Enrollment of Minors in Research – Principles and Guidelines

Parents or legal guardians are authorized to grant permission for their minor children to be enrolled in research by completion of a consent form. Informing, empowering, and showing respect for children can be served by obtaining their assent to participate in research. Whoever is legally permitted to grant permission will be permitted to sign the HIPAA Authorization Form.

NOTE: In contrast to HHS policy, FDA regulations require parental consent for all drug trials.

Ages 7 to 17

Whereas parents or legal guardians are authorized to grant permission for their minor children to be enrolled in research, the assent of minors between the ages of 7 and 17 is usually required for participation in a research protocol. Therefore, a minor between the ages of seven (7) and seventeen (17), who is capable of giving assent, should be requested to assent to participation in a research protocol.

Please note: If the minor is the parent of a child or has married, parental permission is generally not required and the minor may grant his or her informed consent. The minor should be assessed to ensure he/she has the capacity to weigh the benefits, risks, alternatives and other required elements of informed consent.

The CCI/IRB may determine that the requirement for minor assent may not apply in the following situations:

1. If the child is not capable of assenting based on the CCI/IRB’s assessment of age, maturity, and psychological state. This judgment may be made by the CCI/IRB in regard to any specific protocol or for each individual child; or

2. When the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

3. When the parents have previously consented to the protocol and the adolescent refuses to assent, the case may be referred to an ad hoc committee of the IRB/CCI. The Office of Legal Counsel should be consulted in these matters.

4. In exceptional situations (e.g. HIV investigations), where the parent and/or legal guardian of the minor may not wish the child to know the precise nature of the disease, the Institutional Review Board/CCI may refer the matter to an ad hoc committee. If the ad hoc committee cannot come to agreement, the matter will be referred to the Institutional Review Board/CCI for disposition.

Ages 7 to 12
Children **ages seven to twelve**, who give assent, are required to sign a separate child assent form. This assent form is in addition to the Informed Consent Document (ICD) that the parent or legal guardian is required to sign.

NOTE: The IRB/CCI should consider whether documentation of assent must include the minor’s signature, be described in a progress note, or witnessed.

**Ages 13 to 17**

In general, parental permission must be sought for research involving minors thirteen to seventeen years old. However, many adolescents of this age have the cognitive ability to understand and the moral insight to appreciate the purpose, procedures, risks, benefits and alternatives to participation in a research protocol. Therefore, the following principles and procedures apply to adolescents in this age group:

1. **Thirteen to seventeen year olds**, capable of giving assent, may sign the same consent document as the parent or legal guardian.

2. Separate paragraphs in the consent document should be directed to the adolescent and the parent. The consent form should have separate signature lines for the adolescent and the parent.

3. **For minimal risk research**, such as questionnaire studies:
   a. The CCI/IRB may waive the usual requirement for affirmative parental permission. The CCI/IRB may approve an alternative mechanism, known as “opt out,” in which parents are notified about the proposed research protocol and have the opportunity to inform the Investigator that they do not want their child to participate. If parents are so notified and do not object to their child’s participation, the child can participate in the study. The assent of the minor is still required.
   b. Where notification of the parents may be potentially harmful to the adolescent, the CCI/IRB, in consultation with legal counsel, may waive parental consent, provided that the committee makes the appropriate findings under state and federal regulations. In these cases, the CCI/IRB may waive parental notification and the research may be conducted with only the consent of the adolescent.

4. For research involving greater than minimal risk with the potential for direct benefit to the subject:
   a. When the parents are not available (i.e. homeless or abandoned minors), the investigator must contact hospital social services to determine legal guardianship, or contact Administration of Children’s Services, to ensure proper guardian consent is obtained.
   b. The CCI/IRB, in consultation with legal counsel, may waive parental consent if seeking consent may be potentially harmful to the adolescent (e.g. in studies of drug abuse, teen pregnancy, HIV, child abuse). In these cases adolescents
should be asked to identify an adult to be present during the consent process and sign the consent form as a witness.

In other selected cases, such as when the adolescent wishes to participate yet his/her parents refuse to consent and there is a prospect of direct benefit to the adolescent, the matter should be referred to an ad hoc committee of the IRB/CCI that will consult with legal counsel.

5. Health Insurance Portability and Accountability Act (HIPAA)
   a. Authorization for use and release of a minor’s protected health information must be obtained from the parent or legal guardian unless a waiver or alteration is approved by the IRB/CCI. The Authorization Form is found at http://www.aecom.yu.edu/uploadedfiles/CCI/forms/hipaa/HIPAA_Authorization.doc, and the Waiver Form is found at http://www.aecom.yu.edu/uploadedfiles/CCI/forms/hipaa/HIPAA_Waiver.doc.
   b. Minor’s are not required to sign the HIPAA Authorization Form except in instances for which the IRB/CCI waives parental consent in accordance with No. 4b of this policy. In such instances, the minor must sign authorization unless waived by the IRB/CCI.

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