IRB Appendix I - Minors

Rev. March 2015

Complete this form to request inclusion of participants who are considered minors.

Minor(s) *- Person(s) who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. For purposes of URI policy, individuals under 18 years of age are considered children in Rhode Island unless they meet the definition of emancipated minors.*

The inclusion of minors as participants in research requires that the investigator comply with the additional protections provided in 45 CFR 46 Subpart D and 21 CFR 50 Subpart D. For more information, see 45 CFR 46 Subpart D: Children

Principal Investigator:

Project Short Title:

1. Select the category that best describes the research and provide the corresponding information:

☐ Not greater than minimal risk --> Go to **Question #2**

☐ More than minimal risk is presented by an intervention or procedure that holds the prospect of direct benefit for the individual minor, or by a monitoring procedure that is likely to contribute to the minor's well-being

a. Explain how the risk is justified by the anticipated benefit to the individual minor.

b. Explain how the relation of the anticipated benefit to the risk is at least as favorable to the minor as that which would be presented by available alternative approaches (e.g., other treatments).

☐ More than minimal risk is presented by an intervention or procedure that holds the prospect of direct benefit for the individual minor, or by a monitoring procedure that is likely to contribute to the minor's well-being

a. Explain how the risk represents a minor increase over minimal risk.

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

c. Explain how the intervention or procedure is likely to yield generalizable knowledge about the minor's disorder or condition that is of vital importance for the understanding or amelioration of the minor's disorder or condition.

2. Explain the process of obtaining informed consent/assent from minors and their parents (i.e., will parents and minor be approached separately or together?).

3. Will the parents or guardians be present with the minor during other discussions of the research?

- ◯ Yes
- ◯ No

4. Will incentives be offered to the research participants?

- ◯ Yes
- ◯ No

If Yes, complete the following:

a. Specify the incentives:

b. The incentives will be offered to: ☐ Parent/Guardian ☐ Child

5. Will sensitive or private information (e.g., questionnaires, test results) be shared with the parents/guardians?

- ◯ Yes
- ◯ No

If **Yes,** explain:

6. If participation is to continue beyond the time that the minor is 18 years of age, describe the process to be used to re-consent the participant.

☐ N/A

7. Is there a possibility that any of the research participants will be wards of the State or any other agency or institution?

- ◯ Yes
- ◯ No