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| Study ID |  | PI |  |  |

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| **Use this form for studies subject to the Revised Common Rule.** |
| Children may only be involved as subjects if all required criteria are met and adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians. |
| **Select appropriate risk level and complete the required criteria.**  **Research not involving greater than minimal risk.** 45 CFR 46.404 / 21 CFR 50.51. Study that involves not greater than minimal risk to children may involve children as subjects only if the IRB finds that no greater than minimal risk to children is presented.  Why does the study meet this criterion?  **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.** 45 CFR 46.405 / 21 CFR 50.52. Study that involves more than minimal risk to children that is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if the IRB finds the following criteria are met:  1. The risk is justified by the anticipated benefit to the subjects.  Why does the study meet this criterion?  2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.  Why does the study meet this criterion?  **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.** 45 CFR 46.406 / 21 CFR 50.53. Study that involves more than minimal risk to children that is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds that the following criteria are met:  1. The risk represents a minor increase over minimal risk.  Why does the study meet this criterion?  2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.  Why does the study meet this criterion?  3. 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.  Why does the study meet this criterion?  **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** 45 CFR 46.407 / 21 CFR 50.54. Where IRB does not believe the study meets the requirements of 46.404, 405, or 406 / 50.51, 52, 53, the study may only involve children if:  1. The IRB finds that the study presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.  Why does the study meet this criterion?  2. The Secretary [The Commissioner of Food and Drugs], after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, {has} determine{d}[s] either:   * That the study in fact satisfies the conditions of 46.404, 405, or 406 / 50.51, 52, or 53 as applicable, or * That the following conditions are met:   + Study presents a reasonable opportunity to further understanding, prevention, or alleviation of a serious problem affecting health or welfare of children;   + Study will be conducted in accordance with sound ethical principles   ***This criteria requires submission and determination by the Secretary and/or the FDA Commissioner.*** |
| **Adequate provisions are made for soliciting the assent of the children.**    Capability of children to provide assent (ages, maturity, psychological state of children involved):  All children are capable of providing assent  Some children are capable of providing assent  No children are capable of providing assent  Judgment made for:  all children  each child  Comments?  After determining capability of children to provide assent, IRB determines whether assent is required:  Assent is not required (must meet one of the criteria below)  Capability of some or all of the children is so limited that they cannot reasonably be consulted.  Why does the study meet this criterion?  That the intervention or procedure involved 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/clinical investigation.  Why does the study meet this criterion?  Children are capable of assenting, but the IRB is waiving the assent. Meets the following requirements to waive assent.  1. Study involves no more than minimal risk to the subject.  Why does the study meet this criterion?  2. Waiver will not adversely affect the rights and welfare of the subjects.  Why does the study meet this criterion?  3. Study could not practicably be carried out without the waiver.  Why does the study meet this criterion?  4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.  Why does the study meet this criterion?   1. Does the research involve using identifiable private information or identifiable biospecimens?   No  Yes  If yes, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.  Why does the research meet this criterion?  Assent is required.  Adequate provisions are made for soliciting the assent of the children.  *5-7 verbal assent*  *8-12 assent form*  *13-18 parental consent form*  *Other,*  Documentation of assent:  Will not be documented  Will be documented  *5-7 verbal assent documented by investigator*  *8-12 signature required on assent form*  *13-18 signature required on parental consent form*  *Other,*  Comments |
| **Adequate provisions are made for soliciting the permission of each child's parents or guardian.**  IRB determines whether parental permission will be obtained.  Parental permission will be obtained.  One or Both Parents?  Parental permission of one parent is sufficient (permitted if research conducted under 404 or 405 / 50.51 or 52).  Parental permission of both parents is required (required if research conducted under 406 or 407/50.53 or § 50.54), 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.”  Documented in accordance with and to the extent required by 46.117 / 50.27  Parental permission will not be obtained (must meet one of the criteria).  Meets the following requirements to waive parental permission:  1. Study involves no more than minimal risk to the subject.  Why does the study meet this criterion?  2. Waiver will not adversely affect the rights and welfare of the subjects.  Why does the study meet this criterion?  3. Study could not practicably be carried out without the waiver.  Why does the study meet this criterion?  4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.  Why does the study meet this criterion?   1. Does the research involve using identifiable private information or identifiable biospecimens?   No  Yes  If yes, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.  Why does the research meet this criterion?  Meets the requirements that the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), provided the following are met:  1. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.  Why does the study meet this criterion?  2. Waiver is not inconsistent with federal, state, or local law.  Check box to confirm.  Comments |
| Wards. Complete if study involves children who are wards of the state or any other agency, institution, or entity and the study is approved under 45 CFR.46.406 or 407 or 21 CFR 50.53 or 54.  1. Must meet one of the following criteria (select appropriate option). Research is:  Related to their status as wards  Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.  2. Requires appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.  Why does the study meet this criterion? |

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| IRB determination made by: | | | | | | | | | |
| Expedited reviewer | | Name: |  | | Date: |  | |  | |
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| Full board | Name of individual completing this form: | | |  | | | Meeting date | |  |
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