**FORM 5.1B CHECKLIST** – **REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN**

**INVESTIGATOR:**

 **IDI REC #**

**STUDY TITLE**

|  |  |  |
| --- | --- | --- |
| **CATEGORY OF****RISK DETERMINATION** | **BENEFIT ASSESSMENT** | **IDI REC ACTION** |
| **I. Minimal (i)** | **With or without direct benefit** | [ ]  **Approvable** |
| Document IDI REC discussion and rationale for determination of Minimal Risk category:\*(Attach to Minutes and include additional sheets as needed) | Document IDI REC discussion about assessment of risk/benefit to child: | Comments: |
| **II. Greater than Minimal Risk** | **Potential benefit to child** | [ ]  **Approvable** |
| \*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category: | Document IDI REC discussion about assessment of risk/benefit to child: | Comments: |
| **CATEGORY OF****RISK DETERMINATION** | **BENEFIT ASSESSMENT** | **IDI REC ACTION** |
| **III. Greater Than Minimal Risk** | **No direct benefit to individual offers general knowledge about the child’s condition or disorder** |  [ ]  **Approvable (case-by-case) (ii)** |
| \*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category: | Document IDI REC 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 participants”** | [ ]  **Not Approvable (iii)** |
| \*Document IDI REC discussion and rationale for determination of Greater than Minimal Risk category: | Document IDI REC discussion about assessment of risk/benefit to child: | Comments: |

1. 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.
2. Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances.

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| --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** |
| Does the research pose greater than minimal risk to children? |[ ] [ ] [ ]
| If yes: Are convincing scientific and ethical justifications given? |[ ] [ ] [ ]
| If yes: Are adequate safeguards in place to minimize these risks? |[ ] [ ] [ ]
| Does the study involve normal volunteers? |[ ] [ ] [ ]
| If yes: Is the inclusion of normal volunteers justified? |[ ] [ ] [ ]
| Have appropriate studies been conducted on animals and adults first? |[ ] [ ] [ ]
| If No: Is the lack of appropriate studies conducted on animals and adults justified? |[ ] [ ] [ ]
| Will older children be enrolled before younger ones? |[ ] [ ] [ ]
| Is permission of both parents necessary? |[ ] [ ] [ ]
| If yes: Are conditions under which one of the parents may be considered "not reasonably available” described? |[ ] [ ] [ ]
| If yes: Are the conditions acceptable? |[ ] [ ] [ ]
| 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? |[ ] [ ] [ ]
| Are provisions made to obtain the assent of children aged 8 year or older and, where appropriate, honoring their dissent? |[ ] [ ] [ ]
| Are provisions made to protect participants' privacy and the confidentiality of information regarding them? |[ ] [ ] [ ]
| Are there special problems that call for the presence of a monitor or advocate during consent procedures? |[ ] [ ] [ ]
| Are special needs of adolescents such as counseling and confidentiality accounted for in the research design? |[ ] [ ] [ ]
| Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers? |[ ] [ ] [ ]
| Does the research involve a condition which has implications for other family member? (for example, genetic risk, HIV infection, Hepatitis C) |[ ] [ ] [ ]
| If yes: Are adequate mechanisms in place to deal with other members of the family? |[ ] [ ] [ ]
| Should parents be required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must participants stay overnight in the hospital when they otherwise would not have to?) | [ ]  | [ ]  | [ ]  |

Comments:

Primary Reviewer Date