TANEY COUNTY HEALTH DEPARTMENT

IRB CHECKLIST – CHILDREN

HRPP # _____

PART A – BACKGROUND INFORMATION

Children Defined: 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.

1. **Child subject age range:**

2. **Please verify that the investigator has provided adequate background information for the proposed research.**

	Yes	No	N/A
a. Information specifying the legal age for consent to treatments or procedures involved in the research under the applicable jurisdiction has been provided	☐	☐	☐
b. For greater than minimal risk research involving wards of the State: • The research is related to their status as wards or conducted in settings in which the majority of subjects are not wards; **AND** a. An advocate has been appointed for each ward/child/subject	☐	☐	☐
1. Overall protections for children in this research are adequate	☐	☐	☐

Comments or Concerns:

PART B – CATEGORY DETERMINATIONS

Child Categories: Research involving children must comply with 45 CFR Part 46, Subpart D. When reviewing research involving children, the IRB must consider several important issues including: (i) the risk-benefit analysis to determine permitted regulatory categories; (ii) assent of the child; and (iii) permission of one or both parents, depending upon the level of risk.

Please verify that the investigator has provided adequate background information for the proposed research.

Please verify that the investigator has submitted sufficient information to determine that the following criteria have been satisfied:

	Yes	No
Category 1 – §46.404 – Research not involving greater than minimal risk: The research is not greater than minimal risk; **AND**: ▪ Permission of at least one parent will be obtained; and • Assent of child will be obtained.	☐	☐

Category 2 – §46.405 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects: 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 will be obtained; and • Assent will be obtained unless the benefit is not available outside the research.	☐	☐
Category 3 – §46.406 – Research involving greater than minimal risk but presenting NO prospect of direct benefit to the individual subjects: The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but will likely yield vitally important generalizable knowledge about the subjects' disorder or condition, **AND**: ▪ Risk represents a minor increase over minimal risk; ▪ The research presents experiences reasonably commensurate with those inherent in subjects' actual or expected medical, dental, psychological, social, or educational ▪ Permission of both parents will be obtained unless either parent is not reasonably available • Assent will be obtained	☐	☐
Category 4 – §46.407 – Research not otherwise approvable: • The research is not otherwise approvable but would help understand, alleviate, or prevent a serious child health problem and should be forwarded to the Director or other researchers for review.	☐	☐
Comments or Concerns:		

PART C – ASSENT PROCEDURES

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research. **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

3. Please recommend whether and how assent should be obtained:	Age Range if Applicable
☐ No Assent Necessary (check one):	
☐ Some or all children are not able to be consulted, taking into account the ages, maturity and psychological state; or	_____
☐ Research holds out a prospect of direct benefit that is (1) important to the health or well-being of the children; AND (2) only available in the context of the research	
☐ Assent not documented but obtained orally	_____
☐ Assent documented using assent form	_____
☐ Assent documented using signature block on informed consent form	_____

Comments or Concerns:

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