IRB GUIDELINE 4
Parental Consent and Child Assent

Research concerned with sensitive issues and involving the participation of children is becoming more common. Federal law defines "children" as 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. Under Florida law, persons under the age of eighteen (18) generally meet this definition of "children", with the exceptions noted below. As a result, permission of the child's parent(s) or guardian(s) must generally be obtained prior to the participation of that child in research. The following exceptions to the general rule apply, where a person under the age of 18 does not meet the federal definition of "child" and may provide legally effective consent to participate in research if either:

1. The research involves the provision of medical care or treatment, (including care or treatment deemed to be experimental) AND the person:
   o a. has graduated from high school, or
   o b. is married, or
   o c. is or has been pregnant.

2. The person is an emancipated minor.

If an emancipated minor provides consent for him or herself, the court order must be copied and included in the research records with the consent document.

Federal regulations that govern research with children include 45 CFR 46, Subpart D and Subpart D of the FDA regulations.

Such research often presents difficult questions related to the protection of human participants. The purpose of these guidelines is to help researchers plan procedures and prepare proposals that can be approved by the Institutional Review Board (IRB).

RISKS

Research on health and social issues often involves requesting sensitive information from participants, some of whom may be children. The procedures for collecting and handling such data often do pose risks to the participants. These risks may include some or all of the following:

1. Violation of Privacy: Collection of data concerning at-risk or socially questionable behavior (for example, questions about substance use or sexual activity) is viewed by many individuals as violations of privacy.
2. **Legal Risks:** Data concerning illegal behaviors may place individuals at risk of legal action, if (a) names can be linked to particular responses or observations and (b) the research has not received specific legal protection (e.g., by Certificate of Confidentiality).

3. **Psychosocial Stress and Related Risks:** Procedures that raise sensitive issues may generate stress for participants. For example, questions about at-risk behaviors may cause students to feel stress related to their self-image or contribute to perceived peer pressure.

4. **Social Relations:** Because relevant questions often request information about the behavior, or relations with, family members, peers, or authorities, some procedures may pose a risk to those relations if confidentiality is not adequately safeguarded.

In addition to these risks, which may be applicable to either child or adult participants, research involving child participants may also pose risks to parents or other family members. In particular, research soliciting information about at-risk behaviors of family members may place those individuals at legal risk. Furthermore, some parents may feel that their right to determine the activities of their children is violated if signed parental consent is not obtained.

**PROTECTION**

In general, protection from these risks may be achieved by (a) ensuring the confidentiality of information obtained about participants, (b) providing access to or information about resources for coping with psychosocial stress caused by the research procedures, and (c) ensuring that the procedures meet the principles of voluntary participation and informed consent. Guidelines for achieving this protection include:

1. **Confidentiality and Anonymity:** Information is considered **confidential** when only the investigator has access to the identity of the individual about whom information is obtained. Information obtained from individual participants must be kept confidential from public scrutiny, from parents and peers, and from legal and school authorities. This is most easily accomplished by collecting data in a manner that insures **anonymity**. Information is considered **anonymous** when names or other identifying information about individual participants can at no point be associated with observations or with responses to a survey or other data collection instruments. However, anonymity is not always compatible with research goals (for example, when data collected from the same individual at different times must be linked for analysis). In these cases, procedures for protecting confidentiality must be fully spelled out. When information that might put participants at legal risk is to be collected, it is the investigator’s responsibility to obtain and document specific legal protection (e.g., by Certificate of Confidentiality obtained from a governmental agency).

2. **Psychosocial Stress:** The procedures needed to help participants cope with psychosocial stress that may arise from participating in research will vary depending on the exact nature of the research. If such procedures are required, it will typically be sufficient to provide participants with information about resources (e.g., counselors) available to them. In cases in which more severe stress seems likely, it may be necessary to ensure that someone qualified to handle such stress be present during data collection.

3. **Voluntary Participation and Informed Consent:** These are basic ethical principles for conducting research with human participants. Participants must be informed that participation is voluntary, that answers to specific questions may be withheld without penalty, and that they may withdraw from the research at any time. Because research of this
type is often conducted in an institutional setting where participant's presence is mandatory (e.g., the school classroom), it is especially important that procedures for meeting this requirement be made explicit in the proposal.

**PARENTAL CONSENT**

- A particular concern with research of this nature is the role of parental consent for the participation of child participants. The general requirement is that explicit parental consent be obtained in writing for each participant. However, there are situations in which such a consent procedure is not appropriate.

- The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waives the requirement to obtain informed consent as outlined in 45 CFR 46.116(c) provided the IRB finds and documents:
  - The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:
    - Public benefit or service programs;
    - Procedures for obtaining benefits or services under those programs;
    - Possible changes in or alternatives to those programs or procedures; or
    - Possible changes in methods or levels of payment for benefits or services under those programs; and
  - The research could not be practicably carried out without the waiver or alteration.

- The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent outlined above, or waives the requirement to obtain informed consent as outlined in 45 CFR 46.116(d) provided the IRB finds and documents:
  - The research involves no more than minimal risk to the participants; and
  - The waiver or alteration will not adversely affect the rights and welfare of the participants; and
  - The research could not practicably be carried out without the waiver or alteration; and
  - Whenever appropriate, the participants will be provided with additional pertinent information after participation; and
  - The research is not subject to FDA regulation.

The IRB may waive the requirement to obtain a signed consent form, in accord with 45 CFR 46.117(c) when:

- The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and the research is not subject to FDA regulation; or
• The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context;

In cases in which the documentation requirement is waived, the IRB may require a script of the information or an implied informed consent form that will be provided during the consent process. That document, if requested by the IRB, is reviewed and approved by the IRB.

Researchers are reminded that the reading level of informed consent documents should be appropriate to the typical educational background of the research population, and that documents designed for college students may not be suitable for seeking parental consent. Researchers should write these documents using short sentences and everyday language. For example, "voluntary participation" may be paraphrased by "you do not have to do this if you don't want to."

OBTAINING AND DOCUMENTING ASSENT FROM CHILDREN

Parental consent is usually a prerequisite to the recruitment of human research participants who are children. However, parental consent constitutes only half of the consent process. Assent, the agreement of a child to participate in research, is the second component of the informed consent procedure for children.

The means of obtaining assent from children must be appropriate for the age ranges and levels of mental development found within the proposed participant pool. The National Commission for the Protection of Human Subjects of Biomedical and Social Science Research expects that assent be requested from children who are 6 years of age or older. However, for children between the ages of 6 and 18, the appropriate method for obtaining assent will vary. The following guidelines were proposed during a panel discussion sponsored by the National Institutes of Health:

Age 6-7

A simple oral description of the child's involvement is given to the participant and verbal assent is requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness.

Age 8-13

A more complete oral description of the research (in layman's terminology) is given to the participant. Verbal assent is requested. The procedure may be documented on the informed consent form by the signature of a witness.
Above age 13

Written assent should be requested from both parent and child, using age-appropriate and background-appropriate documents.

Although age is used as the primary criteria in determining an appropriate means of obtaining assent, factors such as literacy and mental development must also be considered. The need for flexibility in the methods for obtaining assent from children is universally recognized. Because a single method of obtaining assent may not be appropriate for all potential participants, investigators may need to be prepared to use different approaches with different participants. As in any consent process, the primary concern is that the participant is able to understand the explanation that is presented. The need for a witness to document verbal assent procedures is dependent upon the complexity of the research and the risks to the participant.

NOTE: A parent or guardian may not be the witness for a child's verbal assent document.

The IRB assesses the potential risks and benefits for each research proposal, and the provisions for permission and assent, to determine if an activity satisfies the conditions for a category of research permitted in children, as specified in DHHS 45 CFR 46.404, 46.405, 46.406 46.407 and 46.409, and FDA 21 CFR 50.51, 50.52, 50.53, 50.54 and 50.56.

The research categories are described below.

- Research that does not involve greater than minimal risk may be approved if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians (45 CFR 46.404 and 21 CFR 50.51).

  For such research the IRB determines whether adequate provisions to solicit the permission of each child's parents or guardian unless one parent is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child is made. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient.

- Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant, or a monitoring procedure that is likely to
contribute to the participant’s well-being, may be approved if the IRB finds that (45 CFR 46.405 and 21 CFR 50.52):
  o  the risk is justified by the anticipated benefit to the participant;
  o  the relationship of anticipated benefit to risk is at least as favorable as that presented by available alternative approaches; and
  o  adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

For such research the IRB determines whether adequate provisions to solicit the permission of each child’s parents or guardian, unless one parent is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child, is made. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient.

• Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition, may be approved if the IRB finds that (45 CFR 46.406 and 21 CFR 50.53):
  o  the risk represents a minor increase over minimal risk;
  o  the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
  o  the intervention or procedure is likely to yield generalizable knowledge about the participant’s disorder or condition which is of vital importance for the understanding or amelioration of the participant’s disorder or condition; and
  o  adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

For such research, the IRB requires the permission of both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child.

• Research that is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children may be approved if the IRB and the Secretary of the Department of Health and Human Services (DHHS), after consultation with a panel of experts in pertinent disciplines and following an opportunity for public review and comment, find that:
  o  the research in fact satisfies one of the above three conditions (45 CFR 46.407 and 21 CFR 50.54); or
- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- the research will be conducted in accordance with sound ethical principles; and
- adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

For such research, the IRB requires the permission of both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child.

If the IRB has determined that the permission of both parents is required, permission granted by one parent will nevertheless be sufficient if the other parent is deceased, unknown, incompetent, not reasonably available or if the parent granting permission has legal responsibility for the care and custody of the child. In order to establish that only one parent has legal responsibility for care and custody of a child, an order issued by a court from the state in which such parent resides must grant sole custody of the child to such parent. A copy of the court order should be retained with the documentation of the parent's permission.