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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 minimal risk research involves children[[1]](#footnote-1) as subjects.  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 specific findings justifying those determinations and the Human Subject Research Office retains this checklist in the protocol file. | |
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|  | The research involves no greater than minimal risk to the children because . |
|  | 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.  Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares 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.** |
|  | 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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|  | | 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)