|  |
| --- |
| 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 greater than minimal risk with a prospect of direct benefit to the children[[1]](#footnote-1) as subjects. To meet the requirements for including children, the IRB must make the following determinations:1. The research involves greater than minimal risk;
2. The research offers a potential for direct benefit to the individual child;
3. The risk of the research is justified by the anticipated direct benefit to the children;
4. The relation of the anticipated benefit to the risk is at least as favorable to the children as that presented by available alternatives; and
5. 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
 |
|  |
| **1** | For each of the following, provide protocol specific findings to justify the response and check the box to the left when complete.  |
| [ ]  | Why does this research involve greater than minimal risk?  |
| [ ]  | What potential direct benefits does this research offer?  |
| [ ]  | One of the following is true**. (Check box that is true**)[ ]  The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.[ ]  The risk to children is presented by a monitoring procedure that is likely to contribute to the subject’s well-being.*Provide protocol specific findings justifying this determination:* |
| [ ]  | Why is the risk justified by the anticipated benefit to the subjects?  |
| [ ]  | Why is the relation of the anticipated benefit to the risk as least as favorable to the children as that presented by available alternatives?  |
|  |  |
| **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.[ ]  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.**  |
|  |  |
|  | **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)* |
|  |
|  |
|[ ]  Whenever appropriate, the subjects will be provided with additional pertinent information after participation.*Provide protocol specific findings justifying this determination:*       |
|  |

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)