



Waiver of Parental Permission

Waiver of Parental permission is permitted under 45 CFR 46.408(c) when it is not a reasonable requirement to protect subjects. This waiver is usually limited to minimal risk research, such as surveys, interviews or focus groups. Research about sexuality, drug use, teen driving habits or other topics of importance to adolescents may not be possible without a waiver. The parents of these teens may not be accessible and therefore, may not be a reasonable requirement.

In order to waive one or all of the elements of consent the IRB must be able to determine that the research meets the criteria specified in 45 CFR 46.116(d). It is not possible to waive consent for FDA-regulated research with the narrow exception of emergency research meeting the requirements of 21 CFR 56.24.

Waiver or alteration of consent

§46.408(c): In addition to the provisions for waiver contained in §46.116 of subpart A , if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and

Important Tips

§46.408(c) requires the substitution of another mechanism to protect the subjects. This could be as simple as requiring assent of teenagers (typically 14 years or older) who are mature enough to fully comprehend the research activities. It could also involve appointing an advocate who provides permission for the child.

If research will be performed in the schools, it may be possible to send information home to parents that allows them to opt out. Then the teens may assent for their own participation provided their parent has not opted out.

The IRB requires the investigator to make a compelling and persuasive argument for why parental permission is not a necessary condition for proceeding with the research.