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Hawaii Pacific Health

55 Merchant Street • Honolulu, Hawaii 96813 • hawaiipacifichealth.org

Request for a Partial Waiver of Authorization for Recruitment

Sponsor _____ **Sponsor Protocol No.** _____

PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. HPH must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h)]

1.	PI Name:		
2.	PI Company Name:		
3.	PI Mailing Address: (street, city, state/province, zip, country)		
4.	PI Phone: ( )	PI Fax: ( )	PI E-mail:
5.	How would the PI prefer to receive study documents? (check one) ☐ Fax ☐ E-mail ☐ Regular Mail		

WAIVER INFORMATION:

1. Specify which, if any, of the following identifiers will be associated with the health information you propose to access, collect, and use for the screening and recruiting process.

☐	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 Geographic Subdivisions Smaller Than a State (specify which of the following identifiers you will use: county, city, parish, or zip code):	☐	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):
☐	Full face photographic images and comparable images:	☐	Any other unique identifying number, characteristic, or code (please specify):

2. List the specific health information that you propose to use in this study. State specifically whether sensitive information (e.g., illegal drug use, sexual practices, HIV status) will be collected. For most retrospective medical record research, a limited range of health information will normally be sufficient for the purposes of the research. A copy of the data collection sheet also should be submitted for medical record review or database research studies. For survey or interview research, the questions to be asked of research subjects should be attached to this application.

3. What is the source of the PHI? List all sources from which you plan to obtain PHI for the study *(e.g. Facility or clinic paper records, a departmental database, your own database)*

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4.	Who will have access to, receive and/or use the information?		
5.	Are the persons who have access to the information required to sign confidentiality statements?	Yes ☐	No ☐
6.	What identifiers are included on the information you plan to disclose?		
7.	List, if any, the individuals or groups outside of HPH to whom you will disclose the PHI (*e.g., research collaborators from other institutions or a research sponsor*). If PHI will NOT be released outside of HPH, please make a statement to that effect.		
8.	In what form will the information be maintained? ☐ Paper ☐ Electronic ☐ Both		
9.	If the information is in paper format, describe the precautions you have to protect the identifiers from improper use and disclosure:		
10.	If data is stored electronically, what safeguards are in place to prevent access to the electronic files? ☐ Password protected ☐ PC ☐ CD ☐ Encryption ☐ Laptop ☐ DVD ☐ Other (please specify): _____ ☐ Portable storage device (type)_____		
11.	Is access to the information restricted to only those who have a need to know for performance of their job?	Yes ☐	No ☐
12.	Is this electronic system used to transmit data outside of your site?	Yes ☐	No ☐
13.	If information is transmitted, what safeguards are in place to prevent inadvertent access to this data during transmission?		
14.	Will you be retaining any identifiable information on potential subjects who do not meet study eligibility requirements? If yes, explain the purpose of retaining the information.	Yes ☐	No ☐
15.	When do you plan to destroy the identifiers? **(Identifiers must be destroyed at the earliest opportunity.)** ☐ Subject Contact ☐ Enrollment ☐ Study Accrual ☐ Other (please specify): _____ 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.		
16.	Please explain how your recruitment meets the following criteria: a. a. Recruitment cannot be practicably carried out without the Partial Waiver of Authorization. _____ b. Recruitment cannot practicably be conducted without the participants' PHI. _____		

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By signing this statement, I am providing written assurance that only information essential to the purpose of recruitment will be collected. Access to the information will be limited to the greatest extent possible. Storing data on portable media devices is highly discouraged. If I do use portable media devices, I understand any identifiable data placed on portable electronic media or other devices must be encrypted. Protected health information collected under this partial waiver will not be re-used or disclosed to any other person or entity.

You may type your name on this form and send it electronically. Your typed name on this form will constitute your signature and agreement with the aforementioned statement.

_____ _____

Signature of Principal Investigator Date

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