UCR | Office of Research Integrity

Request for HIPAA Waiver IRB Approval Number _____

This form is to be used in conjunction with the Application for IRB Review

Study Title:
Sponsor/Funding Agency (if funded):
Principal Investigator Name:

A. What is the purpose of this form?

The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that "whenever appropriate, the subjects will be provided with additional pertinent information after participation."

Which type of waiver is this request for?

☐ **TOTAL WAIVER**

When a total waiver of the HIPAA Authorization is requested, the lead researcher is requesting permission to access, use or disclose a research subject's PHI for his or her research study *without* seeking the subject's specific authorization for that use or disclosure.

☐ **PARTIAL WAIVER**

When a partial waiver is requested, the lead researcher is requesting the HIPAA Research Authorization be waived for a portion of the study, such as a waiver for subject identification or recruitment purposes.

Note: A partial waiver for subject selection and recruitment requires written HIPAA Research Authorization for further access to protected health information.

Examples:

1. A researcher may request a partial waiver of HIPAA Research Authorization to recruit potential subjects if the patients have signed the UC Notice of Privacy Practices.
2. A researcher may request a partial waiver of HIPAA Research Authorization to allow a treating physician to obtain verbal permission to disclose name and contact information of a patient interested in being contacted by the researcher for further study information.

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Please specify the purpose for which you are requesting the (total or partial) waiver:

Please respond to *every* question on this application. Incomplete applications will be returned, and will result in a delay of your study being reviewed.

1. Does the use or disclosure of PHI involve no more than minimal risk to the privacy of the individual, based on at least the presence of the following:

    a. An adequate plan to protect the identifiers from improper use and disclosure.
    b. An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
    c. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.

☐ **YES** ☐ **NO**

2. Describe in detail, the plan to *protect* the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure. Describe your data security methods. The use of encryption software is required if identifiers are going to be stored.

3. Describe the plan to *destroy* the identifiers at the earliest opportunity, or provide justification for retaining the identifiers.

4. Will granting a waiver adversely affect the privacy rights of the individual?

☐ **YES** ☐ **NO**

Please explain your answer:

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5. Could the research be practicably done without the waiver?

☐ **YES** ☐ **NO**

If "no" justify below:

6. Could the research practicably be done without access to, use or disclosure of the PHI identified below?

☐ **YES** ☐ **NO**

Fully identify the PHI that will be used under this waiver request: (E.g. Full or partial Medical Records, including laboratory reports, progress notes for certain dates, etc.)

7. Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the research? *(Please describe your risk/benefit analysis relating to the waiver request below.)*

☐ **YES** ☐ **NO**

8. If the Lead Researcher is applying for a ***partial waiver*** for subject identification, describe how potential subjects will be identified:

9. Will the Principal Investigator be the **only** member of the research team who will **access**, **use** or **disclose** PHI?

☐ **YES** ☐ **NO**

If no, please name all of the individuals who will have access to PHI during the research study, including students. As PI, you must ensure that these individuals have current Human Subjects Training & HIPAA Training. These individuals must also be listed as part of key personnel in the project roster of your IRB application. (Add more rows if necessary)

Name, Job Description/Role

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By signing this form, I attest that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted. If all of these criteria are met, the IRB may grant a Waiver of Authorization. The IRB's action will be documented and communicated to the Principal Investigator.

INVESTIGATORS AGREEMENT:
As Principal Investigator of this study, I assure the Office of Research Integrity that the following statements are true:

The information that is provided in this form is true and accurate. I will seek and obtain prior written approval from the IRB for any substantive modifications to the proposal, including but not limited to, changes in procedures and co-investigators.

I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to the individuals whose PHI is being obtained.

I will not begin my research, including subject identification or recruitment, until I have received written notification of IRB approval and will comply with all IRB requests to report on the status of the study.

I will not reuse or disclose any PHI to any other person or entity, except as required by law, for the authorized oversight of research or for other permitted research.

I will conduct the research in compliance with all applicable federal and state laws and regulations and UCR policies governing human subject research.

_____

Signature of Principal Investigator Date

FACULTY ADVISOR AGREEMENT:
Student Research (i.e., research performed by medical students, graduate students, residents, or fellows) requires the approval of your Faculty Advisor. As an Advisor to the Student Investigator, I assume responsibility for ensuring that the Student complies with all applicable federal and state laws and regulations as well as UCR policies governing human subject research.

☐ **YES** ☐ **Not Applicable**

_____

Signature of Faculty Advisor Date

Print **Reset**