

Research Compliance Office

IRB Determinations about Parental Permission

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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

46.406/50.53



- 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

46.407/50.54



- 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

Consent form and Signature lines



- 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.*

Consent form and Signature lines



- 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