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Hawai'i Pacific Health Research Institute

Guidelines for Retrospective Medical Records Review Research

Introduction

All research conducted at Hawai'i Pacific Health (HPH) must adhere to federal regulations overseen by the Office for Human Research Protections and the Food and Drug Administration. Code of Federal Regulations, Title 45, Part 46 (45 CFR 46) state that any human subjects research must be approved by an Institutional Review Board (IRB).

45 CFR 46.101(b) provides exemptions to IRB approval, one of which may cover retrospective medical records review research, specifically:
45 CFR 46.101 (b) (4)
Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or **if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.** (Emphasis added)

45 CFR 46.101 (i)
...However, the exemptions at 45 CFR 46.101 (b) do not apply to research involving prisoners, subpart C.

Under the exemption, an investigator must not keep coded data sheets and must be **unable** to link collected data with the record from which the data were extracted.

Additionally, covered entities of HPH must adhere to regulations of the Health Insurance Portability and Accountability Act (HIPAA), which require authorization for the use of protected health information (PHI) in research. An investigator may request a waiver of authorization requirement with the following assurances:

a. The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the HPH Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure is permitted by the Privacy Rule.
b. The research could not practicably be conducted without the requested waiver or alteration.
c. The research could not practicably be conducted without access to and use of the PHI.

Paragraph a. requires that **none** of the following identifiers be collected:

1. Names
2. Addresses
3. Dates(including birth, admission, discharge, death) or any age over 89
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and comparable images
18. Any other unique identifying number, characteristic, or code

While paragraph a.(above) implies that the investigator may use a preliminary code, **remember that 45 CFR 46.101(b)(4) forbids the use of coded data.**

Also, to qualify for a waiver, the research protocol must list all PHI that is to be collected. PHI not listed cannot be collected.

Studies that pose **more than** minimal risk to the privacy of subjects, such as studies involving recording of information about HIV status, psychiatric illness, or substance abuse, even though they might otherwise qualify for exemption and waiver of authorization, shall be subject to full Privacy Board review.

Procedure

If an investigator structures a research protocol to adhere to the suggestions in the introduction, the study may qualify for exemption from IRB review and for a waiver of privacy authorization. Please note, all studies conducted at any HPH affiliate must be reviewed by the HPH Scientific Review Committee unless determined to exempt as per policy.

The investigator should submit the following to Christine Nelson at Christine.Nelson@kapiolani.org :

1. Full protocol
2. Data collection sheet
3. HPH Request for Exemption Determination Form
4. HPH Request for Full Waiver of Authorization Requirement Form

For help please contact Christine Nelson at 808-535-7215