



OBTAINING AND DOCUMENTING ASSENT FROM MINORS

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

The means of obtaining assent from minors must be appropriate for the age ranges and levels of mental development found within the proposed subject pool. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research expects that assent be requested from children who are 7 years of age or older. However, for children between the ages of 7 and 18, the appropriate method for obtaining assent will vary.

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| Age 6-7 | A simple oral description of the child's involvement is given to the subject and oral 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 subject. 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 minors is universally recognized. Because a single method of obtaining assent may not be appropriate for all potential subjects, investigators may need to be prepared to use different approaches with different subjects. As in any consent process, the primary concern is that the subject 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 subject. Minor status may be defined differently by federal government agencies.



OBTAINING ASSENT FROM CHILDREN OR MINORS

Parents, legal guardians, or a legally authorized official must sign consent forms permitting minors to participate in research projects. The Informed Consent Document for children or minors must be prepared with the same thoroughness as the Informed Consent Document for adults. An Informed Consent Document for children or minors must be completed by the child or minor’s parent/guardian.

Both children and minors are required to sign an “Assent” Form. The following are two samples of Assent Forms. Language must be simplified as appropriate for the age group used as subjects, such as:

SAMPLE ASSENT DOCUMENT FOR RESEARCH INVOLVING MINORS
(Note: This format is suggested by the IRB. Please print on college or department letterhead.)

CHILD/MINOR ASSENT FORM

I, _____, understand that mom and dad have said it’s okay for me to take part in a project about _____ under the direction of _____. I am taking part because I want to. I have been told that I can stop at any time I want to and nothing will happen to me if I want to stop.

Signature

Witness by Parent/Guardian

* * * * **OR** * * * * *

I, _____, understand that my parents have given permission for me to participate in a study concerning _____ under the direction of _____. My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose not to participate, it will not affect my grade (treatment/care, etc., as appropriate) in any way.

Signature

Witness by Parent/Guardian

For children unable to read and sign written assent forms, a verbal script for assent should be submitted in lieu of the above.



LETTER OF CONSENT
(REQUEST FOR WAIVER OF STANDARD INFORMED CONSENT FORM)

[Please follow the directions printed in red and print on college or department letterhead.]

Dear _____,

I am a professor/graduate student under the direction of Professor Insert PI's name here, in the insert College/Department name here at Florida Gulf Coast University. I am conducting a research study entitled Insert the Project Title Here. The purpose of the research is to Insert a variation of the hypothesis statement or research question here.

You are being asked to participate in this study. Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, it will not affect your [or your child's] grade (treatment/care, etc.). The results of the research study may be published, but your [or your child's] name will not be used. Your participation will involve Insert a summary of the subject's role, including the expected duration of the subject's participation.

Although there may be no direct benefit to you (or your child), the possible benefit of your participation is Insert an explanation of the anticipated benefits of the study.

Insert an explanation of any anticipated discomfort or risks involved. Describe the procedures designed to minimize any risks.

If you have any questions concerning the research study [or your child's participation in this study], please call me [or Dr. Co-PI] at Insert phone number. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects' Institutional Review Board through Sandra Terranova, Office of Research and Sponsored Programs, at 239-590-7522.

If this is to be attached to an anonymous questionnaire, include: Return of the questionnaire will be considered your consent to participate.

Sincerely,

Insert Your Name, Title
Department

*** Alternate closing for Parental/Guardian Consent ***

I give consent for my child/ward Insert child's name to participate in the above study.

Signature

Date



GUIDELINES FOR PARENTAL CONSENT

Research concerned with sensitive issues and involving the participation of minors is becoming more common. In Florida, individuals under the age of 18 are generally considered minors. Such research often presents difficult questions related to the protection of human subjects. The purpose of these guidelines is to help researchers plan procedures and prepare proposals that can be approved by the Behavioral IRB.

RISKS

Research on health and social issues often involves requesting sensitive information from subjects, some of whom may be minors. The procedures for collecting and handling such data often do pose risks to the subjects. 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) are 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 minor or adult subjects, research involving minor subjects 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 subjects, (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 subjects 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 subjects 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 subjects 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 subjects 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 subjects 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 subjects. Subjects **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 subjects' presence is mandatory (e.g., the school classroom), it is especially important that procedures for meeting this requirement be made explicit in the proposal.

The procedure for obtaining informed consent must be documented; often this requirement can be met by informing subjects that responding to survey items constitutes permission to use the collected data, without identifying individual subjects, in published reports of the research.

PARENTAL CONSENT

A particular concern with research of this nature is the role of parental consent for the participation of minor subjects. The general requirement is that explicit parental consent be obtained in writing for each subject. However, there are situations in which such a consent procedure is not appropriate. The IRB **may** approve the research as meeting Federal requirements for exemption when **all** of the following conditions are met:

1. Data collection is **anonymous**; that is, at no point are subjects' name associated with information about them.
2. Data are collected as part of a required or elective education program in which subjects are already participating; for example, a school curriculum, school band, school sports, etc.
3. Participating in the research does not involve risks greater than those incurred by participating in the relevant educational program.

These conditions are not met, and parental consent **is** required, when:

1. A data base linking identifying information with responses is maintained, or subjects' identities can be otherwise linked to information about them; or
2. The research instruments elicit information about the behavior of specific individuals, rather than about conceptual knowledge covered by the educational program.

There may be additional exceptions to this requirement in other special circumstances. Such circumstances must meet criteria established by 45 CFR 46 at sections 116.d. and 408.c. Usually such exceptions are based on demonstrating one or more of the following:

1. That seeking parental consent increases the risk to subjects;
2. That no meaningful parental consent can be obtained; or
3. That the research cannot practically be conducted if parental consent is required (please note that "practically" here refers to insurmountable obstacles rather than the researcher's convenience).

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."