Overview
When a study involves children and the research poses greater than minimal risk with no potential for direct benefit (45 CFR §46.406/21 CFR §50.53 or 45 CFR §46.407/21 CFR §50.54), “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”. The federal regulations do not provide specific guidance about what constitutes “not reasonably available”.

Meeting These Requirements
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.

“Not reasonably available” does not refer to a situation in which 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. Some examples of not reasonably available include:
- The other parent is on active military duty
- The other parent is incarcerated
- The whereabouts of the other parent are unknown

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 Verification of Human Subjects Training form (F107) 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, email, 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 research 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.