|  |  |  |
| --- | --- | --- |
|  | **Special Population Review Form—Children** | **irb - forms** |

**Title of Protocol:**

*Children/Minors:* Persons under age 18.

**1. State reasons for including this population in your project:**

**2. Check one of the four categories below and respond to the relevant questions as they pertain to your protocol.**

[ ]  **Children’s Risk Level (CRL) #1** (45 CFR 46.404)—Research not involving greater than minimal risk. 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. Research in this category requires both assent of the child and permission of both parents unless the IRB determines the permission of one parent is sufficient.

**• Provide protocol-specific information justifying this category:**

[ ]  **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 both parents unless the IRB determines the permission of one parent is sufficient.

• Provide protocol-specific justification in the following responses:

**(a)** How is the risk justified by the anticipated benefit to the subjects?

**(b)** How is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?

[ ]  **CRL #3** (45 CFR 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 reasonably available parent or when only one parent has responsibility for care and custody of the child. Guardian consent should be substituted for parental under appropriate legal constraints.

**NOTE**: The permission of both parents is required if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise the permission of one parent is required).

• Provide protocol-specific justification in the following responses:

**(a)** How does the risk represent a minor increase over minimal risk?

**(b)** How does the intervention or procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations?

**(c)** How isthe intervention or procedure likely to yield generalizable knowledge about the subjects’ disorder or condition?

[ ]  **CRL #4** (45 CFR 46.407)—Research not meeting the specifications above, 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.

**NOTE:** The permission of both parents is required if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise the permission of one parent is required).

• **Provide protocol-specific justification for the above:**

**3. Indicate which ONE of the following provisions for permission of parents and guardians is proposed:**

**(a)** [ ] The permission of both parents is required if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise the permission of one parent is required.

**(b)** [ ] The permission of one parent is sufficient, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. (Not allowed for CRL #3 or #4). Provide rationale for permission of one parent:

**4. Indicate whether assent will be obtained from all, some, or none of the children:**

**(a)**[ ] All children

**(i)** If so, how will assent be documented (e.g., child assent form, child’s signature on main consent document)?

**(b)**[ ] Some children (Complete Items i-iii.)

**(i)** If so, how will assent be documented (e.g., child assent form, child’s signature on main consent document)?

**(ii)** Which categories of children will not be required to assent:

[ ]  Those who are not capable of providing assent based on their age, maturity, or psychological state.

[ ]  Those whose capability is so limited that they could not reasonably be consulted for the intervention.

[ ]  Those for whom the research holds out a prospect of direct benefit that is important to their health or well-being and is available only in the context of the research.

[ ]  Those for whom the assent can be waived using the criteria for waiver of informed consent (submit [Waiver of Informed Consent](http://www.uab.edu/irb/forms/request-consent-waiver.doc) form).

**(iii)** Provide protocol-specific explanation for categories checked in Item ii:

**(c)** [ ] None of the children.

**(i)** Explain why (see categories under 4.b.ii.):

**PI Name:**      **PI Signature: Date:**