



**Institutional Review Board
Vulnerable Populations: Children**

Research Proposal Title: _____

Principal Investigator: _____

Campus: _____ **Department:** _____

Phone: _____ **Email Address:** _____

SECTION 1: Select the category that best describes your proposed research.

Please check the box(es) that best describes your proposed research. Answer the corresponding questions and then complete Sections 2 – 4 and Section 5, if applicable.

Note: When reviewing these categories, consider whether the research poses greater than minimal risk to subjects (i.e., full committee review). Expedited research usually falls within Category 1; Full committee research usually falls within Category 2 or 3.

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CATEGORY 1 ([§46.404](#)) - This proposed research poses no greater than minimal risk to children if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. (Note: for research that qualifies for Expedited level of review).

- Indicate why the proposed research poses no greater than minimal risk to children.

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CATEGORY 2 ([§46.405](#)) - This proposed research poses greater than minimal risk to children and includes an intervention or procedure that **DOES hold out the prospect of a direct benefit** for the individual child **or** a monitoring procedure that is likely to contribute to the child's well-being.

- Explain why the risk is justified by the anticipated benefit to the child.

- Explain why the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.



CATEGORY 3 ([§46.406](#)) - This proposed research poses greater than minimal risk to children and is presented by an intervention or procedure that **DOES NOT hold out the prospect of direct benefit** for the individual subject **or** by a monitoring procedure which is not likely to contribute to the well-being of the subject but is likely to yield generalizable knowledge about the subject's disorder or condition.

- Justify why the risk represents a minor increase over minimal risk.

- Explain why the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.

- Identify the subjects' disorder or condition.

- Explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.



CATEGORY 4 ([§46.407](#)) - This proposed research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The Secretary of HHS will review and after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) there will follow opportunity for public review and comment.

- Justify why the that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

- Identify the subjects' disorder or condition.

- Explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Section 2: Parental Permission

- **Select one statement that best describes how you will obtain parental permission. Answer the corresponding questions.**

☐ I will obtain the permission of each parent or guardian, unless a parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. [required for Categories 3 & 4 above]

☐ I will obtain the permission of one parent or guardian.

Section 3: Assent

- **Select which best describes how you will be obtaining assent and answering the corresponding questions.**

☐ I will obtain assent from all children.

☐ I will obtain assent from some children.

Explain which children will not be asked for assent.

☐ I will not obtain assent from any of the children because the capability of these children is so limited that they cannot reasonably be consulted.

Explain the limitations of the children's ability to assent based on their ages, maturity and psychological state.

Principal Investigator Signature: _____ **Date:** _____

Email forms and supporting documentation to: irb@tccd.edu.