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**Supplement Form A**

**Research Involving Children as Subjects**

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| **PI Name:** | **Date:** Click here to enter a date. | |
| Protocol Title: | | WMed IRB #:  *(for IRB Office use only)* |

Please see appendix A at the end of this document for a better understanding of Michigan legal requirements.

1. **Children as Subjects**
   1. **What is the age range of the children in this research?**

* 1. **Where will the children participate?**

Home

School Name of school:

If checked, have you obtained the necessary permission from the school district?

Yes  No *(Attach/upload documentation of permission)*

University lab/office:

Inpatient Hospital/Facility:

Borgess

Bronson

Other

Outpatient Clinic/Facility *(ie. Woodbridge Family Practice, WMed Clinics)*:

Other - Specify:

If checked, have you obtained the necessary permission?

Yes  No *(Attach/upload documentation of permission)*

* 1. **Are any of the children wards (46.409) of the State or any other agency, institution, or entity?**  Yes  No

If yes, provide details:

1. **Allowable Categories**

**Check the category below that best represents the degree of risk and benefit to which the children in this study will be exposed.**

*More than one category may be indicated such as when a protocol involves both an experimental and a control group; in these cases, please specify which category you believe applies to which group:*

**Category 1 (46.404/50.51): (Research not involving greater than minimal risk.)** *Minimal risk*means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Provide rationale:

**Category 2 (46.405/50.52): (Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.)** More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being.

Provide rationale for why/how:

1. the risk is justified by the anticipated benefit to the subjects:

1. 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 (46.406/50.53): (Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.)** More than minimal risk to children 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.

Which intervention(s) or procedure(s) present more than minimal risk without offering the prospect of direct benefit to individual subjects:

Provide rationale for why/how:

1. The risk of the intervention(s) or procedure(s) represents a minor increase over minimal risk:

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

1. The intervention(s) or procedure(s) 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 (46.407/50.54): (Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.)** The proposed research does not meet the criteria of the above categories but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Provide justification for why this research should be approved:

1. **Parental Permission (46.408/50.55)**
   1. **What permission will be obtained from the parents?**

In general, permission from both parents is required for research involving children 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. For Categories 404/51 & 405/52, however, the IRB may find that the permission of one parent is sufficient.

Permission will be obtained from both parents where possible.

Permission from only one parent is being requested

A waiver of parental permission is being requested - *complete Supplement Form E*

Provide justification for a waiver:

* 1. **If the research is being conducted in a group setting (e.g., a classroom), explain what provisions have been made for children whose parents have not given permission for** **them to participate**:

1. **Assent from Children (46.408/50.55)**

Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

* 1. **Please indicate whether the children you intend to include in the research are generally capable of providing assent taking into account the ages, maturity and psychological state of the children proposed to be involved. Please be specific:**

All are capable:

None are capable: Explain:

Some are capable: Explain:

* 1. **If children are capable of providing assent, are you planning to obtain assent from the children?**  Yes  No  NA (children are not capable to provide assent)

If Yes, describe the proposed process for obtaining assent, including who will be involved and the setting and circumstances under which it will be sought:

If No, one of the two options below must be true:

**You are requesting a waiver of assent.** Explain how the research meets the criteria for a waiver (i.e., the research is no more than minimal risk, the waiver will not adversely affect the rights and welfare of subjects, the research is not practicable without the waiver, and, when appropriate, subjects will be provided with pertinent information after participation):

**The intervention(s) or procedure(s) involved in 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.**

Explain:

* 1. **If assent will be obtained, describe if and how assent will be documented. Attach copies of proposed assent forms, if any.**  NA

**Appendix A**

Michigan law defines the “age of majority” in MCL 722.51 (The Age of Majority Act of 1971, MCL 722.51-722.55). An individual who is eighteen or older is an “adult” and is able to consent to undergo most medical procedures. Parents or legal guardians generally must consent on behalf of children younger than eighteen, with the following exceptions:

* Emancipated minors (generally those who are validly married or are on active duty in the United States armed forces) (MCL 722.4e(1)(g));
* Children seeking prenatal and pregnancy-related care (excluding abortions)(MCL 333.9132; MCL 722.903);
* Children age 14 and above seeking limited outpatient mental health services (MCL 330.1707);
* Children receiving substance abuse treatment (MCL 330.1264); and
* Children seeking treatment for sexually transmitted diseases, including HIV/AIDS (MCL 333.5127).

The latter four exceptions are intended to permit children to seek the designated services confidentially. If research involves only the above services either alone or accompanied only by surveys, interviews, medical records reviews, or similar minimal risk activities, a minor generally may consent in his or her own right if receiving the services confidentially. However, if the minor is not otherwise receiving the services confidentially, or if the research involves experimental procedures, unapproved drugs or devices, or any intervention that might add to the minor’s risk, consent of a parent with legal custody (or, in the case of certain research involving more than minimal risk, both parents) or legal guardian is required.