

Guidance: Consent and 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”.

Overarching Principles:

When IRB determines the risk of a study to be **46.406/50.53** – *Research involving greater than minimal risk to subject with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects’ disorder or condition*, the permission of both parents, “if reasonably available”, is required.

- The permission process with each parent can occur independently at different times and by different methods prior to involvement of the child in research
- When children are in the shared legal custody of two parents or guardians, each parent’s right of decision-making is to be respected. If one parent agrees to be contacted and declines to give permission, in other words affirmatively says no to participation by the child in research, the child cannot participate. This does not mean the parent is not reasonably available.
- The term reasonably available should be applied both to the whereabouts of parents and to the mechanism that can be used to secure their permission. For example, parents may be reasonably available because they have been located; however, there may be no reasonably available mechanism to obtain signature on a permission form.

Application of “Reasonably Available” to Locating a Parent:

Overall if a parent’s role in the care of and/or decision-making about the child, even on a limited basis, is such that his or her involvement and availability may be readily ascertained, the parent is considered reasonably available and attempts at contact should be pursued. Not available is not intended to mean that a parent is temporarily unavailable, unless there are specific circumstances where time is of the essence. A parent who is not reasonably available is one whose whereabouts are unknown or there is no way to reach them by phone, mail, email, fax or any type of videoconferencing or has not responded to multiple contact attempts. Not available does not apply to situations when a parent is at work, traveling, caring for other children or living in another state or country.

Examples of situations when one may reasonably conclude a parent is not reasonably available could include:

- One parent is incarcerated and not contactable*; or
- One parent is active military duty and not contactable; or
- One parents whereabouts are unknown; or
- One parent is known but uninvolved in the child’s care and multiple attempts have been made to contact the parent*. In this situation, the timing and methods of contact should be thoroughly documented and be appropriate based on the timing and need for consent for the study. For example, some protocols

have specific eligibility requirements and investigational windows for when a research intervention/assessment needs to begin; or

- One parent has been contacted and actively declined to participate in the *permission process*. In this situation, the parent is refusing to participate in the process entirely. This is different than saying “no” that the child should not participate in research.

*Non-contactable means, for example, that:

- It has been predetermined by a prison, detention unit or the armed services that an individual is not to be contacted while incarcerated or during active service duty; or
- Attempts were made to contact the parent, but contact is not made within the period of time required to enroll the minor in research

Application of “Reasonably Available” regarding documentation of permission by a second parent:

A determination that a parent is “not reasonably available” per the regulations may include circumstances in which a parent is available to participate in the consent process and give their permission for their child’s participation, but is not able to provide a valid signature. Under these circumstances, a waiver of documentation of consent is not allowed, as the research is greater than minimal risk. In this situation, where the second parent agrees to participation but cannot provide a signature, the minor would be allowed to participate with the second parent being deemed “not reasonably available”* criterion to provide a signature.

*Not reasonably available in regards to not being able to provide documentation means, for example:

- A legal guardian who can be contacted via telephone for discussion, but does not have access to email or a printer. This could be due to lack of access to printer or computer, lack of smart phone, remote travel locations, lack of understanding of technology (older grandparent with no email address), etc.

It is highly recommended to consult the IRB in specific situations for guidance.

Additional Information:

Code of Federal Regulations 45 CFR Part 46

[§46.408 Requirements for permission by parents or guardians and for assent by children](#)