APPLICATION FOR IRB WAIVER OF AUTHORIZATION OR ALTERED AUTHORIZATION UNDER THE HIPAA PRIVACY RULE

I. Purpose of this Request

This form was created to facilitate the submission and review of a request to use/disclose protected health information (PHI) under an IRB approved Waiver of or Altered Authorization. This application must be completed in order to use/disclose PHI located either in a medical record or in a database.

HIPAA regulations state that receipt of a patient's Authorization prior to using or disclosing PHI is the preferred method. Alternatively, it recommends disclosing only a Limited Data Set under a negotiated Data Use Agreement, rather than via a Waiver of Authorization. Data Use Agreements eliminate the need to keep an accounting of disclosures; while Waivers require PHI disclosures to be tracked for six years. However, if it is practically impossible (impracticable) to receive a patient's Authorization or to limit the data set so that a Data Use Agreement can be executed, HIPAA has created allowances if the requests are approved by the covered entity.

Please select the type of activity you would like to conduct (check all that apply):

☐ **Eligibility Screening**
The activity of identifying patients who may be prospective study participants.

☐ **Partial Waiver of Authorization**
This request covers the requirements for contacting potentially eligible patients who were identified via a preparatory-to-research activity. The Privacy Rule imposes limitations on the use and disclosure of PHI for the purpose of recruiting.

- Researchers are required to obtain a subject's research Authorization after recruiting and enrolling a subject via a partial Waiver and prior to creating or using PHI during research procedures.
- If the subject does not enroll, and you wish to disclose PHI (to the study sponsor, for example), you must keep an accounting of the disclosure.

☐ **Waiver of Authorization (for all uses of PHI)**
If you are applying for approval of a <u>new</u> minimal risk study (such as a retrospective medical record review), and you believe it would be impracticable to obtain a signed Authorization from some or all of the research subjects, and you must have more PHI than a Limited Data Set, you may apply to the IRB for a Waiver of Authorization to use/disclose their PHI.

☐ **Altered Authorization** – telephone contact
☐ **Altered Authorization** – telephone consent
☐ **Altered Authorization** – waiver of documentation of consent

If you are applying for approval of a <u>new</u> minimal risk initial review or exemption application, and you are seeking either a Waiver of some of the required elements of **informed consent** or a waiver of documentation of informed consent from the IRB (such as for survey or interview research), you may request an **Altered Authorization**, which asks the IRB to waive some of the elements of a complete HIPAA Authorization normally required under the Privacy Rule. (For example, verbal Authorization from subjects over the phone in order to allow eligibility screening and PHI sharing).

II. Definitions

Covered Entity – A "covered entity" is a facility as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act, better known as "HIPAA". HIPAA standards apply only to the following types of facilities, which are considered covered entities:

- Health care providers who transmit any health information electronically in connection with certain transactions
- Health plans
- Health care clearinghouses

Data Use Agreement - A Data Use Agreement (DUA) is a contractual document used by a covered entity in order to allow the transfer of data that has been partially de-identified into a Limited Data Set. Often, this data is a necessary component of a research project.

Limited Data Set – A "Limited Data Set" is a limited set of identifiable patient information as defined by HIPAA. A Limited Data Set of information may be disclosed to an outside party without a patient's authorization if certain conditions are met. First, the purpose of the disclosure may only be for research, public health or health care operations. Second, the person receiving the information must sign a Data Use Agreement.

The health information that may remain in a Limited Data Set includes:

- dates such as admission, discharge, service, DOB, DOD;
- city, state, five digit or more zip code; and
- ages (under 89 ½) in years, months or days or hours.

It is important to note that this information is still protected health information or "PHI" under HIPAA. It is not de-identified information and is still subject to the requirements of the Privacy Regulations.

Protected Health Information (PHI) – Protected health information generally refers to demographic information, medical history, test and laboratory results, insurance information and other data that a healthcare professional collects to identify an individual and determine appropriate care. The identifiable health information is also known as the "18 Identifiers." In order for patient information to be considered completely de-identified, all 18 identifiers must be removed. *See the table on page 4 for a list of the identifiers considered to be PHI under the HIPAA Privacy Rule.*

Note: If you need additional information, please see the HIPAA website here. You may also review CH IRB's policy, *Authorization or Use of Protected Health Information* here.

III. Protected Health Information Required to Conduct Study

1. The Privacy Rule and California state law require an IRB to determine that the researchers will use only the minimum amount of PHI necessary to conduct the research. Therefore, please explain why you cannot receive the patient's Authorization or why your requested information cannot be limited to a Limited Data Set. For most retrospective medical record research, a limited range of health information will normally be sufficient for the purposes of the research. In order for an IRB to grant a Waiver of Authorization or Altered Authorization, the research cannot practicably be conducted without it. Criteria the IRB considers in determining whether a Waiver of or Altered Authorization should be granted include: the number of research subjects proposed, difficulties of

obtaining individual Authorization, time constraints, time since last contact with the research subjects, and need to have historical controls.

Select and explain all that apply:

☐ The research involves no more than minimal risk to the subjects.
☐ The waiver of authorization will not adversely affect the rights and welfare of the subjects.
☐ The research could not practicably be carried out without the waiver of authorization.
☐ The patients are not currently under the care of the investigators
☐ Number of research subjects proposed: _____
☐ Difficulties of obtaining individual Authorization: _____
☐ Time constraints: _____
☐ Time since last contact with the research subjects: _____
☐ The need to have historical controls
☐ Other: _____

2. List **all** of the individuals who will receive and/or use the PHI.

3. What is the source of the PHI? List **all** of the sources from which you plan to obtain/use/disclose PHI for the study and where they are located *(e.g. hospital and/or physician office patient medical records, a departmental database, your own database).*

- Source: _____
  From (institution): _____ Is this a covered entity? ☐ YES ☐ NO
- Source: _____
  From (institution): _____ Is this a covered entity? ☐ YES ☐ NO
- Source: _____
  From (institution): _____ Is this a covered entity? ☐ YES ☐ NO

4. Specify which, if any, of the following identifiers will be associated with the health information you propose to collect.

☐ None of the data listed below will be collected.

☐	Names	☐	Telephone Numbers
☐	Address	☐	E-mail Addresses
☐	Fax Numbers	☐	Medical Record Numbers
☐	Social Security Numbers	☐	Account Numbers
☐	Health Plan Beneficiary Number	☐	Vehicle Identifiers and Serial Numbers
☐	Certificate/License Numbers	☐	Web Universal Resource Locators (URL)
☐	Device Identifiers and Serial Numbers	☐	Biometric Identifiers (finger and voice prints)
☐	Internet Protocol (IP) Address Numbers	☐	Any Elements of Dates (specify which of the following identifiers you will use: birth date, admission date, discharge date, date of death, age over 89):
☐	Any Geographic Subdivisions Smaller Than a State (specify which of the following identifiers you will use: county, city, parish, or zip code):		
☐	Full face photographic images and comparable images	☐	Any other unique identifying number, characteristic, or code (please specify):

- Please attach a list of the specific health information that you propose to use or a copy of the data collection form. ☐ Attached ☐ N/A

- For survey or interview research, the questions to be asked of research subjects should be attached to this application. ☐ Attached ☐ N/A

5. State specifically whether sensitive information (e.g., illegal drug use, sexual practices, HIV status) will be collected.

☐ Sensitive information will not be collected.
☐ Sensitive information will be collected:

6. List, if any, the individuals or groups outside of the covered entities listed in #3 above to whom you will disclose the PHI (*e.g., research collaborators from other institutions or a research sponsor*). If PHI will NOT be released to outsiders in this study, please make a statement to that effect. *Note: The Privacy Rule requires researchers to keep a detailed accounting of releases of PHI. This accounting must be made available upon request to the individual who is the subject of the PHI. If you can share with the collaborators or sponsor health information that is de-identified, or that is a Limited Data Set under a Data Use Agreement, you will not need to keep an accounting.*

☐ PHI will not be disclosed to outsiders of this study.
☐ PHI will be disclosed to outsiders of this study:

7. Describe your plan to protect PHI from unauthorized use or disclosure. Specify the measures that will be implemented by your research group to safeguard the PHI from unauthorized use or disclosure for both paper and electronic forms of PHI. (Examples include locking up your research files while they are unsupervised, using screensavers, shredding excess copies of paper documents, protections for codes that link patients to their data, and security measures to protect storage and

transmission of electronic data.) If PHI is to be disclosed to outsiders, describe the plans of any research collaborators to protect the PHI you will share with them.

☐ All data will be stored in REDCap
☐ All data will be stored on an encrypted document/flash drive
☐ All data will be stored on a password-protected Cottage Health computer
☐ All data will be shared via encrypted email
☐ A code breaker will be used in order to link patients with their data
☐ Screensavers will lock access after idle time
☐ All paper records will be stored in locked cabinets
☐ Research files (electronic and/or paper) will be locked while unsupervised
☐ Excess electronic and/or paper documents will be destroyed/shredded
☐ Other: _____

8. Describe your plan for destroying the identifiers at or before the conclusion of the study or provide a justification for long term or permanent retention of the identifiers. Specify which identifiers and information will be destroyed. If long term retention is requested, such as maintenance of a database, specify the security measures you will use. In general, covered entities that release PHI for research must maintain a record of that release for six years to provide for participant access to his or her study records.

☐ Excess PHI will be destroyed/shredded, as needed
☐ Upon closure of this study, the study records, either in electronic or paper form, shall be maintained for six years in a locked manner at Santa Barbara Cottage Hospital or a secure off-site storage facility.
☐ Other: _____

IV. Researcher Assurances

As Principal Investigator of the research project described below, I make the following assurances to the IRB regarding the use and disclosure of PHI:

"The investigators and research staff who use and disclose PHI in connection with this research will not reuse the PHI or disclose it to any person or entity other than those authorized to receive it, except: 1) as required by law, 2) for authorized oversight of the research, or 3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed."

My signature below includes a request for a Waiver of Consent as per 45 CFR 46.116(d) in order to engage in this research activity.

_____ _____

Signature of Principal Investigator Date