BYU
Human Research Protection Program

IRB REVIEWER CHECKLIST FOR SUBPART D- ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH

The purpose of this checklist is to provide support for IRB members when research subjects are minors. This checklist must be used for all reviews (initial, continuing, modification, for both full board and expedited categories).

Project Title: Enter text.	**IRB#:** Enter text.	**Principal Investigator:** Enter text.

1 Research involving children under 45 CFR §46.405 (Check if **"Yes".** All must be checked)

☐	The research involves greater than minimal risk to subjects. *Provide protocol specific findings justifying this determination:*
☐	The research presents the prospect of direct benefit to the individual subjects. *Provide protocol specific findings justifying this determination:*
☐	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:*
☐	The risk is justified by the anticipated benefit to the subjects. *Provide protocol specific findings justifying this determination:*
☐	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. *Provide protocol specific findings justifying this determination:*

2 Research involving children under 45 CFR §46.404 (Check if **"Yes".**)

☐	No greater than minimal risk to children is presented. *Provide protocol specific findings justifying this determination:*

3 Research involving children under 45 CFR §46.406 (Check if **"Yes".** All must be checked)

☐	The research involves greater than minimal risk to children 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 which is not likely to contribute to the well-being of the subject. *Provide protocol specific findings justifying this determination:*
☐	The risk represents a minor increase over minimal risk where the researcher has presented sufficient evidence that the procedures, population, and the qualifications of research personnel support all of the following to be true: **(Check boxes that are true. All must be checked.)** ☐ The increase in the probability and magnitude of harm is only slightly more than minimal risk. ☐ Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period). ☐ There is no, or an extremely small probability, that participants will experience as severe the potential pain, discomfort, stress, or harm associated with the procedure. *Provide protocol specific findings justifying this determination:*
☐	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. *Provide protocol specific findings justifying this determination:*

☐	The risk is justified by the anticipated benefit to the subjects. *Provide protocol specific findings justifying this determination:*
☐	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. *Provide protocol specific findings justifying this determination:*

4	**Not otherwise approvable research involving children under 45 CFR §46.407** (Check if **"Yes".** All must be checked)
☐	The research does not meet the requirements of Sections 2, 3, or 4 *Provide protocol specific findings justifying this determination:*
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. *Provide protocol specific findings justifying this determination:*

5	**Research involving wards of the state or any other agency, institution, or entity under 45 CFR §46.409 (Check if "Yes". All must be checked)**
☐	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 for research approved under §46.406 or §46.407. *Provide protocol specific findings justifying 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 protocol specific findings justifying 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 protocol specific findings justifying this determination:*

6	**Adequate provisions for soliciting the permission of parents or guardians** (Check if **"Yes".** All must be checked)
☐	**One of the following is true: (Check box that is true)** ☐ **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. (Cannot be selected for Section 4 or 5 criteria)** ☐ **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.** ☐ For non FDA-regulated research, parental permission is waived under criteria in Section 8

7	**Waiver of Parental Permission under 45 CFR §46.408(c)** (Check if **"Yes".** All must be checked)
☐	The research is not FDA-regulated.
☐	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. *Provide protocol specific findings justifying this determination:*

☐	An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. *Provide protocol specific findings justifying this determination:*
☐	The waiver is consistent with Federal, State, or local law. *Provide protocol specific findings justifying this determination:*

8 Adequate provisions to solicit the assent of children (Check if **"Yes".** All must be checked)

☐	Assent will be obtained from: **(Check box that is true)** ☐ All children. **(Complete Section 11)** ☐ None of the children. **(Complete Section 10)** ☐ Some children. **(Complete Section 10 and Section 11. The protocol needs to describe which children will not be asked for assent)**

9 Reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c) (Check if **"Yes".** All must be checked)

☐	One or more of the following are true. **(Check all boxes that are true.)** ☐ The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted. ☐ 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 is available only in the context of the research. ☐ Assent is waived because the research meets the same conditions as those required for a waiver of informed consent in research involving adults (45 CFR 46.116(f)(3)).

10 Documentation of assent (Check if **"Yes".** All must be checked)

☐	If **"Yes"**, specify the process for documentation: ☐ Investigator will document assent in the consent signature block. ☐ Investigator will document verbal assent as described in the protocol.