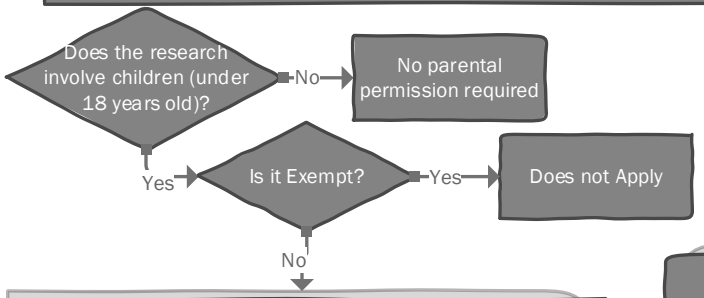
When do You Need Parental Permission for Research with Children?



An Institutional Review Board (IRB) may waive the requirements for obtaining parental or guardian permission if it makes and documents the findings under either 45 CFR 46.116(c) or (d). However, the FDA does not allow the waiver for parental permission for research involving an FDA-regulated product.

What is the Level of Risk to Children?

- Does the research involve greater than minimal risk[1]? — No → § 46.404
- Yes → Does the research present the prospect of direct benefit to the individual subject? — Yes → § 46.405
- No → Is the research likely to yield generalizable knowledge about the subject's disorder or condition? — Yes → § 46.406
- No → Is the research not otherwise approvable which presents an opportunity to understand, present, alleviate a serious problem affecting the health or welfare of children? — Yes → § 46.407[2]

Do you need to seek Parental Permission from Both Parents?

- § 46.404 → Permission from one parent may be sufficient
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- § 46.406 → Is one of the parents deceased, unknown, incompetent, or not reasonably available to provide permission?
  - Yes → Permission from one parent is allowed
  - No → Does one parent have legal responsibility for the care and custody of the child?
    - Yes → Permission from one parent is allowed
    - No → Both parents must give their permission
- § 46.407[2] → Is one of the parents deceased, unknown, incompetent, or not reasonably available to provide permission?
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No parent permission[3], active parent permission vs. notification with opt-out

- Permission from one parent may be sufficient → Does it meet the criteria for a waiver of informed consent[3]?
  - Yes → No parental consent/permission required. Notification with an opt-out may still be required.
  - No → Is the research designed with a condition or for a subject population for which parental permission is not a reasonable requirement to protect the subjects, (i.e. neglected/ abused children, 17 year olds in college classes)?
    - Yes → No parental consent/permission required. Notification with an opt-out may still be required.
    - No → Written or Verbal Parent Permission should be obtained

*A waiver of parental permission may also be granted to FLEX-eligible studies if justified by the PI and consistent with any relevant requirements of the research site. See the HRPP website for additional information.

[1] Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life and during the performance of routine physical and psychological examinations or tests.

[2] Must be reviewed by the Secretary

[3] The IRB may waive the requirement for informed consent if,
A) The research involves minimal risk to subjects;
B) The waiver or alteration will not adversely affect the rights and welfare of subjects;
- AND -
C) The research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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