Not Reasonably Available

Overview:

Federal regulations for research involving children charge IRBs with determining that provisions are made for soliciting parental permission in order to protect children. This document provides guidance to define the term "not reasonably available".

Description:

Under these regulations, IRBs may determine that permission from one parent is sufficient for research presenting no more than minimal risk or for studies that pose greater than minimal risk but that have the potential for direct benefit to participants. However, for research that poses greater than minimal risk with no potential for direct benefit, "both parents must give their permission 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." When there is disagreement between both parents, the child may not be enrolled in the research study.

If the parent who is present can provide documented proof that s/he has sole legal responsibility for the child, permission from that parent is sufficient. Such proof would include a copy of the court order granting sole custody and legal decision-making authority to the parent who is present, including sole legal authority to make medical decisions for the child or a copy of the birth certificate listing "unknown" for the other parent.

While the regulations do not provide specific guidance about what constitutes "not reasonably available," this does not refer to situations where one parent is simply not present during the consenting process. A parent who is "not reasonably available" is one who cannot be contacted by phone, email, mail or fax: for example, a parent on active military duty. If the other parent is "not available" simply because s/he is at work, traveling, or caring for other children, or even if s/he lives in another city or state, it is the investigators' responsibility to attempt to obtain that parent's permission before enrolling the child in the research.

In the event that the signature of both parents is required, the parent who is present should be asked to provide the other parent's contact information, including address, home and work phone and fax numbers, email address, etc., and a concerted effort should be made to contact the absent parent by phone. Once contacted, a research investigator or other research staff who is eligible to obtain parental permission based on the approved protocol (section 4.12-4.13) must be available to provide him or her with all the information required to make a fully informed decision about

whether to permit the child's participation. Since written informed consent is required, the approved consent document should be mailed and/or faxed, along with a cover letter or note from the investigator explaining the circumstances. The executed consent can be returned via mail, e-mail, or fax. In the event of a time sensitive consent, the IRB will also permit the parent to take a picture of the signature page with a smart phone and send it via text messaging.

If the absent parent cannot be reached by telephone, email or fax after repeated attempts and no other contact information is available, the investigator may determine that the parent is "not reasonably available." Note that it is very important to retain dated copies of any letters, faxes or emails sent to the absent parent, and a log of all phone calls –attempted and answered – should be kept and documentation entered into the medical record. **IMPORTANT NOTE**: If the second parent subsequently responds and refuses to provide permission, the child's participation must end.

The amount of time and effort that investigators should devote to contacting an absent parent will vary depending on the individual circumstances and the constraints posed by the research protocol. However, investigators must have standard operating procedures in place for contacting the absent parent, and all such efforts must be documented in the research record.

OSIRIS:

Section 4 – Subject Recruitment and Informed Consent Procedures

> Question 4.12: Describe the process that you will employ to ensure the subjects are fully informed about this research study. Include language related to both how parental permission and child assent (if applicable) will be handled. Also include a discussion about how consent for continued participation will be obtained in the event that a child reaches the age of majority.
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> Question 4.13: Are you requesting an exception to either IRB policy related to the informed consent process?

Additional Information:

Code of Federal Regulations 45 CFR Part 46

§46.408 Requirements for permission by parents or guardians and for assent by children

> Institutional Review Board (IRB) may find that the permission of one parent is sufficient for research to be conducted under 46.404 or 46.405. When research is to be conducted under 46.406 and 46.407 permission must be obtained from both parents, 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.