



Protocols with Minors as Participants

For protocols involving children (under 18 years of age), answer each of the following questions with a brief statement.

1. Age(s) of children?

2. Minimal risk means that the risks of harm anticipated in the proposed research are not greater—considering probability and magnitude—than those ordinarily encountered in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. Is this study of greater than minimal risk to the child? If so, describe.

3. Is there the prospect of direct benefit to the child? If so, specify.

4. What alternative treatment methods are available? Is the anticipated benefit from the experimental method as great or greater than benefit from alternative methods? Compare risk to the child from the experimental and alternative methods.

5. Will this study yield generalizable knowledge about the child's disorder or condition?

6. Describe your procedure for obtaining assent (affirmative oral agreement to participate in the research) from the child. If waiver of assent is requested, specify reason.

7. Describe your procedure for obtaining permission and written consent from parent(s) or guardian(s).