PI:  Protocol #  Date of Review:

 **“Children"** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.[ HHS regulation 45 CFR 46.402(a) and FDA regulation 21 CFR 50.3(o)]. In Pennsylvania individuals aged 17 and younger are considered children.

|  |
| --- |
| **( 1 ) Level of Risk**- Select 1 (plus any required sub-selections) then provide rationale below |
| [ ]  None of the permissible categories apply to proposed research **►** STOP! **Subpart D NOT met.** |
| [ ]  No greater than minimal risk.[HHS §46.404] [FDA § 50.51]  |
| [ ]  Greater than minimal risk **WITH** the prospect of direct benefit. * *More than minimal risk to children is presented by*:

[ ]  an intervention or procedure that holds out the prospect of direct benefit for the subject-OR-[ ]  a monitoring procedure which is likely to contribute to the well-being of the subject* *In addition, the IRB has found that*:

**[ ]**  (a) the risk is justified by the anticipated benefit to the subject-AND- **[ ]**  (b) the relation of the anticipated benefit to the risk is at least as favorable to the subject as that  presented by available alternative approaches.[HHS §46.405] [FDA § 50.52] |
| [ ]  Greater than minimal risk **WITH NO** prospect of direct benefit but likely to yield generalizable  knowledge about the subject’s disorder or condition.* *More than minimal risk to children is presented by*:

**[ ]**  an intervention or procedure that does not hold out the prospect of direct benefit for the individual  subject-OR-**[ ]** a monitoring procedure which is not likely to contribute to the well-being of the subject. * *In addition, the IRB has found that:*

**[ ]**  (a) the risk represents a minor increase over minimal risk;**[ ]**  (b) the intervention or procedure presents experiences to subjects that are reasonably  commensurate with those inherent in their actual or expected medical, dental, psychological,  social educational situations; -AND-**[ ]**  (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects'  disorder or condition which is of vital importance for the understanding or amelioration of the  subjects' disorder or condition. [HHS §46.406] [FDA § 50.53]\*\*Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.[HHS §46.408(b)] [FDA § 50.55] |
| Provide rationale for level of risk then move on to section 2:       |

|  |
| --- |
| **( 2 ) Parental Permission:** Where both parents are alive, known, competent, reasonably available, and are legally responsible for the care or custody of the child, the IRB is required to determine whether the permission of both parents is required or whether the permission of one parent is sufficient. Please address this requirement in determining if the permission of one parent is sufficient. Parental permission may not be waived for FDA regulated research. |
| **(a.)**Can parental permission be waived?(Choose one) | **[ ]**  **Yes -**Parental permission waived under [HHS §46.408(c)]: Parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. | **[ ]  Yes** **-**Parental permission waived under [HHS §46.116]: * the research involves no more than minimal risk to the subjects;
* the waiver or alteration will not adversely affect the rights and welfare of the subjects;
* the research could not practicably be carried out without the waiver or alteration; and,
* whenever appropriate, the subjects will be provided with additional pertinent information after participation.
 | **[ ]  N0-**Waiver of parental permission is not appropriate. |
| Please describe how waiver criteria chosen above are met(if applicable):  |  |
| **(b.)** If permission is not waived; Is permission of one parent sufficient for studies conducted under [HHS §46.404] [FDA § 50.51] or [HHS §46.405] [FDA § 50.52]? | **[ ]**  **Yes****[ ]  No** |
| **Provide Rationale:**  |
| **(c.)** Are adequate provisions made for soliciting the permission of each child's parents or guardian?[HHS §46.116] [FDA §50.55] | **[ ]**  **Yes****[ ]  No ►** STOP! [HHS §46.116] [FDA §50.55] **NOT** met. |
| **Provide Rationale:** |
| **(d.)** Will permission by parents or guardians be documented in accordance with and to the extent required by; [HHS §46.117 of Subpart A] [FDA §50.27 & 56.109(c)]? | **[ ]**  **Yes****[ ]  No**  |
| **Provide Rationale:** |

|  |
| --- |
| **( 3 ) Assent of children:** HHS regulation 45 CFR 46.402(a) and FDA regulation 21 CFR 50.3(n): “Assent” means a child’s affirmative agreement to participate in a clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. [HHS §46.408(a)] [FDA §50.55(b)] |
| Is assent required? (choose all that apply) | **[ ]**  **No - (Choose rationale below)** | **[ ]  Yes -**The IRB has determined that: * some or all of the children involved in the research are capable of assenting,
* that assent is required,
* and that adequate provisions are made for soliciting the assent of children.

[HHS §46.408(e)][FDA §50.55(g)]  |
| [ ]  Assent is not required because the IRB has determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted.[HHS §46.408(a)] [FDA §50.55(c)(1)] |
| [ ]  Assent is not required because the IRB has determined that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children AND is available only in the context of the research. [HHS §46.408(a)] [FDA §50.55(c)(2)] |
| [ ]  The IRB has determined that the conditions for waiver of assent are met;* Assent may only be waived when research is no more than minimal risk as determined in Section 1 of this form] [HHS §46.404] [FDA § 50.51];
* Waiver will not adversely affect the rights/welfare of subjects
* Research could not practicably be carried out w/o waiver
* Pertinent information provided later, if appropriate
 |
| 1. Please describe below how the criteria chosen above are met.

*If multiple criteria apply, be sure to distinguish by age group or other factor* |
|       |
| 1. If assent is required, please outline the assenting process below.

*If multiple processes exist, be sure to distinguish each process by age group or other factor.* |
|       |
| 1. If assent is required, please outline the assent documentation plan below or justify why documentation is not required.

*If multiple scenarios exist, be sure to distinguish each one by age group or other factor.* |
|       |