

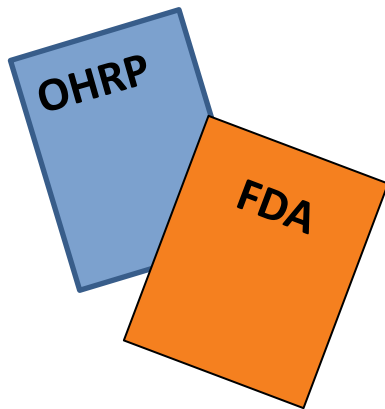


Children's Findings – Assent and Permission

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April 2012

Federal Regulations

- Belmont Report – Respect for Persons
- OHRP – Subpart D
- FDA 21 CFR 50 – Subpart D
- AAHRPP



All take into consideration our responsibility to protect those who are vulnerable or who have limited autonomy

Assent and Permission Considerations

- **Signatory requirements (parental permission)**
 - One or two signatures/waivers
- **Assent**
 - Age appropriate/capability
 - IRB Role
 - Resources



Children's Findings

OHRP 45 CFR FDA 21 CFR	Risk Level	Benefit Possibilities
46.404 50.51	Not > minimal	Not specified
46.405 50.52	> minimal	Prospect of direct benefit
46.406 50.53	> minimal	No prospect of direct benefit, but likely to yield generalizable knowledge
46.407 50.54	Research not otherwise approvable...	

Requirements for **Permission and Assent**

45 CFR 46.408 and **21 CFR 50.55**



- One or two signatures may be required for the research
- “adequate provisions are made for soliciting assent of the child and permission of parents or guardians”

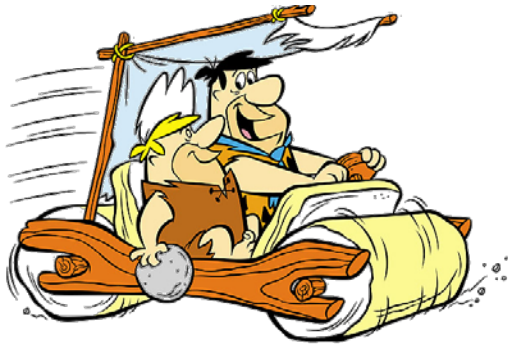
OHRP 45 CFR FDA 21 CFR
46.404 50.51
46.405 50.52
46.406 50.53
46.407 50.54



Requirements for **Permission...**

45 CFR 46.408 and **21 CFR 50.55**

There are
3 different signature conditions:



ONE is sufficient

or

TWO are required (by the IRB)

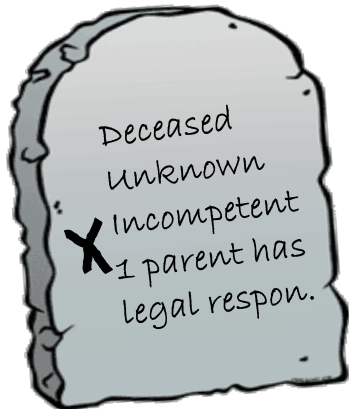
Not reasonably available has low threshold

46.404

50.51

46.405

50.52



or

**TWO are required
(regulatory requirement)**

46.406

50.53

46.407

50.54

Question: What Is Child Assent?

Assent: a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(This process) should reflect a reasonable effort to enable the child to understand, to the degree...capable, what their participation...will involve.

45 CFR 46.402(b); OHRP Guidance Category: Research With Children



Requirements for... **Assent**

45 CFR 46.408 and **21 CFR 50.55**

The IRB determines the capability of children to assent

The IRB must consider:

- age, psychological state, maturity
- Research can proceed without assent if the IRB determines:
research holds out prospect of direct benefit,
and benefit is only available in the context of clinical investigation



Question: When Is Assent Not Required?

When the IRB determines:

- Capability is limited, child cannot be reasonably consulted
- Research holds prospect of direct benefit to health or well being and only available through research
- IRB has waived assent process
per 45 CFR 46.116 or 21 CFR 50.55(d)

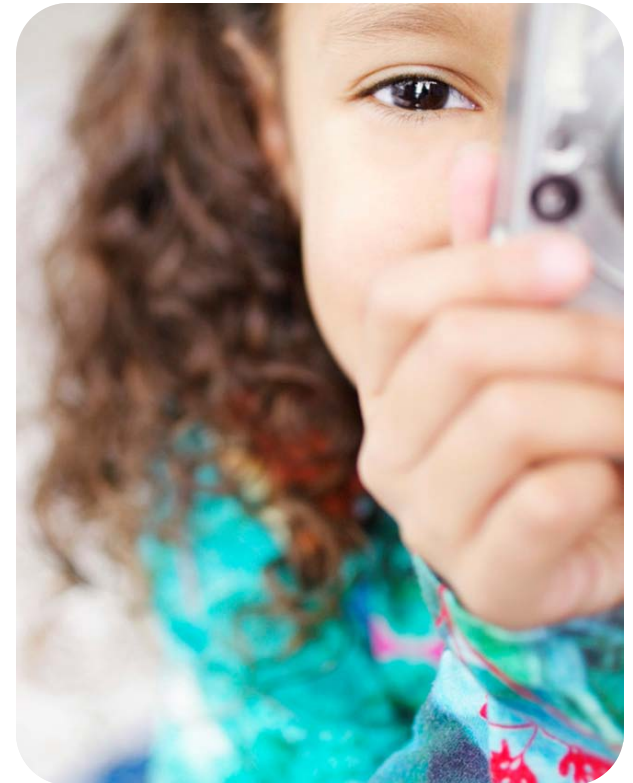
- (1) No more than minimal risk
- (2) Waiver does not adversely affect rights and welfare
- (3) Could not be practicably be carried out
- (4) Provide additional information where appropriate after participation

Assent Decisions

- Assent is required, when:
 - Age 7 and older (CA state law)
- IRB may determine how or whether to document assent (HRPP Ch. 12.2.3)
 - Signed form
 - Age appropriate documents
 - Oral assent

HRPP Ch. 12.2.3 also states:

**Generally, children above age 7
may be asked to give their
assent**



IRB Role: HRPP Ch. 9

Procedures for assessing and ensuring participants' capacity, understanding, and assent:

- In certain instances, it may be possible for investigators to **enhance understanding** for potentially **vulnerable participants** (i.e., children)

- Examples include:
 - **translation** (via assent) into languages the participants **understand**
 - **reading** the (assent) form to participants slowly/ensuring their understanding paragraph by paragraph
 - the **inclusion of** a... monitor/participant **advocate**

- IRB verifies that such procedures are a part of the research plan

Question: What happens when there is a disagreement between a child and his/her parents?

- *IF* a child is determined to be capable, then the IRB requires assent be sought.
Dissent: child prevails unless IRB waives assent or conditions are met to waive assent.
- *IF* a child assents, parental permission is still required unless parental permission is waived.



OHRP FAQs on Clinical Research, Q9

GUI-C24 (California Law)

Family Code 6902; 6924-9 ; 7002 Emancipated Minors; Unemancipated minors' consent for research

Minors who may Consent as Adults, including Emancipated Minors

In California, ...an “emancipated minor” may consent to participation in any type of research.

In addition, ***for research involving treatment*** certain ***un-emancipated minors may consent to research involving specific types of medical treatment. For example:***

- Outpatient mental health treatment for a minor 12 years or older when certain criteria are met,
- Hospital, medical or surgical care related to prevention or treatment of pregnancy for minors (any age),
- Care for alcohol or drug abuse.

Resources

- ***GUI-C24*** – Consent for Protocols Involving Children and Consenting Minors
- ***GUI- C34*** – Parental Permission
- ***HRPP*** Chapters 5,8,9, 12 and 15 (Permission and Assent)
- Regulations and Guidance on Clinical Research, OHRP FAQs

