**IRB Full Board Review Checklist**

IRB File No.: **«Tracking\_Number»**

**Attachment 1 - Children**

Under the regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable jurisdiction in which the research will be conducted.

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| **Category Determination** | |
| **Category 1:** [**45 CFR 46.404**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.404) **– Research not involving greater than minimal risk**  The research meets **all** of the following conditions:   * The research is not greater than minimal risk, **AND** * Permission of at least one parent or guardian will be obtained (or waived); **AND** * Assent of child will be obtained (or waived), if child is capable of providing assent   Yes  No – document justification in the comments section | |
| **Category 2:** [**45 CFR 46.405**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.405) **– Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects**  The research meets **all** of the following conditions:   * The research involves greater than minimal risk, but presents the prospect of direct benefit to individual subjects, **AND** * Risk is justified by anticipated benefit to subject; **AND** * Benefit to risk ratio is at least as favorable as that presented by alternative approaches; **AND** * Permission of at least one parent or guardian will be obtained (or waived); **AND** * Assent of child will be obtained (or waived), if child is capable of providing assent, unless the benefit is not available outside the research   Yes  No – document justification in the comments section | |
| **Category 3:** [**45 CFR 46.406**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.406) **– 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.**  The research meets **all** of the following conditions:   * The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield vitally important generalizable knowledge about the subjects’ disorder or condition, **AND** * Risk represents a minor increase over minimal risk; **AND** * The research presents experiences reasonably commensurate with those inherent in subjects’ actual or expected medical, dental, psychological, social or educational situations; **AND** * Permission of both parents or guardian will be obtained (or waived) unless either parent is not reasonably available or does not have legal responsibility for care and custody of the child; **AND** * Assent of child will be obtained (or waived), if child is capable of providing assent.   Yes  No – document justification in the comments section | |
| **Category 4 –** [**45 CFR 46.407**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.407) **– Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**  The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and should be forwarded to the HHS Secretary for review.  Yes  No – document justification in the comments section | |
| **Child Assent Procedures** | |
| 4a. Age range of minor subjects: |  |
| 4b. Assent of child participants will be sought in a manner appropriate to their level of development and cognitive understanding.  *Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed to be assent.*  Yes  No – document justification in the comments section  N/A, assent process will be waived / is not required  *Some or all children are not able to be consulted, considering age, maturity, and psychological state;* **OR** *the research provides the prospect of direct benefit that is important to their health or well-being and is only available in the context of the research.*  *If it is determined that subjects are capable of assenting, the assent requirement may be waived under the same conditions for which informed consent may be waived* [[45 CFR 46.408(a)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)] | |
| 4c. Assent of child participants will be adequately documented in a manner appropriate to child participants’ level of development and cognitive understanding.  Yes  No –complete 4d  N/A, documentation of assent process will be waived / is not required  *If it is determined that subjects are capable of assenting, the assent requirement may be waived under the same conditions for which informed consent may be waived* [[45 CFR 46.408(a)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)] | |
| 4d. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented [[45 CFR 46.408(e)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)]. If protocol does not appropriately or adequately document assent, please recommend how assent should be obtained (see [*Assent Guidelines*](https://www.eiu.edu/grants/Assent%20Guidelines.docx) *for more information*):  Assent not documented, but obtained orally  Assent documented using an assent form  Assent documented using signature block on parent permission form | |
| Comments: | |
| Signature of IRB Chair: | |