Syracuse University Institutional Review Board

Vulnerable Populations:

CHILDREN

Principal Investigator:

Study Title:

*Attach this completed form to the IRB Application when “Children/Minors” is checked in Section 6 – Characteristics of Participants.*

**Place a check in the box beside the category that best describes your proposed research.**

**CATEGORY 1 (§46.404)** This proposed research poses no greater than minimal risk to children.

**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.

**CATEGORY 3 (§46.406)** This proposed research poses greater than minimal risk to children and includes 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.

**CATEGORY 4 (§46.407)** This proposed research does not meet the requirements of Categories 1, 2 or 3 above.

Does the research involve minimal risk?

No  Yes

**OR**

Does the research involve more than minimal risk with the prospect of direct benefit to the individual child?

No  Yes

If yes:

The permission of both parents will be obtained unless one 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.

The permission of one parent is sufficient.

Please justify your answer:

If the research involves more than minimal risk without the prospect of direct benefit to the individual child, explain why the risk represents a minor increase over minimal risk. Include in your explanation how adequate provisions will be made for soliciting the assent of the children and the permission (parental/guardian informed consent) of their parents/guardians.\*

Adequate provisions will be made for soliciting the assent of:

all of the children.

some of the children.

none of the children.

If assent is not a requirement for some or all of the children, which of the following are true

The children are not capable of providing assent based on age, maturity or psychological state.

The capability of the children is so limited that they could not reasonably be consulted.

The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

Assent can be waived using the criteria for waiver of informed consent. (This requires a determination by the IRB that waiver of consent is justified.)

Please justify your answer:

Explain the process you will use to document assent.

If you are doing research outside of New York State, and anticipate obtaining written consent from an authorized legal guardian, provide the definition of a guardian in the jurisdiction in which enrollment will take place.

N/A

**\*NOTE. When research is covered by** [**§46.406**](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.406#46.406) **or** [**§46.407**](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.407#46.407)**, informed consent must be obtained from both parents unless one 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**