**IRB Expedited Review Checklist**

IRB File No.:

**Attachment 1 – Children [**[**45 CFR 46, Subpart D**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html)**]**

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. [[45 CFR 46.402](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.402)]

|  |  |
| --- | --- |
| 1. The research involves no more minimal risk to subjects  Yes  No – Full Board Review is required [[45 CFR 46.404](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.404)]; document rationale in the comments section | |
| 2. Informed consent of at least one parent or guardian will be adequately solicited [[45 CFR 46.408(b)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)]  Yes  No – document justification in the comments section  Parental informed consent will be waived; appropriate mechanisms are in place [[45 CFR 46.408(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)] | |
| 3. Informed consent of at least one parent or guardian will be adequately documented  Yes  No – document justification in the comments section  N/A, documentation of parental consent will be waived [[45 CFR 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.117)] and [[45 CFR 46.408(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.408)] | |
| **Assent:** | |
| 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 is 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. 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 Reviewer: | |