IRB Determinations about Parental Permission

Anastasia Doherty
Sr. IRB Manager
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Research Involving Children

Parental Permission

- Regulations require investigators to obtain the "permission of the child's parents or guardian" before enrolling a child in a study.
- The IRB may find the permission of one parent is sufficient for research conducted under "404" and "405".
- Regulations require permission of both parents for research conducted under "406" and "407" studies.

FDA regulations are nearly identical: 21 CFR Part 50 Subpart D
46.404/50.51 and 46.405/50.52

IRB may find one parent signature sufficient

- In Minimal risk research (46.404/50.51) and greater than minimal risk research, with prospect of direct benefit (46.405/50.52), the IRB may find permission of one parent is sufficient.

- **In this case** only one parent is required to sign the consent, even if both are present (although we encourage both to sign, if they are both present).
46.404/50.51 and 46.405/50.52
IRB may find *two parent signatures required*

- In **Minimal risk research** (46.404/50.51) and **Research involving greater than minimal risk, with prospect of direct benefit** (46.405/50.52) the IRB may require the permission of both parents, but only when both parents are *reasonably available*.

- *Reasonably available means* both parents are present at the consent process or one parent can take the consent form home for the other parent to sign.
In Research involving greater than minimal risk with no prospect of direct benefit (46.406/50.53), the permission of both parents is required, unless one parent is deceased, unknown, incompetent, **not reasonably available**, or only one parent has legal responsibility for the care and custody of the child.

- **Not reasonably available:**
  - **Means** the other parent is not contactable by phone, mail, email or fax or the other parent’s whereabouts are unknown.
  - **Does not mean** the other parent is at work, at home, lives in another city, state or country, but is contactable by phone, mail, email or fax.
Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health & welfare of children (46.407/50.54) the permission of both parents is required, unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child.

Same threshold as 46.406/50.53
For 46.404/50.51 and 46.405/50.52 findings, no matter if the IRB determined one parent signature is sufficient, or that two parent signatures are required:

- The consent form includes signature lines for both parents

- The staff adds the appropriate language to the consent form, based on the IRB’s determination, and returns it to the PD.
The IRB determines the protocol finding is 46.406/50.53 or 46.407/50/54, the consent form has special requirements:

- The consent form includes signature lines for **both parents**
- Language is included in the consent form, after the parent signature lines:
  - [ ] The other parent is deceased
  - [ ] The other parent is unknown
  - [ ] The other parent is incompetent
  - [ ] **The other parent is not reasonably available**
  - [ ] One parent has legal responsibility for the care and custody of the child
Things to think about:

- If a study has multiple procedures, encourage investigators to consider separate consent forms for the different parts of the study so they don’t have to get two parent signatures (under 46.406/50.53 requirements) when some subjects will only enroll in the minimal risk part of a study

  - MRI without or with sedation
  - Blood draw study with an optional skin biopsy