

**IRB Waiver - Documentation of Consent and Authorization**

**SP Code:**       **Date:**

**Title:**

**Principal Investigator:**

**Routing Location:**       **Phone:**

**Request waiver of written informed consent and HIPAA Authorization. (Complete**

**Sections 1 and 2)**

**Note: The required info sheets or phone scripts may be combined as long as all elements of informed consent and authorization are included.**

**Request waiver of written informed consent only (Complete Section 1)**

**Request waiver of written HIPAA Authorization only (Complete Section 2)**

**SECTION 1: Informed Consent**

**1. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (Place an X before the item applicable to your request.)**

46.117(c)(1) that 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.

46.117(c)(2) that the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context.

1. **For your selected option, explain how your research meets the waiver criteria.**

1. **Will your consent process include:**

Phone call with script

Mailed information sheet

Information sheet handed to subject

Other: Please Explain:

1. **Prior to submission, please ensure all of the following required elements are included in the script by checking the box to the left (please provide a copy of the sample script.)**

Purpose of the study

Risks

Benefits

Duration of the study

Statement indicating this is research

Describe how confidentiality is maintained

Study contact information

Statement that participation is voluntary

**Section 2: HIPAA Authorization**

PHI is Information that relates to the past, present, or future physical or mental health or condition of an individual (including the provision of health care to an individual or payment for the provision of health care) which identifies the individual or to which there is a reasonable basis to believe the information can be used to identify the individual. PHI includes demographic information.

To be considered PHI, information must contain one of the following HIPAA identifiers: name, DOB, dates of specimen collection or treatment, address, phone number, FAX number, MHN, SSN, email addresses, health plan ID numbers, account numbers, device identifiers and serial numbers, certificate or license numbers (including license plates), vehicle identification numbers, URL’s IP addresses, biometric identifiers, full face or comparable images, unique codes created from an individual’s identifiable information.

**1. Does this research use or disclose protected health information (PHI)?**

Yes

No (Skip to signature)

**2. The Federal Privacy Rule allows the IRB to approve alteration of the authorization (waive documentation) (45 CFR 164.512 (i)(2)(ii))provided that the IRB determines and documents that:**

1. **The use or disclosure of PHI involves no more than minimal risk to privacy.**
   1. Describe your plan to protect the identifiers from improper use or disclosure:

b. Describe your plan to destroy identifiers at the earliest opportunity or justify why you plan to retain identifiers;

c. How will you make sure the PHI will not be re-used or shared improperly?

1. **The research could not practicably be conducted without the waiver.**
   1. Please explain, in detail, why this research could not be conducted without a waiver of the requirement to obtain authorization;

1. **The research could not practicably be conducted without access to and use of PHI.**
   1. Describe the specific PHI to be used or disclosed.

b. Why is use or disclosure of PHI necessary for this research?

**D. Although subjects will provide authorization to use PHI for this research, it is not practicable to obtain their signature because:**

a. You must provide subjects with information regarding the Privacy Rule. The following elements must be included in your information sheet:

Explanation of who at Marshfield Clinic (name or class of persons) will have access to protected health information for research.

Explanation of with whom, external to Marshfield Clinic, protected health information will be shared (name of organization and class of persons) (only if applicable).

Description of how protected health information will be used for research at Marshfield Clinic or externally.

A statement that this permission to use protected health information will last until the research activity is complete, or that the permission will not expire.

A statement that an individual may take back their permission by providing a written statement to the investigator.

A statement that once protected health information is shared outside of Marshfield Clinic, it may possibly be re-disseminated and no longer protected by Privacy Rule regulations (only if applicable).

Assurance that an individual’s decision to not provide permission for use of protected health information for this research will not affect their relationship with Marshfield Clinic in terms of treatment payment or eligibility for benefits.

1. **Will your authorization process include:**

Phone call with script

Mailed information sheet

Information sheet handed to subject

**SIGNATURE**

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Signature of Principal Investigator Date

Printed Name of Principal Investigator Routing Location

Printed Name of Person Completing Waiver Routing Location

**Submit completed paperwork to: Office of Research Integrity & Protections – 1R4**