
Yale University Institutional Review Boards

310 PR.2 Submission of Protocols for Research Involving Children

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Overview

Children are considered vulnerable research subjects and hence their involvement in research requires that additional protections be incorporated into the research protocol. This procedure describes the additional requirements that must be addressed in protocols submitted to the IRB which propose including children as research subjects.

Preparation of Protocols Involving Children

In addition to the standard requirements for research protocol submissions to the IRB (See IRB Procedure 100 PR.4 Submission Requirements for IRB Review), protocols that will involve children must include the following:

- The proposed number of children to be enrolled as well as their age range(s).
- Considerations to be made to obtain parental permission and child assent in accordance with IRB Policy 310, Participation of Children in Research. In particular, the description should address:
 - How the potential subjects' maturity will be assessed to determine ability for the child to provide assent.
 - Which members of the research team will obtain assent.
 - Where and when during the enrollment process parental permission and child assent will be obtained.
 - What types of assent documents will be used.
 - Reasons why signed assent will or will not be requested.
 - How the child's assent will be documented by the researcher.
 - How it will be determined whether subjects/parents/guardians understand the research.
 - Justification of a waiver of parental permission or child assent, if such a waiver is requested.
 - When applicable, the process for obtaining informed consent from the child should the duration of the research extend beyond the child turning eighteen years old.
- Copies of all parental permission and assent forms in the format they will be given to subjects.
- A description of any limits to the child's confidentiality such as mandatory reporting as well as any limits on the child's confidentiality with respect to their parent or guardian. In most cases where it is determined that an intervention is necessary to protect the child, it is considered appropriate to contact the parent or guardian.
- Copies of approval letters from other University review committees as appropriate (e.g., Pediatric Protocol Review Committee, Psychology Subject Pool, etc).

Studies Involving Wards of the State

If there is the possibility that the protocol will involve children who are wards of the state, the application must address the following:

- How will wards be identified and recruited to participate in the research?
- How will the permission for participation of the ward(s) be obtained?
- How will the investigator ensure that the appropriate person grants permission for each ward to participate in the research?
- How will the investigator determine whether there has been a change in guardianship status during the course of the research and permission should be obtained from the new guardian?

Studies Conducted in Schools

If the study will be conducted in a school, the IRB application must address the following:

- How students will be recruited without undue influence of peers, parents, teachers.
- A description of any individually identified information that will be shared with the school.

See also IRB Guidance 310 GD.1: K-12 School Based Research.