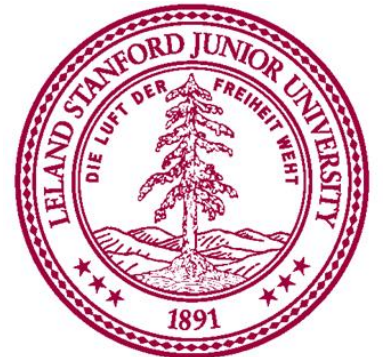


Children's Findings

Research Compliance Office
Stanford University



<http://researchcompliance.stanford.edu>



Children's Finding 404/50.51

- The research presents **no greater than minimal risk** to children; and
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians (45 CFR 46.408).

OHRP 45 CFR 46.404/ FDA 21 CFR 50.51



Children's Finding 404/50.51 Examples

- Venipuncture/fingerstick
- Single Chest x-ray
- Bone density test
- Vision testing/Hearing testing
- Complete neurological exam
- Oral glucose tolerance test
- Standard Psychological tests



Children's Finding 405/50.52

- Risk is justified by the **anticipated benefits to the subjects;**
- Relation of the anticipated benefit to the risk presented by the study is **at least as favorable to the subjects as that provided by available alternative approaches;** and
- Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians (45 CFR 46.408).

OHRP 45 CFR 46.405/ FDA 21 CFR 50.52



Children's Finding 405/50.52 Examples

- Most IND and IDE studies
- Certain Pharmacokinetic Studies
- Imaging Studies



Signature Requirements 404/50.51 and 405/50.52

The consent form includes signature lines for
Both parents:

Signature of LAR (parent, guardian, or conservator)	Date
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Authority to Act for participant

(If available) Signature of other parent or guardian	Date
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Authority to Act for participant



Children's Finding 406/50.53

- Risk represents a **minor increase over minimal risk**;
- Intervention or procedure presents experiences to subjects that are reasonably **commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations**;
- Intervention or procedure is **likely to yield generalizable knowledge about the subjects' disorder or condition** which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians (45 CFR 46.408).

OHRP 45 CFR 46.406/ FDA 21 CFR 50.53



Children's Finding 406/50.53 Examples

- Urine via catheter
- Certain Biopsies
- Lumbar puncture
- Small amount of additional tissue obtained at surgery
- MRI (with sedation, depending on the amount and duration of sedation)



Signature Requirements 406/50.53

- 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

Checkboxes must appear on consent



Children's Finding 407/50.54

- Research not otherwise approvable which presents an opportunity to understand, prevent, alleviate a serious problem affecting the health or welfare of children.
- Sent to OHRP and/or FDA

OHRP 45 CFR 46.407/ FDA 21 CFR 50.54



Questions?



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