

 HAWAII HEALTH SYSTEMS CORPORATION "Quality Healthcare For All" POLICY	Department: Quality Through Compliance	Policy No.: CMP 046A
		Revision No.:
Subject: HIPAA Research Purposes Use and Disclosure	Issued by: Audit and Compliance Committee	Effective Date: September 19, 2013
	Approved by:  HHSC Board of Directors By: Carol A. VanCamp Its: Secretary/Treasurer	Supersedes Policy: Page: 1 of 4

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I. **PURPOSE:** This Policy delineates the circumstances and process by which protected health information may be used and disclosed by Hawaii Health Systems Corporation (HHSC) for research purposes, in accordance with state and federal laws.

II. **DEFINITIONS:**

Individually identifiable health information - Information that is a subset of health information, including demographic information collected from an individual, and:

1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse;
2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and;
3. That identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Disclosure – means the release, transfer, or provision of access to PHI, or divulging PHI in any other manner outside the entity holding it.

Protected health information (PHI) - means individually identifiable health information that is transmitted by electronic media; maintained in any electronic medium; or transmitted or maintained in any other form or medium. Protected health information *excludes* individually identifiable health information in: education records covered by the Family Educational Right and Privacy Act (as amended, 20 U.S.C. 1232g) and records described at 20 U.S.C. 1232g(a)(4)(B)(iv).

Research - means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.

Treatment - means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Use - means employment, application, utilization, examination or analysis of protected health information within an entity that maintains such information.

III. **POLICY:**

- A. Research that includes treatment: Hawaii Health Systems Corporation (HHSC) must obtain a valid authorization for the use or disclosure of protected health information created for the

purpose, in whole or in part, of research that includes treatment of the individual.

1. *Content requirements for research that includes treatment:* This authorization shall contain required elements, as applicable, and in accordance with HHSC policy (CMP 028A "Uses and disclosures of protected health information for which an authorization is required"). The authorization must include:
 - a) Description of protected health information requested for use or disclosure:
 - i. Description of such information in a specific and meaningful way;
 - ii. Description of each purpose of such request;
 - iii. Description of extent to which such information will be used or disclosed to carry out treatment, payment or health care operations;
 - iv. Description of any protected health information that will not be used or disclosed for purposes permitted by HHSC policies (CMP 029A), reserving the right of HHSC to make a use or disclosure that is required by law or permitted in order to prevent or lessen serious and imminent threats to health and safety, in accordance with HHSC policy (CMP 030A).
 - b) Identification of users:
 - i. Name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
 - ii. Name or other specific identification of the person(s), or class of persons, to whom HHSC may make the requested use or disclosure;
 - c) Expiration date or expiration event that relates to the individual or the purpose of the use or disclosure.
 - d) Rights of individual:
 - i. Statement that individual may inspect or copy the protected health information to be used or disclosed, but that right of access may be temporarily suspended for as long as the research is in progress and will be reinstated upon completion of the research;
 - ii. Statement that individual may refuse to sign the authorization;
 - iii. Statement that individual may revoke the authorization in writing and the exceptions to the right to revoke, together with description of how the individual may revoke the authorization.
 - e) If use or disclosure of the requested information will result in direct or indirect remuneration to HHSC from a third party, a statement that such remuneration will result;
 - f) Statement that information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer be protected by 45 CFR, Part 164, Subpart E (Standards for Privacy of Individually Identifiable Information);
 - g) If HHSC has obtained or intends to obtain the individual's consent under HHSC policy (CMP 024A--Consent to use and disclose for treatment, payment and health care operations) or has provided or intends to provide the individual with a notice under HHSC policy (CMP 028A--Notice of Privacy Practice), a statement that refers to that consent and notice, as applicable, and that statements made pursuant to this authorization are binding;
 - h) Signature of individual and date, and;
 - i) If signed by a personal representative of the individual, a description of such representative's authority to act for individual.
2. Optional procedure - An authorization may be in the same document as:
 - a) Consent to participate in the research;
 - b) Consent to use or disclose protected health information to carry out treatment, payment or health care operations;

- c) A notice of privacy practices.
- 3. Other requirements - An authorization must comply with other requirements, as applicable, in accordance with HHSC policy (CMP 029A--Uses and disclosures of protected health information for which an authorization is required).
- B. *Research that does not include treatment:* HHSC may use and disclose protected health information for research that does not include treatment of the individual, regardless of the source of funding of the research, without written consent or authorization of the individual or the opportunity for individual to agree or object, provided that:
 - 1. HHSC obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization for use or disclosure of protected health information has been approved by the Institutional Review Board ("IRB") established in accordance with HHSC Policy RES 001A.
 - 2. Waiver criteria - The waiver, in whole or in part, of the authorization shall satisfy the following criteria:
 - a) Use or disclosure of protected health information involves no more than minimal risk to the individuals;
 - b) The alteration or waiver will not adversely affect the privacy rights and welfare of the individuals;
 - c) The research could not practicably be conducted without the alteration or waiver;
 - d) The research could not be practicably be conducted without access to and use of the protected health information;
 - e) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
 - f) There is an adequate plan to protect the identifiers from improper use and disclosure;
 - g) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law, and;
 - h) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by 45 CFR, Parts 160 and 164 (Standards for Privacy of Individually Identifiable Health Information).
 - 3. Review and approval procedures - The IRB shall follow the requirements of the Common Rule, including the normal review procedures or the expedited review procedures.
 - 4. Documentation of waiver approval - Documentation must include all of the following:
 - a) Identification and date of action - A statement identifying the IRB and the date on which the alteration or waiver of authorization was approved.
 - b) Waiver criteria - A statement that the IRB has determined that the alteration or waiver, in whole or in part, of authorization satisfied the waiver criteria.
 - c) Protected health information needed - A brief description of the protected health information for which use or access has been determined to be the minimum necessary by the IRB.
 - d) Review and approval procedures - A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or

- expedited review procedures.
 - e) Required signature - The document must be signed by the chair or other member, as designated by the chair, of the IRB.
 - 5. Reviews preparatory to research - HHSC obtains from the researcher representations that:
 - a) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
 - b) No protected health information is to be removed from the covered entity by the researcher in the course of the review, and;
 - c) The protected health information for which use or access is sought is necessary for the research purpose.
 - 6. Research on decedent's information - HHSC obtains from the researcher:
 - a) Representation that the use or disclosure that is sought is solely for research on the protected health information of decedents;
 - b) Documentation, at the request of HHSC, of the death of such individuals, and;
 - c) Representation that the protected health information for which use or disclosure is sought is necessary for the research purpose.
 - C. Research Using De-identified Protected Health Information:
 - 1. De-identification - HHSC may use and disclose information that has been "de-identified" of all individually identifiable health information for research purposes, provided that:
 - a) Requirements for de-identification have been met in accordance with HHSC policy (CMP 033A-- De-Identification of protected health information), and;
 - b) The IRB, upon request, reviews all manuscripts, abstracts or other publicly-released information related to the research prior to public release or publication.
 - 2. Re-identification - HHSC may assign a code or other means of record identification to allow information that is de-identified to be re-identified provided that:
 - a) Requirements for re-identification have been met in accordance with HHSC policy (CMP 033A--De-Identification of protected health information), and;
 - b) Such re-identified information is used and disclosed only as permitted or required by administrative policies governing the use and disclosure of protected health information and in accordance with state and federal laws.
 - D. HHSC facilities shall implement procedures to operationalize this Policy.
- IV. APPLICABILITY:** This Policy applies to all HHSC facilities.
- V. AUTHORITY:** 45 CFR §164.508; §164.508(f); §164.512(i); §164.514(a)-(b) (Standards for Privacy of Individually Identifiable Health Information).
- VI. ATTACHMENT:** None.