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ELECTRONIC SUBMISSION REQUIRED

APPENDIX H
Children

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

Children/Child *- 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 MU HSRC policy, individuals under 18 years of age are considered children in Michigan unless they meet the definition of emancipated minors.*

The inclusion of children 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.

Investigator Name

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 child, or by a monitoring procedure that is likely to contribute to the child's well-being
	a. Explain how the risk is justified by the anticipated benefit to the individual child.
	b. Explain how the relation of the anticipated benefit to the risk is at least as favorable to the child 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 *does not* hold the prospect of direct benefit for the individual child, or by a monitoring procedure that is not likely to contribute to the child'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 children 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 child's disorder or condition that is of vital importance for the understanding or amelioration of the child's disorder or condition.

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

3. Will the parents or guardians be present with the child 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 (below):		
b. The incentives will be offered to:	Child	
	Parent	

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 child 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	