|  | Point Addressed | Comment |
| --- | --- | --- |
| 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](mailto:askeirb@pitt.edu) with questions prior to obtaining consent/assent.  If the child-participant is a **ward of the state**, contact [askirb@pitt.edu](mailto: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: |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_

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

|  |
| --- |
| *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 |