Touro University Nevada

Touro University Nevada **I**nstitutional **R**eview **B**oard (**IRB**)

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**Addendum 2: Research with Children**

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| **Principal Investigator:** |  |
| **Study Title:** |  |

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

The HHS regulations at 45 CFR part 46, subpart D permit IRBs to approve 1-3 categories of research involving children as subjects. The fourth category of research requires a special level of HHS review beyond that available to the IRB.

**For any research involving children, identify and explain which of the four categories of research apply to that study, if any.**

1. Research **not involving greater than minimal risk** to the children.

To approve research in this category **all of the conditions** **below must be satisfied**.

1. The research presents no greater than minimal risk to the children.

**Explain how this condition is met:**

1. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at [45 CFR 46.408](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408).

**Explain how this condition is met:**

1. Research **involving greater than minimal risk** **but presenting the prospect of direct benefit** to the individual child subjects involved in the research. (*Note:* ***signatures of both parents may be required****.*)

To approve research in this category **all 3 conditions below must be satisfied**.

1. The risk is justified by the anticipated benefits to the subjects.

**Explain how this condition is met:**

1. The relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches.

**Explain how this condition is met:**

1. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

**Explain how this condition is met:**

1. Research **involving greater than minimal risk and no prospect of direct benefit** to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. (*Note:* ***signature of both parents will be required****.*)

In order to approve research in this category, **all of the 4 conditions must be satisfied**.

1. The risk of the research represents a minor increase over minimal risk.

**Explain how this condition is met:**

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

**Explain how this condition is met:**

1. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition.

**Explain how this condition is met:**

1. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

**Explain how this condition is met:**

1. This research is not otherwise approvable but presents an opportunity to understand, prevent,

or alleviate a serious problem affecting the health or welfare of children. Research falling into this category can be approved only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts, determines that the research satisfies applicable conditions under 45 CFR 46.407. Contact IRB with any further questions.