

FORM 6: Special Population Review (Children/Minors)

Instructions: In MS Word, highlight the shaded underlined box and replace with your text.
Double-click checkboxes to check/uncheck.

Definition: In Alabama, a child/minor is any person under 18 years of age.

A. State the reasons for including this population in your project:

B. Check the category into which you would recommend the proposed research be placed and respond to the relevant questions:

- Children's Risk Level (CRL) #1 (45 CFR 46.404) Research not involving greater than minimal risk. Research in this category requires both assent of the child and permission of at least one parent or guardian.

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 or psychological examinations or tests.

- CRL #2 (45 CFR 46.405) Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches. This requires both the assent of the child and permission of at least one parent or guardian.

- a) Is the risk justified by the anticipated benefit to the subjects? Yes No
- b) Is the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches? Yes No
- c) Are adequate provisions being made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408? Yes No

- CRL #3 (45CFR 46.406) Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding. Permission must be obtained from both parents unless there is only one reasonable available parent. Guardian consent should be substituted for parental under appropriate legal constraints.

- a) Does the risk represent a minor increase over minimal risk? Yes No
- b) Does the 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?
 Yes No
- c) Does the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition? Yes No
- d) Are adequate provisions being made for soliciting assent of the children and permission of their parents or guardians, as set for in § 46.408.? Yes No

- CRL #4 (45 CFR 46.407) Research not meeting any of the above the specifications, but which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. This category is considered so serious that it must be submitted to a ruling by the Secretary of DHHS following consultation with an appropriate panel of experts.