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| | OHR-26  5/2012 | | --- | | Research Involving Children | |
| **Principal Investigator:** |
| **Protocol Title:** |
| Children\* may be involved in research if the conditions in the shaded boxes in each section are met. All sections must be completed.  \* HHS regulation 45 CFR 46.402(a) and FDA regulation 21 CFR 50.3(o): “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(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. |
| **INVESTIGATOR**: Please respond to all items in shaded areas. |

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| **Level of Risk: Choose one of the following 4 categories** | | | | | | | | | | |
| **1**.  No greater than minimal risk. [HHS §46.404] [FDA § 50.51] | | | | | | **►**  **►**  **►**  **►**  **►**  **►** |  | ***INVESTIGATOR:*** *Provide rationale here* | | |
| **2.** Greater than minimal risk with 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 individual subject  OR  a monitoring procedure which is likely to contribute to the well-being of the subject.  In addition,  (a) the risk is justified by the anticipated benefit to the subjects  AND  (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. [HHS §46.405] [FDA § 50.52] | | | | | |
| **3.**  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,  (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] | | | | | | |  | | | |
| **4.**  None of the permissible categories apply to proposed research **►** STOP! Consult the Director or Associate Director, OHR | | | | | | |
| **Documentation of parental permission:** Permission by parent(s) or guardian shall be documented in accordance with and to the extent required by [HHS §46.117 of Subpart A] [FDA §50.27 & 56.109(c)] Please confirm that parental permission will be documented by signature(s) on the parental permission document.  YES  NO | | | | | | | | | | |
| For research covered under §46.406 and §46.407, 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]  Please provide status of both parents with respect to the above criteria:  PARENT 1.  PARENT 2: | | | | | | | | | | |
| **This Section To Be Completed by IRB Reviewer:** | | | | | | | | | | |
| **Parental permission:** Adequate provisions under [HHS §46.116] [FDA §50.55] are made for soliciting the permission of one or both of child's parents or guardian prior to initiating any research. This refers to the general requirements for informed consent as embodied in the OHR-8 and OHR-2, informed consent template and [HHS §46.408] concerning requirements for permission from parent(s) or guardians. | | | | | | | | | | |
| **No ►** STOP! [HHS §46.408] [FDA §50.55] **NOT** met.  **Yes** | | | | | | | | | | |
| **Waiver of parental permission:** | | | | | | | | | | |
| **Is the research regulated by FDA?** | | | | | | | | | | |
| **No ► CONTINUE** | | | | | | | | | |  |
| **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]: Waiver requires 1. No more than minimal risk, 2. Waiver will not adversely affect the rights/welfare of subjects, 3. Research could not be practicably carried out w/o waiver, 4. Pertinent information provided later, if appropriate. (all 4 conditions must be met) | | | | | | | | | |
| **No ►** STOP! [HHS §46.408(c) or ] [HHS §46.408} **NOT** met. | | | | | | | | | | |
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| **Assent of children:** 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)] | | | | | | | | | | |
| Some or all of the children involved in the research are capable of assenting. | **Can assent**  **be waived?** | **►**  **►**  **►**  **►**  **►** | **Yes: All 4 conditions are met**  [Note: 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]   * No more than minimal risk * 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 | | | | | |  | |
| **No** **►** Assent is required & adequate provisions are made for soliciting the assent of children.  [HHS §46.408(e)]  [FDA §50.55(g)] | **Must assent be documented?** | **No ►** Provide justification. | | | |
| **Yes** **►** Specify how assent will be documented. | | | |
| Assent is not required because 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 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)] | | | | | | | | |
| **IRB REVIEWER COMMENTS:** | | | | | | | | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Principal Investigator Date** | | | | | | | | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of IRB Reviewer Date** | | | | | | | | | | |