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**Supplement Form E**

**Request for Waiver, Alteration and/or Documentation of Consent**

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

Complete this form if you are requesting a waiver or alteration of consent/parental permission or a waiver of documentation of consent/parental permission. Assent for children is addressed in Supplement A.

**NOTES:**

Waivers of consent are not permissible for federally funded research using Newborn Blood Spots.

Waivers and Alterations of Consent are not permitted for FDA-regulated research other than limited exceptions for Planned Emergency Research, certain studies evaluating the safety and/or effectiveness of In Vitro Diagnostic Devices (IVD), and waivers of documentation of consent for minimal risk activities.

Waivers of documentation of consent via a signed written consent form are permissible under both the Common Rule and FDA regulations as long as the criteria for such waivers are satisfied.

Please contact the IRB office at 269.337.4345 if your research is Planned Emergency Research, evaluating an IVD, includes Newborn Blood Spots, or if you have any questions about waivers or alterations.

1. **Request for Waiver of Informed Consent or Parental Permission**

The IRB may waive the requirement to obtain consent from research subjects the investigator justifies, and the IRB agrees, that specific criteria have been met.

* 1. **Is the request for a full or partial waiver?**

Full Waiver – Consent will not be sought from any subjects

Partial Waiver – Consent will not be sought for some subjects (e.g., historical cohort) or for some activities (e.g., screening)

If request is for a partial waiver, explain what you are requesting:

* 1. **There are three general categories of consent waivers, select the appropriate category for this request and then fill out the applicable section.** None of these waivers are permissible for FDA-regulated research. (However, please note that FDA does not generally consider review of patient records to assess potential subjects’ eligibility to be a research activity that requires prior consent.). Please also review the attached Appendix A regarding Michigan Law.

General (46.116(d))

State or Local Public Benefit or Service Programs (46.116(c))

Parental Permission is not in the best interests of children (46.408(c))

* + 1. General

In order to waive the requirement for informed consent or parental permission, ALL of the following criteria must be met:

The research involves no more than minimal risk\*. Please explain:

\**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.*

The waiver or alteration will not adversely affect the rights and welfare of the subjects. Please explain:

The research could not be carried out without the waiver. Please explain:

Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain:

* + 1. State or Local Public Benefit or Service Programs

In order to waive the requirement for informed consent, ALL of the following criteria must be met:

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. Please explain:

The research is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Please explain:

The research could not practicably be carried out without the waiver. Please explain:

* + 1. Parental Permission is not in the best interests of children

In order to waive the requirement for informed consent, ALL of the following criteria must be met:

The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. (for example, neglected or abused children, see MDHHS Child Protection Law at <http://www.michigan.gov/mdhhs/> for definitions of “child abuse” and/or “child neglect”). Please explain:

A mechanism is substituted for parental permission to ensure the protection of children. The choice of an appropriate mechanism (e.g., child advocate, witness, etc.) should be in keeping with the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition. Please explain:

1. **Request for an Alteration of Consent (alteration or exclusion of one or more of the required elements of consent)**
   1. **Explain which element(s) of consent you wish to alter or exclude and why?** A listing of the FDA and Common Rule Elements of Consent is at the end of this form for reference.

* 1. **There are two categories of permissible alterations, select the appropriate category for this request and then fill out the applicable section.** Alterations of consent are not permissible for FDA-regulated research.

General (46.116(d))

State or Local Public Benefit or Service Programs (46.116(c))

* + 1. General

In order for an IRB to grant an alteration of consent or parental permission, ALL of the following criteria must be met:

The research involves no more than minimal risk. Please explain:

The alteration will not adversely affect the rights and welfare of the subjects. Please explain:

The research could not be carried out without the alteration. Please explain:

Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain:

* + 1. State or Local Public Benefit or Service Programs

In order for an IRB to grant an alteration of consent or parental permission, ALL of the following criteria must be met:

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. Please explain:

The research is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Please explain:

The research could not practicably be carried out without the alteration. Please explain:

* 1. **Is the alteration for the purposes of deception (withholding the true purpose or certain aspects of the research)?**

Yes  No

If yes, answer the following:

* + 1. Explain why deception is necessary in this research:

* + 1. Describe any provisions for debriefing of subjects after participation, and if not, explain why subjects won’t be debriefed. Include any written debriefing materials or scripts with your submission.

* + 1. Explain whether subjects will be able to disallow use of their data for research after debriefing, and if not, provide justification:

1. **Request for Waiver of Documentation of Consent** (waiver of the requirement to document consent using a signed written consent form)
   1. **Is the request for a full or partial waiver?**

Full Waiver – Signed written consent will not be obtained from any subjects (e.g., a verbal consent process will be used)

Partial Waiver – Signed written consent will not be obtained from some subjects or for some activities (e.g., a verbal consent process will be used for some screening activities)

If request is for a partial waiver, explain what you are requesting:

* 1. **There are two categories of waivers of documentation of consent, select the appropriate category for this request and then fill out the applicable section.**

General (46.117(c)/56.109(c)) - Permissible under Common Rule and FDA

Consent as only identifying record (46.116(c)) - Permissible under Common Rule only

* + 1. General:

The research involves no more than minimal risk; and involves only procedures that do not require written consent outside of research. Please explain:

* + 1. Consent as only identifying record:

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Please explain:

* 1. **Please explain how the elements of consent will be presented to potential subjects.**

Copies of scripts, information sheets, survey introductions, videos, and other materials or aides should be included with your submission. If your script, survey introduction, information sheet or other mechanism will not include all required elements of consent (see checklist at the end of this form), you also will need to request an alteration of consent (see question 2 above).

* 1. **Please explain if and how, in the absence of signed written consent forms, consent will be documented (e.g. tape recordings, videos, chart notes, completion of a survey, etc.)**

**Federal Consent Elements Checklist**

**HHS:**

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|  | A statement that the study involves research |
|  | An explanation of the purposes of the research |
|  | The expected duration of the subject's participation |
|  | A description of the procedures to be followed |
|  | Identification of any procedures which are experimental |
|  | A description of any reasonably foreseeable risks or discomforts to the subject |
|  | A description of any benefits to the subject or to others which may reasonably be expected from the research |
|  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
|  | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
|  | For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained |
| (1)  (2)  (3) | An explanation of (1) whom to contact for answers to pertinent questions about the research and (2) research subjects' rights, and (3) whom to contact in the event of a research-related injury to the subject |
| (1)  (2)  (3) | A statement that (1) participation is voluntary, (2) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and (3) the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled |
| **Additional elements, required if applicable to the study:** | |
|  | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable |
|  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |
|  | Any additional costs to the subject that may result from participation in the research |
|  | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
|  | A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject |
|  | The approximate number of subjects involved in the study |

**FDA regulated trials:**

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|  | In addition to the above, if a trial involves FDA regulated materials, the consent form must contain a statement disclosing that the FDA has access to review and copy all relevant records. |
|  | This statement must be included verbatim if registration on clinicaltrials.gov is required by [FDAAA 801](https://clinicaltrials.gov/ct2/manage-recs/fdaaa):  *“A description of this clinical trial will be available on , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”* |

**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.