Appendix B: Research Involving Children as Subjects

45 CFR 46.401 covers specific requirements for research involving children. The regulations define 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." Children are considered a protected population because of their inability to provide legal consent. Instead, the typical process involves permission from the parent or guardian and assent from the child. Requirements regarding this depend on the risk level of the research. A thorough risk/benefit analysis is required.

Projects involving no more than minimal risk require the assent of the children and the permission of the parents or guardians. **Please note** that the portion of Exempt Category 2 regarding educational survey or interview procedures does not apply to children, nor does the observation of public behavior unless the investigator is not participating in the activities being observed.

If the research involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects, the risk must be justified by the anticipated benefit to the subject, and adequate provisions must be made for obtaining the assent of the children.

If the research involves greater than minimal risk and no prospect of direct benefit to the individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition, the permission of both parents is required 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.

1. Provide a justification for the inclusion of minors that documents the benefits that are likely to accrue to a child participating in the project.

2. Specify how **parental permission** will be obtained and documented. Attach copies of all letters and permission forms.

3. Specify how you will obtain **assent** of minor subjects. Attach copies of assent forms for children who can read (8 to 17 years) or script (for children under 8 years) for verbal assent. If you will not be obtaining assent, please justify why assent shouldn't be required.

4. If subjects are school children and class time is used to collect data, describe in detail the activity planned for non-participants. Who will supervise those children? This information must also be included in the consent form.

5. For projects involving children under 8 years of age, what non-verbal cues will you watch for to indicate the child is ready to end or pause participation?

6. Specify provisions for minimizing **coercion** of minors to participate.