

Southern Utah University Institutional Review Board
REVIEWER CHECKLIST
CHILDREN AS SUBJECTS IN RESEARCH

This form should be downloaded and opened with Adobe Reader or Adobe Acrobat.

Reviewer

Reviewer's College

Date

Reviewer's E-mail

Reviewer's Phone Extension

Title of Proposed Research

Principle Investigator (PI)

PI's E-mail

PI's College

RISK DETERMINATION

Select One

Minimal: 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 or during the performance of routine physical or psychological examinations or tests.

Greater than Minimal Risk

BENEFIT ASSESSMENT

Select One

Potential benefit(s) to child

No direct benefit to individual but offers general knowledge about the child's condition or disorder

No direct benefit to child but potential to, "understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects"

IRB ACTION

Select One

Should be Approved

Approvable on case-by-case basis (Risk may not be more than a minor increase over minimal risk.)

Should Not Approve (Approval of research must be made the Secretary of Health and Human Services with input from selected experts, and following opportunity for public review and comment.

If research is no more than minimal risk. (One parent/guardian may sign the parental permission document.)

If research involves greater than minimal risk but presents the prospect of direct benefit to the individual subject. (One parent/guardian may sign the parental permission document.)

If research involves greater than minimal risk and has no prospect of direct benefit to the individual subject, but is likely to yield generalizable knowledge about the subject's disorder or condition. (Both parents/guardians must sign the parental permission document.)

If research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (Both parents/guardians may sign the parental permission document.)

Check the appropriate boxes below. If you answer No, describe in Requested Revisions/ Clarifications section.

If greater than minimal risk, convincing scientific and ethical justifications are provided.

YES NO N/A

If the study involves normal volunteers, this has been justified.

YES NO N/A

Have appropriate studies been conducted on animals and adults to justify studies on children?

YES NO N/A

If no to the above, the lack of appropriate studies conducted on animal and adults has been justified.

YES NO N/A

The appropriate age groups have been included for proposed research questions.

YES NO N/A

Efforts have been made to ensure that parents' permission to involve children is free from coercion, exploitation, and/or unrealistic promises.

YES NO N/A

Assent will be obtained from children 7-17 years of age and dissent has been adequately handled.

YES NO N/A

Reporting of abuse or neglect has been addressed, if applicable.

YES NO N/A

Implications for other family members as a result of this research has been adequately addressed (i.e., genetic risk, HIV infection, etc.).

YES NO N/A

Requested Revisions/Clarifications: Provide more information if you answered "No" to any questions above.