Marquette University
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MARQUETTE UNIVERSITY

Protocol #:

ORSP #:

Sponsor Tracking #:

Institutional Review Board
Waiver to Obtain/Document/Alter Informed Consent

Whenever possible, potential research subjects should be given an explanation of what their voluntary participation entails as it relates to the risks, benefits, alternatives, study activities, and confidentiality of the IRB approved study. The potential subject's agreement to participate is typically documented (e.g., signed by subject) on an IRB approved consent form. However, the Department of Health and Human Services allows an IRB to approve, (a) a waiver of consent, (b) an alternative form of consent, or (c) a waiver of documentation of consent so long as certain criteria are met.

Note:

- The IRB **cannot** approve waivers of the consent for research that is subject to **FDA regulations**, except for planned emergency/acute care research as provided under FDA regulations.
- "Consent" applies to adults (18 and older).
- "Assent" applies to minors (17 and younger).
- "Parental Permission" applies to parents of minors.
- "Obtain Documentation" refers to obtaining the subject's signature.

Directions: If you are requesting IRB approval to waive, alter, or not document informed consent, complete this addendum and include it with your IRB submission.

SECTION 1: This request is to (check all that apply):

☐ Waive the requirement to obtain informed consent/assent **[COMPLETE SECTION 2 & 3]**

☐ Alter the required elements of consent/assent **[COMPLETE SECTION 2& 3]**

☐ Waive the requirement to obtain documentation of informed consent/assent **[COMPLETE SECTION 2 & 4]**

SECTION 2: Briefly explain why you are making this request. E.g., study does not involve interacting with human subjects, obtaining signed consents would be the only identifiable link, the subject population are undocumented residents, online survey or telephone interview projects only, etc.

SECTION 3: Answer all **A's** OR **B's** and provide an explanation for how your project meets each criteria for waiving or **altering the consent** process.

A1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials.

☐ YES
☐ NO

A1. 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.

☐ YES
☐ NO

A2. The research could not practicably be carried out without the waiver or alteration.

☐ YES
☐ NO

OR

B1. Explain how the research involves no more than minimal risk to the subjects;

B2. Explain how the waiver or alteration will not adversely affect the rights and welfare of the subjects;

B3. Explain how the research could not practicably be carried out without the waiver or alteration; and

B4. Whenever appropriate, explain how the subjects will be provided with additional pertinent information after participation.

SECTION 4: Answer all A's OR B's and provide an explanation for how your project meets each criteria for waiving the requirement to document consent.

A1. Would the only record linking the subject and the research be the consent document?

☐ YES
☐ NO

A2. Would the principal risk be potential harm resulting from a breach of confidentiality?

☐ YES
☐ NO

A3. Will each subject be asked whether they want a signed copy of the consent form?

- ☐ YES
- ☐ NO

OR

B1. Does the research present no more than minimal risk to the subject?

- ☐ YES
- ☐ NO

B2. Does it involve procedures for which written consent is normally required outside of the research context? E.g., MRI scans, clinical treatment, etc.

- ☐ YES
- ☐ NO