**This form should be used when children/wards are a targeted study population.**

* **Children:** Individuals 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.
* **Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
* **Permission**: Agreement of parent(s) or guardian(s) to the participation of their child or ward in research.
* **Parent:** A child's biological or adoptive parent.
* **Guardian:** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**To be granted the correct regulatory category, waiver, or alteration of assent or parental permission, regulatory language must be documented, reviewed, and approved as part of the IRB materials. Provide protocol specific justification for each item to assist the IRB with their review.**

|  |  |  |
| --- | --- | --- |
| **Basic Information** | | |
| **Title of Study:** | |  |
| **Short Title:** | |  |
| **Principal Investigator Name:** | |  |
| **Section 1: General Information** | | |
| Age range of children (check all that apply):  7 and under 8-13 14-17 | | |
| Are the children wards of the state?  Yes  No | | |
| Where will the children complete the research?  Home  School  UA Other: | | |
| If activities will take place at a school, do you have approval from:  District  School Teacher  *\*District and school principal approval are required prior to submission to the IRB. Provide copies of these approval in “Local Site Documents” under “Other attachments” in the eIRB system.* | | |
| **Section 2: Risk Level of Children/Wards Participation**  **Select the most appropriate box below** | | |
|  | 45 CFR 46.404/ 21 CFR 50.51   * Research involving no greater risk (minimal risk) than daily life during the performance of examinations or psychological examinations or tests. | |
|  | 45 CFR 46.405/ 21 CFR 50.52   * Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects where the risk is justified by the anticipated benefit to the participants. * The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. | |
|  | 45 CFR 46.406/ 21 CFR 50.53   * 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 where the risk represents a minor increase over minimal risk. * The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. * The intervention or procedure is likely to yield generalizable knowledge about the participants’ disorder or condition that is of vital importance for the understanding or amelioration of the participants’ disorder or condition. | |
|  | 45 CFR 46.407/ 21 CFR 50.54   * Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. | |
|  | *(Wards only)* 45 CFR 46.409(a)(1)/ 21 CFR 50.56   * Research approved under 45 CFR 46.406/ 21 CFR 50.53 or 45 CFR 46.407/21 CFR 50.54 and the research is related to their status as wards. * An advocate has been appointed 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. * The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. | |
| **Provide justification for the request to include children and why it fits the criteria selected above:** | | |
| **Section 3: Parental Permission**  **Answer the question by selecting the most appropriate box below** | | |
| What parental permission will be obtained?  Obtained from both parents or Legally Authorized Representative (LAR)  Obtained from only one parent (45 CFR 46.408(b) and 21 CFR 50.55(e)(1)) or LAR   * Research involving not greater than minimal risk as defined in 45 CFR 46.404/ 21 CFR 50.51 or 45 CFR 46.405/ 21 CFR 50.52 in Section 2 above   Waiver of Parental Permission (45 CFR 46.116(f)(3))   * Research involves no more than minimal risk to 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 * If the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format * Whenever appropriate, the subjects will be provided with additional pertinent information after participation   Waiver of Parental Permission (45 CFR 46.408(c))   * 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, 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   Waiver of Parental Permission (45 CFR 46.116(e)(3))   * The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study evaluate, or otherwise examine (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration | | |
| **If a Waiver of Parental Permission is being requested, provide justification for the waiver:** | | |
| **If permission is going to be obtained from someone other than the parent, how will the Legally Authorized Representative (LAR) be determined? Explain:** | | |
| **Section 4: Child Assent** | | |
| If obtaining assent, explain how it will be obtained: | | |
| If requesting a Waiver of Assent, ***select the most appropriate box below:*** | | |
|  | Waiver of Assent (45 CFR 46.408(a) and 21 CFR 50.55(c)(1))\*   * The IRB has taken into account the ages, maturity, and psychological state of the children involved and determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted; therefore, the assent of the children is not a necessary condition for proceeding with the research.   *\*Note that if your age range is between 0-7 years, this box may be checked* | |
|  | Waiver of Assent (45 CFR 46.408(a) and 21 CFR 50.55(c)(2))\*   * 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 that the intervention is only available in the context of the research. * Therefore, the assent of the children is not a necessary condition for proceeding with the research.   *\*Note that this request may only be used when 45 CFR 46.405 has been checked in the section above* | |
|  | Waiver of Assent (45 CFR 46.116(f)(3)) and 21 CFR 50.55(d))   * The research involves no more than minimal risk to 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. * If the research involves using identifiable private information or identifiable biospecimens, the research could not be carried out without using such information or biospecimens in an identifiable format. * Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | |
|  | Waiver of Assent (45 CFR 46.116(e)(3))   * The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study evaluate, or otherwise examine (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration. | |
| **If requesting a Waiver of Assent, provide justification for the request:** | | |