimes called an “opt out” procedure) typically involves distributing a letter to the children’s parents describing the study and instructing them to return the form only if they do not want their child to participate. In the absence of a response (failure to object) from a parent, the researcher assumes that the parent agrees that the child may participate.

2. A request from a researcher to the IRB to approve a passive parental consent procedure is not a request for the IRB to waive parental consent; it is rather a request to the IRB to waive documentation (parent’s signature) of parental consent.

3. Researchers requesting a passive parental consent procedure for a study must provide a justification that addresses the following regulatory requirements:
   a. The only record linking the participant and the research would be the consent document when the principal risk would be potential harm resulting from a breach of confidentiality AND the research is not subject to FDA regulation; or
   b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

4. If a study in which a researcher proposes a passive parental consent procedure will take place in a K-12 school, educational program, or after-school program setting, the study must meet the following criteria in addition to the regulatory requirements (see 3a-b in this section):
   a. Participation in the study presents no more than minimal risk to children;
   b. The principal/director must give permission/agree in writing to the passive parental consent procedure;
   c. The researcher sends information to parents at least one week in advance of proposed data collection, including a due date for forms to be returned; and
   d. The researcher sends a reminder to parents several days after sending the initial information.

5. Some parents may feel that their right to determine the activities of their children has been violated if signed parental consent is not obtained.

C. Assent

1. Assent is a child’s affirmative agreement to participate in a research study. Researchers may only seek assent from children whose parents have given prior consent (unless waived by the IRB).

2. Consent for involvement of a child in a study is a two-stage process. The first stage is obtaining parental consent; if parents give consent, the second stage is obtaining the assent of the child. A child can only indicate assent by actively agreeing to participate; a child who simply goes along without actively refusing or objecting to participate has NOT provided assent.

3. Assent information should be separate from parental consent information. Researchers should solicit assent directly from children where possible, and in an environment/setting that minimizes influence, or the perception of influence, from parents, persons of authority (e.g., teachers), or researchers.

4. The means of obtaining assent from children must be age- and developmentally-appropriate for the proposed population. A researcher may need to be flexible in the approaches for obtaining assent; a single
method of obtaining assent may not be appropriate for all potential subjects. The IRB will determine for each study whether all or some children are capable of giving assent.

5. As the ability of children to understand the elements of assent generally increases with age, researchers will likely provide less detailed explanations to younger children and more detailed explanations to older students. Due to individual differences in the development of children's ability to understand the researcher's requests, there is a necessary age overlap in the categories listed below.

   a. Children ages 2-7: A simple oral request for assent is sufficient, and assent may be oral or documented in writing. For example, the researcher might ask the child if he or she would join the researcher in the next room to look at pictures. If the child were to say "yes", that would imply assent for this age group. If the child were to say "no", the researcher should respect the child's wishes. It should be possible, however, to ask the child once again several minutes later. Sometimes children may not communicate verbally their refusal to participate. For example, a child may begin working on another task unrelated to the research activity. The researcher should be aware of such a cue and end the activity.

   b. Children ages 6-14: The request for assent should include: (1) a general description of the purpose of the child's participation; (2) a brief description of the experimental tasks/participation; (3) an assurance that the child's participation is voluntary and that he or she may withdraw from the study at any point; and (4) an offer to answer questions. A researcher studying reading comprehension might say the following: "I am studying how fourth grade students read. I am going to ask you to read a few stories for me and answer questions about the stories when you are finished. You don't have to read if you do not want to do so. If at any point you want to stop, that is fine; you may stop and go back to class." Assent may be oral or documented in writing.

   c. Children ages 12-17: The request for assent should include the elements of informed consent presented to adults, but presented in language appropriate to the child's level of comprehension. Written assent should be obtained.

6. Researchers working in educational settings should ensure that children know that participation in a research study is separate from any instruction, and that refusal to participate/withdrawal from participation will affect neither their participation in any standard (non-experimental) educational activities, nor their grade or class standing.

7. When most members of a group to be studied are minors but some individuals may be over 18 years of age (e.g., a high school), researchers should treat anyone over the age of 18 as an adult unless the individual has a legal guardian and cannot legally give consent. In such settings, researchers do not need to obtain parental consent for participation in the study of individuals who have reached the age of majority and who have appropriate decisional capacity and legal status; researchers may solicit their consent.

8. Researchers should plan to solicit the consent of children who turn 18 years of age during study participation once they have achieved the age of majority.

For more information on the UNH Institutional Review Board or institutional requirements regarding research involving human subjects, please contact Research Integrity Services staff (Julie Simpson, 603/862-2003, or Theresa Cherouvis, 603/862-3536). Additional materials are available on the IRB webpage at http://unh.edu/research/human-subjects.