



Supplement A. Research Involving Minors Under 18

The IRB is required to consider the benefits, risks and discomforts of the research and assess the justification for minor's participation in light of the benefits to the minor or to society as a whole. In calculating the risks and benefits, the IRB must consider the circumstances of the minors under study, the magnitude of risks or discomforts that may result from participating in the research, and the potential benefits the research may provide to the minor or to other minors with the same disease or condition.

“Minimal risk” is defined as a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests. [See more information about minimal risk here.](#)

I. Potential Risks to Minor Participants

Check A or B.

- A. This proposed research poses no greater than minimal risk to participants.

If checked, explain below.

- B. This proposed research poses greater than minimal risks to participants.

If checked, explain below.

II. Direct Benefits to Minor Participants

Check A or B.

- A. This proposed research offers direct benefits to participants.

If checked, explain below.

- B. This proposed research does not offer direct benefits to participants.

If checked, explain below.

If A is checked in both I and II, you may stop here. Obtain permission from one parent or guardian and assent from the child. Attach this form to your proposal and prepare the consent and assent materials. If B is checked in either I or II, continue to page 2.

III. Indirect Benefits to Minor Participants

If B was checked in I or II, check one of the following:

- A. This proposed research offers indirect benefits to participants, such as by contributing to generalizable knowledge or societal benefit.

If checked, explain below.

- B. This proposed research offers no direct or indirect benefits to participants, but instead provides an opportunity to understand, prevent, or alleviate a serious problem affecting health or welfare of children.

If checked, explain below. If unchecked, go to page 2.

IV. Risk-Benefit Assessment

Check one of the following:

- A. In what way do the benefits of this research outweigh the potential risks to the minor participant?

- B. If the benefits of the research do not outweigh the potential risks to participants, what alternative methods could answer the same questions?

If any of the boxes on this page are checked, permission is required from both parents. Please prepare the consent and assent forms and submit this document, along with the research proposal, to the IRB.

Example Assent

Example Parent Consent

Signature of Principal Investigator: