

SC 501-A

01/01/07

Investigator:

IRB #:

Study Title:

CATEGORY OF RISK DETERMINATION	BENEFIT ASSESSMENT	IRB ACTION
I. Minimal (i)	With or without direct benefit	<input type="checkbox"/> Approvable
Document IRB discussion and rational for determination of Minimal Risk category: *(Attach to Minutes and include additional sheets as needed)	Document IRB discussion about assessment of risk/benefit to child:	Comments:
II. Greater than Minimal Risk	Potential benefit to child	<input type="checkbox"/> Approvable
*Document IRB discussion and rational for determination of Greater than Minimal Risk category:	Document IRB discussion about assessment of risk/benefit to child:	Comments:

CATEGORY OF RISK DETERMINATION	BENEFIT ASSESSMENT	IRB ACTION
III. Greater Than Minimal Risk	No direct benefit to individual offers general knowledge about the child's condition or disorder	<input type="checkbox"/> Approvable (case-by-case) (ii)
Document IRB discussion and rationale for determination of Greater than Minimal Risk category:	Document IRB discussion about assessment of risk/benefit to child:	Comments:
IV. Greater than Minimal risk	No direct benefit to child offers potential to, "understand prevent, or alleviate a serious problem affecting the health and welfare of subjects"	<input type="checkbox"/> Not Approvable (iii)
*Document IRB discussion and rationale for determination of Greater than Minimal Risk category:	Document IRB discussion about assessment of risk/benefit to child:	Comments:

- i) 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.
- ii) Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.
- iii) Approval to proceed with this category of research must be made by the Secretary of the HHS with input from selected experts, and following opportunity for public review and comment.

CHECKLIST – REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN

	Yes	No	NA
Does the research pose greater than minimal risk to children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are convincing scientific and ethical justifications given?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are adequate safeguards in place to minimize these risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve normal volunteers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Is the inclusion of normal volunteers justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have appropriate studies been conducted on animals and adults first?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If No: Is the lack of appropriate studies conducted on animals and adults justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will older children be enrolled before younger ones?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is permission of both parents necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are conditions under which one of the parents may be considered "not reasonably available" described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are the conditions acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to protect subjects' privacy and the confidentiality of information regarding them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there special problems that call for the presence of a monitor or advocate during consent procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the research involve a condition which has implications for other family member? (for example, genetic risk, HIV infection, Hepatitis C)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are adequate mechanisms in place to deal with other members of the family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Should parents be required to be present during the conduct of the research? (Are proposed subjects to be very young? Are the procedures involved painful? Must subjects stay overnight in the hospital when they otherwise would not have to?)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

Primary Reviewer _____

Date _____