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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when the research involves a minor increase over minimal risk to the children[[1]](#footnote-1) as subjects. To meet the requirements for including children, the IRB must make the following determinations:   1. The risk represents a minor increase over minimal risk; 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; 3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and 4. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.   When the research involves more than one cohort and the risks/benefits differ between the cohorts, the reviewer(s) must apply the categories to each cohort in the study by completing more than one checklist.  When applicable, this checklist or equivalent must be used for all applicable initial reviews, continuing review, and review of modifications. If the determinations are the same as the previous determinations, the reviewer does not need to upload the checklist and can indicate in the notes that the determinations are unchanged from last review.  When the determinations in the checklist are required, the Designated Reviewer completes this checklist, or equivalent, and uploads the completed checklist to the applicable submission in the HSRO’s electronic system.  When the determinations in the checklist are required, one of the following two options may be used:   1. The convened IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained. 2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol | |
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| **1** | For each of the following, provide protocol specific findings to justify the response. |
|  | Why does this research involve a minor increase over minimal risk? |
|  | How do the interventions or procedures present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations? |
|  | How are the interventions or procedures likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition? |
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| **2** | **Parental Permission - For each of the following, check the applicable boxes and provide the additional information requested.** |
|  | Adequate provisions are in place for soliciting the permission of parents or guardians[[2]](#endnote-1).  Permission is to be obtained from both parents 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.  Parental permission is waived because **Caution: Florida law does not permit children to be involved in human subject research without parental or guardian consent.** |
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| 3 | **Assent - For each of the following check the applicable boxes and provide the additional information requested.** |
|  | Adequate provisions are made for soliciting the assent of the children. Assent will be obtained from: **(Check box that is true)**  All children.  None of the children.  Some children. *Specify which children* |
|  | If assent will not be obtained from any of the children, one or more of the following are true. **(Check all boxes that are true.)**  Assent is waived because the capacity of the children is so limited that they cannot reasonably be consulted  Assent is waived because 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.  The requirements for a waiver of consent under 45 CFR 46.116(f) are met.  Not applicable. Assent will be obtained from all children. |
|  | Documentation of assent  Not applicable, assent will not be obtained.  Investigator will document assent in the consent signature block.  The child will sign an information sheet.  Other *(NOTE: The protocol should describe the process of assent documentation)* |
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| 3 | **If the research involves Wards of the State, answer the following.** |
|  | This research intends to involve Wards of the State. ***If not checked, Stop.*** ***There is no need to complete this section***. **If checked, a*ll of the following must also be checked to include Wards of the State.*** |
|  | One of the following is true: **(Check box that is true**)  The research is related to their status as wards.  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 protocol specific findings justifying this determination:* |
|  | An advocate will be 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. *Provide information to support this determination:* |
|  | The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child’s participation in the research.  *Provide information to support this determination:* |
|  | The advocate 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.  *Provide information to support this determination***:** |
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|  | | Whenever appropriate, the subjects will be provided with additional pertinent information after participation.  *Provide protocol specific findings justifying this determination:* |
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1. The definition of “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. Investigators must consult legal counsel if there is any question as to the ability of a minor to consent to procedures. [↑](#footnote-ref-1)
2. [↑](#endnote-ref-1)