|  | Point Addressed | Comment |
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| Q1 | Consent/assent process for: Initial Consent [ ]  Reconsent [ ]  Other [ ]   |  |
| Q2 | Age of child-participant at the time of the consent/assent process:      *If the participant reaches the age of 18 and is still undergoing research procedures, obtain continuing consent and complete an adult consent process form.* |  |
| Q3 | Where did the consent/assent process take place?       (e.g., in-person, remote via Teams or ZOOM) |  |
| Q4 | Did the IRB determine that one or both parents must provide permission for the child-participant to participate in research?  One Parent [ ]  Both Parents [ ]  |  |
| Q5 | Who was present during the consent/assent process?      (e.g., child-participant, mother(s), father(s), legal guardian, CRC, investigator) If **both parents** must provide permission and only one parent is present, provide the reason and complete a separate consent/assent note when the second parent provides consent which must be obtained prior to performing study procedures.      If a **legal guardian** is providing permission, file a copy of the court order or legal document establishing guardianship and right to consent for participation in research with the signed consent form. Contact askirb@pitt.edu with questions prior to obtaining consent/assent.If the child-participant is a **ward of the state**, contact askirb@pitt.edu prior to obtaining consent/assent.  |  |
| Q6 | Was an adequate opportunity provided for the individual(s) involved in the consent/assent process to read the consent form? Yes [ ]  No [ ]  |  |
| Q7 | Who reviewed the consent form and explained the details of the study to the individual(s) involved in the consent/assent process?      (e.g., investigator, CRC) |  |
| Q8 | Were all questions of the individual(s) involved in the consent/assent process adequately addressed?  Yes [ ]  No [ ]  |  |
| Q9 | Did the IRB determine that assent must be obtained from the child-participant? Yes [ ]  No [ ]  **Skip to Q11** |  |
| Q10 | How did the child-participant provide positive affirmation to participate in the study? Written Assent [ ]  **(**e.g., signed/dated Child Assent section of Consent Form) Verbal Assent [ ]  **Provide reason:**       (e.g., developmentally unable to provide written assent) Assent Not Provided [ ]  **Provide reason:**       (e.g., developmentally unable to provide written and verbal assent)  |  |
| Q11 | Was the consent form signed and dated by all parties prior to performance of any study related procedures? Yes [ ]  No [ ]  |  |
| Q12 | Was a copy of the consent form provided to the individual(s) providing consent and/or assent? Yes [ ]  No [ ]  |  |
| Q13 | Additional details surrounding the consent/assent process:       |  |

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Printed Name of Person Completing this Form Signature of Person Completing this Form Date

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| *If the person completing this form was not present for the consent discussion, an individual that was present should sign and date this form to verify the information provided is accurate.*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Person Present for Consenting Signature of Person Present for Consenting Date |