Children in Research

When is a child capable of assent?

There is no absolute regulatory or ethical standard for assent. 45 CFR 46.408(a) requires that "adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent." In short, it's the IRB's call. But some guidance is offered: "In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved."

Taking this guidance into account, IRB policy requires researchers to obtain written assent from all subjects between the ages of 8 and 17 unless a clear justification of waiver or alteration of assent is provided and approved.

Back to Top

What about documenting assent?

There is no absolute regulatory or ethical standard for documentation of assent. 45 CFR 46.408(e) states: "When the IRB determines that assent is required, it shall also determine whether and how assent must be documented." There's a strong implication that documentation would be the usual requirement. That is, the regulations give the IRB the authority to waive the requirement for assent in certain circumstances. That level of regulatory oversight suggests that failure to solicit assent is a serious violation; that, in turn, suggests that there should be a mechanism for knowing whether such a violation has occurred.

The IRB expects investigators to describe what they are doing about assent of minors in research, and how they're documenting it. We often encourage (or even require) the use of a written assent form for a couple of reasons:

- First of all, it is symbolic – saying that the child's right to involvement in this process is real.
- Second, the form, if well done, is a useful tool in explaining the study to a child and serves as a reference source for that child.
- Third, making the investigator think through a study well enough to be able to write a clear and simple assent form may make the researcher actually understand the study better and do a better job on the adults' consent form, too.
- Fourth, the use of a form satisfies the documentation issue.

An oral assent process with less detailed documentation may certainly also be acceptable, especially in studies of very low risk. Researchers may wish to propose this option.

Back to Top

Is assent always required?
There is an assent requirement for each of the four categories(45 CFR 46.404 - 407) of allowable research. However, the IRB has the same authority to waive the requirement that it has to waive consent in other contexts (as set forth in 45 CFR 46.116). The first requirement for the waiver of consent is that the research not involve greater than minimal risk—as such, this is only applicable to the first of the four categories.

There's also a special consideration. A parent or guardian may choose to have a child receive medical treatment over that child's objections. When a study provides access to a therapy not otherwise available, and that therapy seems likely to be superior to anything available outside of a study context, the parents' right to make medical decisions for a child may come into conflict with the child's right to grant or withhold assent. In that case, an IRB may waive the requirement for assent. Again, the researcher should consider these facts and propose a waiver if deemed appropriate.
This IRB has viewed this as having no real impact on the level of information it is appropriate to provide to the child. If the child is old enough to be involved in the process, s/he should be involved in the process. The ethical principle of respect for persons doesn't go away, simply because the decisional authority resides elsewhere. But now the exchange becomes an information-only process rather than an information-and-assent process, and it's best to avoid terms like "assent" or "assent form" and use "information" or "info sheet."

Back to Top

What should be covered in an assent process?
The regulations provide little guidance. The essential elements of the consent information should be provided, at a level and to the extent that the child is able to understand it. A lot of the formulaic elements (like compensation) can be omitted, but one should include:

1. What the subject is being asked to do,
2. What the risks are likely to be,
3. What benefits there might be,
4. That participation is entirely voluntary,
5. A statement of what the research is about.

Back to Top

Is parental permission always required?
There is a parental permission requirement for each of the four categories of allowable research (45 CFR 46.404 - 407). However, the IRB has the same authority to waive the requirement that it has to waive consent in other contexts (as set forth in 45 CFR 46.116). The first requirement for the waiver of consent is that the research not involve greater than minimal risk—so, like the waiver of assent, this is only applicable to the first of the four categories(45 CFR 46.404).

There are circumstances in which getting parental permission may be against the best interests of the child. The specific example cited in 45 CFR 46.408(c) is a study of abused or neglected children. In that case, the IRB may waive the requirement for parental permission, provided that adequate other protections are in place to protect the rights and welfare of the children. Appropriate protections would be very study-specific; for the example cited, there may be a person-appointed by a court or a child protection agency who would be an appropriate person to approve (or not) the inclusion of the child in the study.
Contact the MCIRB in cases where applicability of the requirement for parent/guardian consent is not clear.

Back to Top

When is permission from both parents required?
For research approved under 45 CFR 46.406 or 407, regulations require permission from both parents. In some situations, this is not always possible as both parents/guardians may not be "reasonably available." For example, there may be only one parent or guardian; one parent may have sole custody after a divorce; one parent may be unavailable for reasons honorable or no. The regulations allow for single-parent or single-guardian permission in such circumstances. A simplified way to read this requirement is that, if there are two parents in the picture, the child may not be enrolled in the research unless both parents agree to grant permission.
Researchers should document in the subject's file the reason(s) for deciding that one parent/guardian is not "reasonably available."

Note that the circumstance where the research has real potential benefit, 45 CFR 46.405, the two-parent/guardian signature requirement does not apply.

Back to Top

What should be covered in a parental permission process?
The requirements are the same as those for a consent process when the prospective subject is a competent adult. 45 CFR 46.408(b) says simply "the IRB shall determine, in accordance with *and to the extent that consent is required by* 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian." (italics added)

Back to Top

What about documentation of parental permission?
The requirements are the same as those for a consent process when the prospective subject is a competent adult. 45 CFR 46.408(d) says simply "Permission by parents or guardians shall be documented in accordance with *and to the extent required by* 46.117 of Subpart A." (italics added)

Back to Top

What about emancipated minors?
Emancipated minors are not specifically covered by federal research regulations and emancipated minor laws do not address research participation. In many jurisdictions, a person may become "emancipated" before the age of majority by marrying or be demonstrating full independence. For example, if the parents of a 16- or 17-year-old are killed, and that "child" is already employed or headed to college on a scholarship or otherwise capable of living independently, no guardian may be appointed and the child may have most of the legal rights of an adult—including the full right to consent to medical care.

Although no emancipated minor statute addresses consent for research participation, the authority to grant such consent seems a reasonable inference from the other legal entitlements of the emancipated state.

Even less clear is the situation of "selective emancipation." Many states have laws allowing minors to seek medical attention for certain problems such as drug abuse, pregnancy, contraception, sexual assault, sexually transmitted diseases or the sequelae of parental abuse or neglect. Sometimes the provision is a part of the emancipated minor statute ("...shall be considered as emancipated for the purposes of..."); sometimes it's separate ("...shall be entitled without parental consent or permission to seek medical attention for..."). Semantically, one can make an argument that the former sort of wording should entitle the minor to give consent for research specifically in the area for which s/he is "selectively emancipated." However, the statute does not actually make such an entitlement explicit, and there is no case law offering guidance.

This IRB has traditionally been very cautious on this point. If the research would qualify for waiver of parental permission, that finding is more clearly allowable than is a finding that the child can be his or her own consent

authority. If the research would not qualify for such a waiver, this IRB has been very reluctant to approve it. Extreme scenarios can be imagined, but they are certainly not common.

Back to Top

What about minors who want to refuse therapy?

The parents' authority to make medical decisions for a child "trump" the child's decision not to grant assent. Although these are matters typically discussed with an attorney, it is appropriate for investigators and IRBs to be aware that the parents' authority may not be absolute in this context. Courts have on many occasions ruled that a "mature adolescent" may decide against further medical care and that such a decision should be honored.

The scenario is easy to imagine: The desperate parents are grasping at any straw to save their child; the child has had enough, and the therapy being offered is a "long shot" with a lot of toxicity. If that therapy is available only in a study context, such a case may fall into the IRB's lap.

Sometimes it's not a practical question, because the child's co-operation is key to the therapy's administration—if the child dissents, it simply isn't going to happen. Other times, the child's active resistance might be required to prevent the therapy, and s/he may be too sick to resist.

Ordinarily, this sort of discrepancy between the parents' decision and the child's decision is symptomatic of a problem that is not a matter of regulatory mandate or legal entitlement. The child may be depressed; the parents may have unrealistic hopes; the child may value different goals and outcomes differently from the parents; the real prospects may have been misunderstood; there may have been mixed messages from different information sources. The first intervention should probably be to try to understand the reasons for the different decisions and see if a resolution can be found that respects everyone's concerns. Social work and clinical psychology consultation may be helpful (remembering that their role is not to talk the child into accepting the therapy).

If no resolution is forthcoming, the arbiter probably should be a court of law rather than the IRB. The decision is likely to hinge on whether the child in question is a "mature adolescent," and the IRB ought not get into the business of making that sort of decision about an individual potential subject.

The IRB's role in such a circumstance should be to insist on respect for the autonomy of the subject. The child's decision should not be lightly overridden by the parents' preferences if the child is mature enough to make the decision. There should be a process, rather than a fiat.

Back to Top

Children in Exempt Research

Exemptions under the federal exempt categories may be applied to research involving children with one exception. Research involving surveys, questionnaires and observation of public behavior can only be except if it involves observation of public behavior in which the investigator plays no part (in research in which no identifiers are recorded).

Back to Top

Are there any other resources on research with children?

OHRP provides a set of Frequently Asked Questions (FAQs) to help clarify issues related to research involving children. You also may access these FAQs from the OHRP website's Policy and Guidance page under the header "children."

Back to Top