Hawaii State Department of Health Data Sharing Policies and Procedures

I. Purpose

The Hawaii State Department of Health (DOH) believes that the data that it collects should facilitate the furtherance of research and policy development within the framework of promoting public health in Hawaii. DOH further recognizes the value of partnerships with outside agency researchers in the advancement of research and evaluation and aims to facilitate these partnerships. To this end, this document aims to: (1) develop DOH data sharing best practices, (2) encourage the sharing of DOH research and evaluation data to improve public health practice, and (3) ensure the data that it collects are used for appropriate purposes, particularly in the context of protecting individual personal or health information.

II. Definitions

CFR – Code of Federal Regulations.

Covered Entity – Any health plan, health care clearinghouse, or health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA. A useful tool for determining whether a person or organization is a covered entity can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.html

Data Archive – A place where machine-readable data are acquired, manipulated, documented, and finally distributed to the scientific community for further analysis.

DC/OC/D – Division Chief / Office Chief / Designee

De-identified Dataset – A dataset that excludes the following 18 identifiers:

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Facsimile numbers
6. Electronic mail addresses
7. Social security numbers

8. Medical record numbers
9. Health plan beneficiary 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 fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification

DOH – Hawaii State Department of Health.

FERPA – The Family Educational Rights and Privacy Act, 20 U.S.C. § 1232g; 34 CFR Part 99, is hereinafter known as "FERPA". It is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Final Research Data – Recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. This does not mean summary statistics or tables; rather, it means the data on which summary statistics and tables are based. For the purposes of this policy, final research data do not include laboratory notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

HRS – Hawaii Revised Statutes. (HRS 323C regulates Privacy of Healthcare Information and HRS 334-5 specifically regulates "Confidentiality of Records" for mental health and addictions)

HIPAA – The Health Insurance Portability and Accountability Act, 45 CFR Parts 160, 162, and 164, is hereinafter known as "HIPAA." The US Department of Health and Human Services issued a Privacy Rule to implement the protections of HIPAA. This Rule sets forth standards to govern the use and disclosure of individuals' protected information by covered entities, as well as standards for individuals' privacy rights to understand and control how their health information is used.

Institutional Review Board – Hereinafter known as "IRB", is a board of the DOH that was established to assure compliance with federal regulations on the protection of human subjects. Any research on human subjects undertaken by DOH staff or using DOH resources must obtain IRB approval or an IRB waiver before initiating any research activities[1] (45 CFR Part 46).

[1] IRB approval must be obtained for all involved institutions. All non-DOH researchers must obtain IRB approval from their institution (if required by that institution).DOH has entered into a cooperative agreement with the University of Hawaii Committee on Human subjects and will accept CHS approval in lieu of DOH IRB approval. The DOH can enter into cooperative agreements with other institutions and accept IRB review from their IRB.

Limited Dataset – Refers to PHI that excludes 18 categories of direct identifiers yet does not have to be fully de-identified. It allows for the retention of dates (birth, death, admission, discharge), and of limited geographic information, and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's authorization or a waiver or an alteration of authorization for its use and disclosure, with a data use agreement.

Non-DOH researchers – Outside agency researchers (e.g., students and faculty at the University of Hawaii; employees of the Department of Education, etc), will hereinafter be referred to as "non-DOH researchers."

Protected Health Information (PHI) – Individually identifiable health information (IIHI) including demographic information, in any form, including information that is transmitted orally, or in written or electronic form, that relates to: the individual's past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information excludes IIHI covered by the Family Educational Rights and Privacy Act (FERPA), employment records held by a covered entity in its role as employer [45 CFR §160.103].

Restricted Data –Datasets that cannot be distributed to the general public, because of, for example, participant confidentiality concerns, third-party licensing or use agreements, or national security considerations.

Staff – All staff, employees, or contractors of DOH are hereinafter referred to as "Staff."

State Public Health Statistics Act – Hawaii Revised Statutes chapter 338, hereinafter referred to as SPHSA "Public health statistics" includes the registration, preparation, transcription, collection, compilation, and preservation of data pertaining to births, adoptions, legitimations, deaths, fetal deaths, morbidity, marital status, and incidental data. The DOH has the authority under SPHSA to: (1) establish a central bureau of public health statistics with suitable offices properly equipped for the safety and preservation of all its official records; (2) install a statewide system of public health statistics; (3) make and amend, after notice and hearing, necessary regulations, give instructions and prescribe forms for collecting, transcribing, compiling, and preserving public health statistics; and (4) enforce regulations pertaining to this act.

Timeliness – In general, DOH considers the timely release and sharing of data to be no later than the acceptance for publication of the main findings from the final dataset. However, the actual time will be influenced by the nature of the data collected.

Contact the DOH IRB Administrator for more information. If a project is using another IRB, evidence of IRB approval from outside institutions must be provided to DOH IRB for recordkeeping (through DOH liaison).

Unique Data – Data that cannot be readily replicated. Examples of studies producing unique data include: large surveys that are too expensive to replicate; studies of unique populations, such as centenarians; studies conducted at unique times, such as a natural disaster; studies of rare phenomena.

III. Policies

A. The State Public Health Statistics Act (SPHSA), Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), 45 Code of Federal Regulations (CFR) Part 46, and 42 CFR Part 2 govern the use of protected information by the DOH. Hawaii Revised Statutes (HRS) section 324-32 specifically authorizes the DOH to release statistical information relating to its health surveillance program, while section 324-31 provides protection for the identity of persons about whom the DOH collects information.

B. Ethics – All DOH staff and non-DOH researchers will observe the highest level of ethics and will be fully compliant with SPHSA, HIPAA, FERPA, 45 CFR Part 46, and 42 CFR Part 2. Failure to comply with these standards may result in civil and/or criminal penalties.

C. Investigators may use different methods to reduce the risk of subject identification. One possible approach is to withhold some part of the data. Another approach is to statistically alter the data in ways that will not compromise secondary analyses but will protect individual subjects' identities. Alternatively, an investigator may restrict access to the data at a controlled site, sometimes referred to as a data enclave. Some investigators may employ hybrid methods, such as releasing a highly redacted dataset for general use but providing access to more sensitive data with stricter controls through a data enclave.

D. Division Chiefs or Office Chiefs are responsible for ensuring that all research being conducted under their jurisdiction is in compliance with DOH policy. Division Chiefs / Office Chiefs may opt to delegate that responsibility to Staff within their jurisdiction. Designation is a formal process and must be accompanied by the completion of the "**DOH Research Oversight Designation Form**". A copy of this form must be sent to the DOH IRB Administrator and Science and Research Group for recordkeeping.

IV. Procedures

Submit the following documents to the Division Chief or Office Chief or their Designee (DC/OC/D) for approval:

1. Hawaii State Department of Health Proposal Approval Form
   Proposal includes:
   - Project title
   - Complete list of investigators, including anyone who will have access to the data
   - Organizational affiliation
   - Contact information
   - Project timeline

- Purpose
- Research questions
- Background
- Methods (including a section on specific DOH data to be used)
- Planned uses of research outcomes
- Consent forms (if applicable)
- Measures to ensure confidentiality
- Variables requested

Review and approval of the full proposal should be based on the following criteria:

- Importance of topic of study to the field of public health
- Originality of the topic/data/methods
- Clarity of the study purpose/goals/hypothesis
- Clarity and validity of the study design and data selection
- Adequacy of the sample and dataset
- Clarity and validity of the statistical methods
- Clarity and validity of the measurement of key variables
- Public health program/policy implications addressed
- Relevance to public health practice
- Relevance to science

2. Hawaii State Department of Health Data Use Agreement
    - If the data being requested is de-identified, a data use agreement is not necessary.
    - If a limited dataset is being requested, a data use agreement is needed.
    - If the dataset being requested contains PHI, then one of the following 3 conditions have to be satisfied in order to comply with HIPAA:
        1. Obtain a waiver of authorization by the presiding IRB (This applies to research use and disclosure without authorization only).
        2. Obtain a business associate agreement.
        3. Obtain authorization from individuals whose PHI is being shared.

3. Agreement by Researchers in Possession of Data Owned by the Hawaii State Department of Health
    - Restrictions on data usage and dissemination.
    - Agreement to share research findings with DOH prior to distribution.