



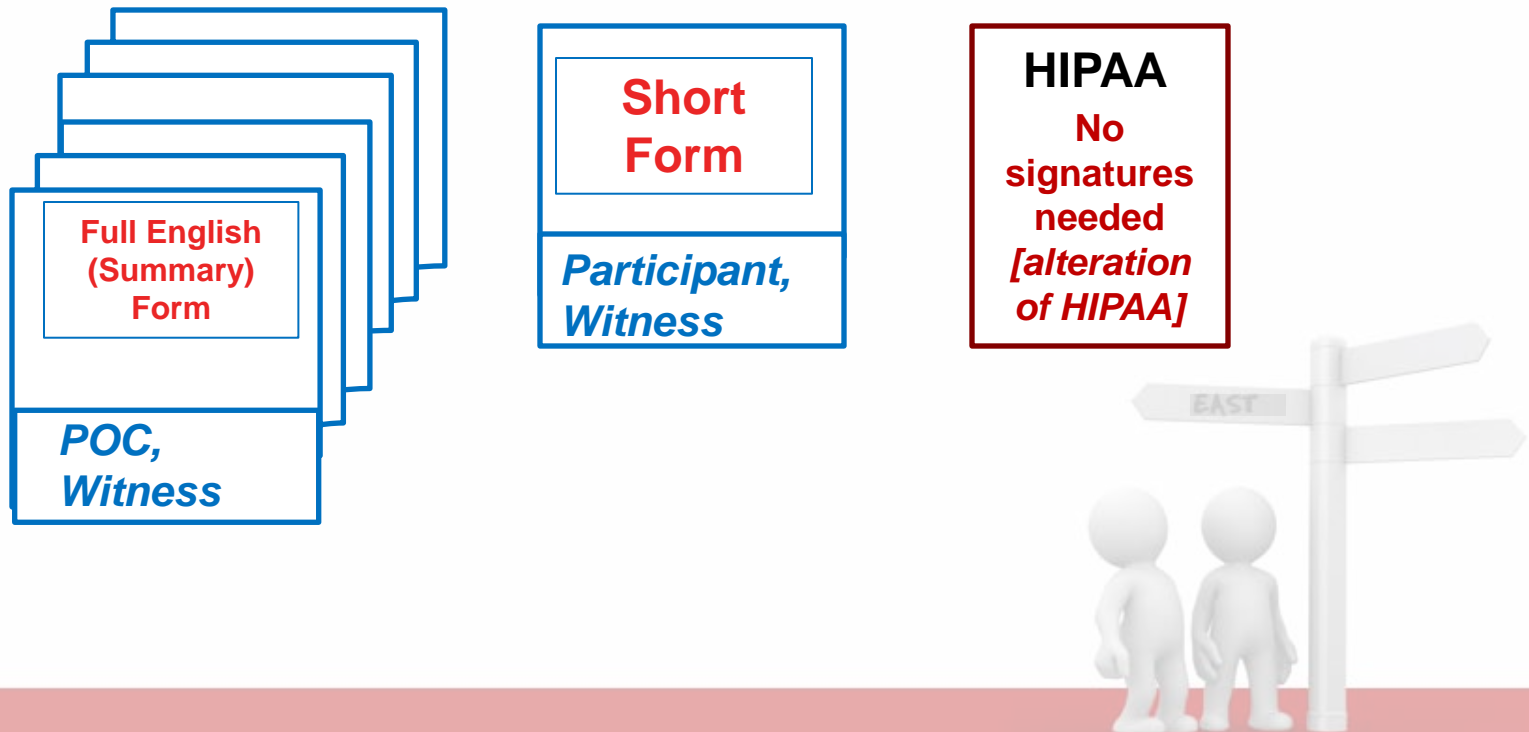
Informed Consent Scenarios

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Short Form Consent Process

OHRP: 45 CFR 46.117(b)(2) & FDA: 21 CFR 50.27(b)(2)

A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative.



HRPP

12.1.4. Short Form Consent Process

The short form consent process may be approved by the IRB, on a protocol-specific basis, for use with participants who are non-English speaking.

...the IRB encourages the use of a full consent form translated into the participant's language whenever possible.

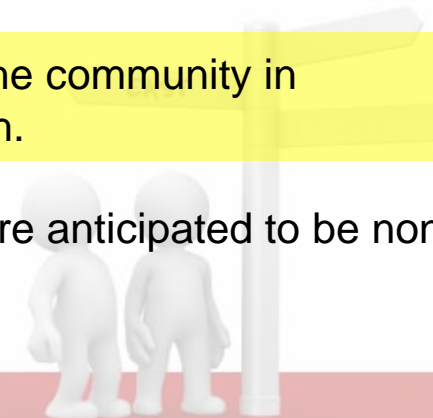
The IRB considers the study complexity and the amount and duration of participant involvement when determining if use of the short form consent process is appropriate and can be approved.

12.2.5. Non-English Speaking Participants

Stanford University is located in a culturally diverse region of California.

Investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English.

When **all of the participants** in a study (i.e., the target population) are anticipated to be non-English speaking, **a full translated consent is required**.





Short Form Consent

- A researcher has asked to include the short form consent process for their project. They may encounter a subject population that does not speak English.
- Why would the IRB consider the following criteria to see if the short form consent process is acceptable for approval?

Location of the study

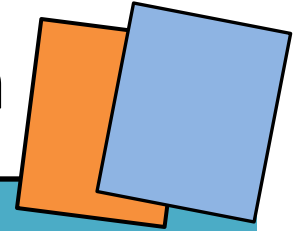
Risk level

Equitable Distribution

Complexity of the study

Duration of study

Risk Level & Benefits – Children’s Research

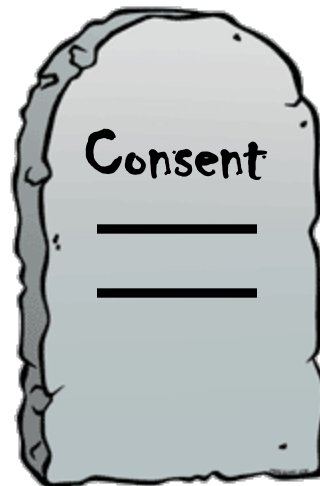
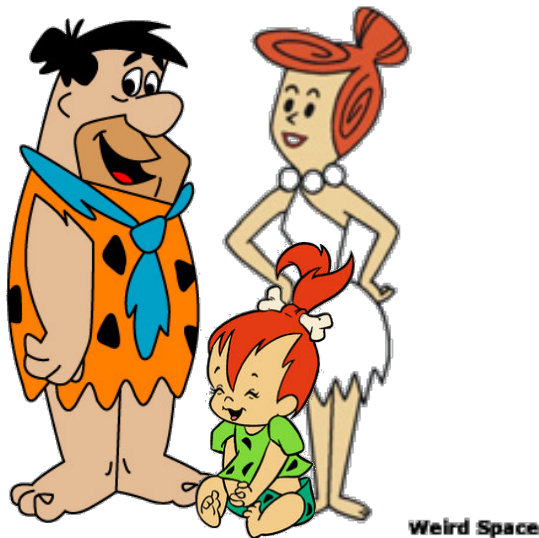


OHRP 45 CFR FDA 21 CFR	Risk Level	Requirements
46.404 50.51	Not > minimal	Adequate provisions made for assent and parental permission
46.405 50.52	> minimal	Prospect of direct benefit
46.406 50.53	> minimal	No prospect of direct benefit Likely to yield generalizable knowledge Presents experiences commensurate with actual/expected situations Risk represents minor increase over minimal risk
46.407 50.54		Research not otherwise approvable...

Adequate provisions are made to solicit assent from the child and permission of their parents or guardians

- A researcher would like to do a study on children; it is approved under Section **45 CFR 46.404**. It involves risk that is no greater than minimal.
- The children in the study are under 2 years of age. The IRB has determined that one parental signature **is sufficient**.

How many parental signature lines should be on the consent form?



Stanford HRPP :
2 signature lines on a
consent form for a
children's study

The consent form includes signature lines for **both parents**:

Signature of LAR Date
(parent, guardian, or conservator)

Authority to Act for participant

(If available) Signature of Date
other parent or guardian

Gui-C34

What if this study falls under **45 CFR 46.405**, and the IRB requests that permission be obtained by both parents, and the second parent is ***not reasonably available***.

What does *not reasonably available* mean for this application?

***Not reasonably available** - means *the other parent is not present during the consenting process, or will not be available prior to start of research procedures.*

Examples of not reasonably available:

The other parent is at work, caring for other children, or traveling

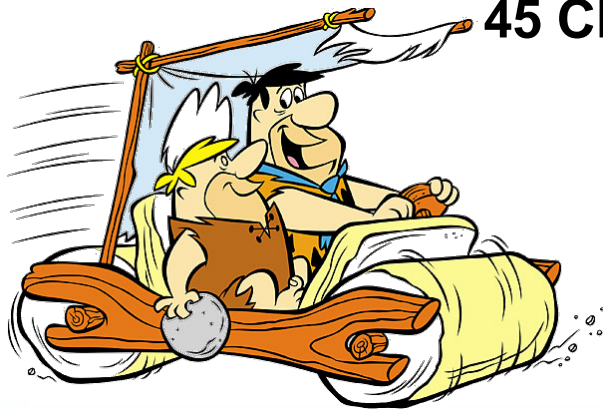
Applies to:

45 CFR 46.404

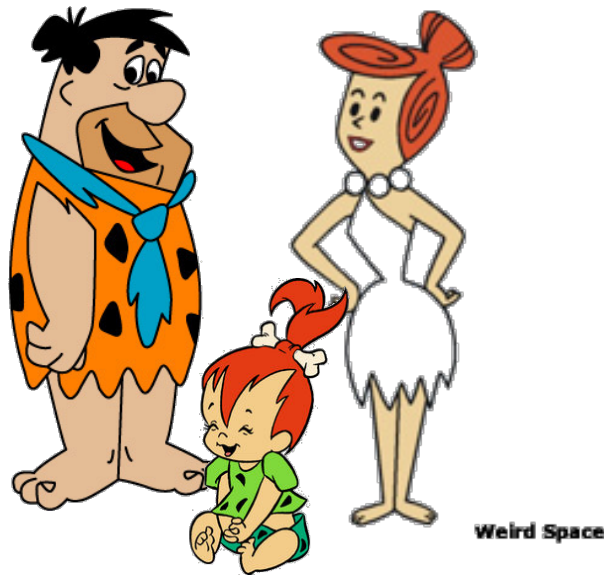
21 CFR 50.51

45 CFR 46.405

21 CFR 50.52



- A researcher would like to do a study on children; it is approved under Section **45 CFR 46.406**. It is a cancer study.
- The children in the study are under 2 years of age. The regulations state that permission be obtained by both parents; therefore **two signatures are required**.
- However, Wilma says that Fred is **not reasonably available** for the study.



What reasons can there be for Fred not signing the consent form, if two parent signatures are required?



Per 45 CFR 46.408...if permission is only obtained from one parent, the reason for not obtaining the permission of the other parent must be documented on the consent as follows:



- the other parent is deceased
- the other parent is unknown
- the other parent is incompetent
- the other parent is **not reasonably available***;
- only one parent has legal responsibility for the care and custody of the child

***Not reasonably available**

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

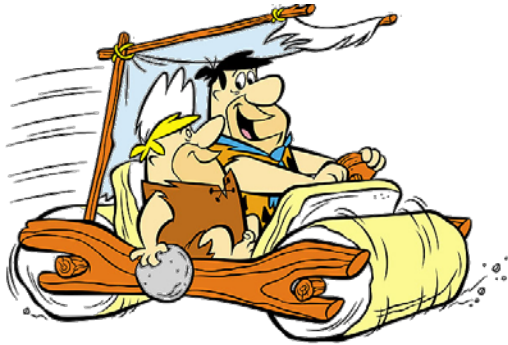


Examples of **not reasonably available**:

- The other parent is on active military duty and is not contactable by phone, mail, email or fax.
- The other parent is incarcerated and is not contactable by phone, mail, email or fax.
- The whereabouts of the other parent are unknown



Remember, there are 3 different signature conditions:



ONE is sufficient



or

TWO are required

not reasonably available has lower threshold

or

TWO are required

not reasonably available : defined by regs



ONE is sufficient

or

TWO are required

not reasonably available is flexible

45 CFR 46.404 21 CFR 50.51

45 CFR 46.405 21 CFR 50.52

or

TWO are required

not reasonably available : defined by regulations

45 CFR 46.406 21 CFR 50.53

45 CFR 46.407 21 CFR 50.54



How many signatures should be on the assent form for the child to sign?

The child is under the age of 2; no assent form is necessary.

