TCSPP Institutional Review Board (IRB)

Supplemental Form C
Research Involving Children

The directive of the IRB is to protect the rights and welfare of human research subjects. The special vulnerability of children makes the consideration involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations (Title 45 CFR 46 Subpart D) are in place for reviewing research involving children. As such, the IRB is required to consider the risks and discomfort in relation to the benefits to the child and/or to society as a whole. To assist the IRB in this consideration please address the following questions.

1. **Please include a brief statement to describe any previous experience you may have working with this subject population.**

[Delete this sentence and place your response here.]

Study Population

2. **To assist the IRB in their consideration of the proposed research, please indicate below whether the study involves children who have a disease or condition or whether the study involves healthy children**.

[*Delete this sentence and place your response here.]*

Justification

3. **Provide justification for including children in this study. Include the following in your justification:**
   - **Describe the potential and/or perceived risks and direct benefits to the children participating in the research.**
   - **If there are no direct benefits to the children state so and describe the benefits to society.**
   - **Indicate whether the research involves children who are healthy and/or with a condition or disorder.**
   - **If using both groups of children provide a justification for each group and identify the risks and direct benefits for each group**.

[*Delete this sentence and place your response here.]*

4. **Indicate the age range of subjects by checking the appropriate box(es).**

☐ 0 - 6 years ☐ 7 - 17 years

5. The Office of Human Research Protections (OHRP) define minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations.

In considering this definition, please check the appropriate box to describe the risk level for this study.

☐ No greater than minimal risk.

☐ Greater than minimal risk but presents the prospect of direct benefit to the subject.

☐ Greater than minimal risk with no prospect of direct benefit but likely to yield knowledge about the subject's disorder or condition.

Consent/Parent Permission

6. Will written parental permission be obtained?

☐ Yes ☐ No

a. Please clarify whether or not the consent of one or both parents will be sought.

Please note if the risk to the subject is more than minimal without the prospect of direct benefit to the subject, the consent of both parents will be required unless one parent is deceased, unknown or reasonably unavailable. Please note if your study is minimal risk only the consent of 1 parent is required.

☐ One parent ☐ Both parents

Assent of the Child

The IRB must determine if appropriate provisions have been made for soliciting the assent of the child if they are capable. Find regulations regarding this here: http://answers.hhs.gov/ohrp/search/results?q=assent&commit=Search+FAQs.

7. Please describe the assent process according to age and submit the documents (i.e., assent script, assent criteria, or assent form) that will be used. For example subjects 0-7 may provide verbal assent and subjects 7-17 may sign a separate Assent form. Documents used to obtain assent must be appropriate for the child's age and reading level.

[*Delete this sentence and place your response here.]*

8. Please describe how it will be determined that the child has agreed to participate.

[*Delete this sentence and place your response here.]*

9. Please describe the developmentally appropriate criteria that will be used to determine if child wishes to discontinue their participation.

[*Delete this sentence and place your response here.]*

10. If applicable submit an assent form(s). Provide the name of the assent form(s).

[*Delete this sentence and place your response here.]*

Wards

11. Will this study involve children who are Wards?*

***Please note children who are wards of the state or any other agency, institution, or entity may be included in research that is greater than minimal risk without prospect of direct benefit to the child, but like to yield generalizable knowledge about the child's disorder, only if the research is:**

- **related to their status as wards or**
- **conducted in schools, camps, hospitals, institutions or similar setting in which the majority of children are not wards.**

☐ Yes ☐ No

12. If your research is greater than minimal risk with no prospect of direct benefit to the child but likely to yield knowledge about the child's disorder or condition, describe how you will ensure that the appropriate person(s) (e.g., legal guardian) grant permission for each ward to participate and how consent will be obtained. If this item does not apply please state so.

[*Delete this sentence and place your response here.]*