

**CALIFORNIA PACIFIC MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD**

**REQUEST TO WAIVE
AUTHORIZATION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION
(HIPAA)
and/or
WRITTEN DOCUMENTATION OF CONSENT**

Waiver of HIPAA Authorization:

HIPAA regulations require that investigators obtain an individual's authorization before accessing or using Protected Health Information (PHI) for the purposes of research. PHI is defined as individually identifiable health information. This regulation applies to data being collected for any research involving human subjects; including review of medical records, database, and/or human biologic specimen. The IRB can waive this requirement if:

- *The use or the disclosure of the PHI involves no more than minimal risk to the privacy of the individual.*
 - a. *There is an adequate plan to protect information identifiers from improper use and disclosure.*
 - b. *There is a plan to destroy identifiers at the earliest opportunity or there is a reasonable justification for maintaining the personal identifiers.*
 - c. *Assurances are made that the PHI will not be reused or disclosed to any other person or entity except as required by law or for oversight of the research.*
- *The research could not practicably be conducted without the waiver.*
- *The research could not practicably be conducted without access to the PHI.*

Waiver of Consent:

Human subjects protection guidelines require that researchers fully inform subjects about the nature of the study and what they will be asked to do, and ensure that subjects are freely agreeing to participate in the research. Researchers must keep written documentation of this informed consent. Under certain circumstances, researchers may apply that these requirements be waived. Waiver of documentation of consent may mean that no written consent documentation is provided to the subject. For example, a telephone interview may utilize a script that verbally informs the potential subject about all the elements of consent, but the subject receives no written information about the study. Waiver of consent may also mean that the subjects are provided with a written informed consent document, but the investigator does not collect the subjects' signature confirming their consent. For example, a mailed survey may include a cover letter outlining all the elements of informed consent, but ending with the statement that completing and returning the survey indicates their consent to participate. The requirements for written documentation of consent can be waived if:

- *The only record linking the subject and the record would be the consent document and the principal risk would be potential harm from a breach of confidentiality and the research presents no more than minimal risk.*
- *It would not be possible to conduct the research if informed consent were required (i.e. retrospective chart reviews) and the research involves no more than minimal risk, the rights and welfare of subjects will not be adversely affected.*

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Title Of Project:		
Principal Investigator:	Sutter Affiliation:	Dept.:
Mailing Address:	Phone Number:	
	Fax No:	
	E-mail address:	
Sub-Investigator (s):		
Name:	Affiliation:	Dept.:
Name:	Affiliation:	Dept.:
Name:	Affiliation:	Dept.:

Please check the waiver you seek to obtain for your study:

Waiver of HIPAA Authorization (complete sections A and C)

Waiver of Consent (complete sections B and C)

Both (complete all sections)

A. Questions pertaining to Waiver of HIPAA Authorization. Please answer these questions if you seek to obtain a waiver of HIPAA authorization:

- 1) Indicate your sources of health information:
 - Physician/clinic records
 - Lab, pathology and/or radiology results
 - Biological samples obtained from the subjects
 - Interviews/Questionnaires
 - Hospital/medical records (in- and out-patient)
 - Mental health records
 - Data previously collected for research purposes
 - Billing records
 - Other (describe)

- 2) Description of the PHI to be used or disclosed for the research:

- 3) Persons who will have access to the PHI in connection with this study: [Identify each person by name or role, if not yet determined].

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4) Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy: *[Minimal risk means that the probability and magnitude of harm are not greater than those ordinarily encountered in daily life or during routine examinations of the general population. The IRB will determine whether a risk is minimal based upon the adequacy of an investigator's plan to protect the identifiers, to destroy them at the earliest opportunity consistent with the research, and to prevent re-use or further disclosure of identifiers.]*

5) Describe the investigator's plan to protect the identifiers from improper use or disclosure and to destroy them at the earliest possible opportunity consistent with the conduct of the research. If there is a legal, health or research justification for retaining identifiers beyond completion of the research, please describe:

6) Explain why it is impracticable to seek subjects' authorization for use or disclosure of the PHI:

7) Explain why it is impracticable to conduct this research without use or disclosure of the PHI:

B. Questions pertaining to <u>Waiver of Consent</u>. Please answer the following questions if you seek to obtain a waiver of consent.
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8) An IRB may waive the requirement for the investigator to obtain a signed consent form (waive the subject's signature), if the consent form is the only record linking the subject to the research and the principal risk would be potential harm resulting from a breach of confidentiality. Please explain how your study meets this requirement:

9) Explain why it is impracticable to seek subjects' written consent:

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10) Describe the risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject: *[Minimal risk means that the probability and magnitude of harm are not greater than those ordinarily encountered in daily life or during routine examinations of the general population. The IRB will make the final judgment as to whether a risk is no more than minimal.]*

C. Required Signatures

I acknowledge that the information contained in this waiver application is accurate and all research staff will comply with the HIPAA regulations and the waiver criteria.

Information I obtain as part of this research (including protected health information) will not be reused or disclosed to any person or entity other than those listed on this form, except as required by law. If at any time, I want to reuse this information for other purposes or disclose the information to other individuals or entities I will seek approval by the California Pacific Medical Center IRB.

Signature of Investigator

Date

The IRB Chair has determined that this request for waiver of authorization satisfies the requirements of the Privacy Rule.

Signature of CPMC IRB Chair *Date Approved*