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Uses and Disclosures for External Research Requests, Internal Research Needs and Waiver of Privacy Rights for Research Purposes

I. Purpose

The intent of this policy is to specify when DHH may use or disclose information about individuals for research purposes.

DHH staff and workforce members should refer to DHH Policy #72 (Public Information) prior to any use or disclosure of Protected Health Information (PHI). If the workforce member determines that there is a conflict between that policy and DHH HIPAA Privacy Policies, the workforce member must contact his/her supervisor prior to the use or disclosure. The supervisor shall then consult with the Privacy Officer and other appropriate DHH executive management.

II. Applicability

DHH's HIPAA Privacy Policies are applicable to DHH's workforce and its business associates.

III. Implementation

The implementation date of these policies is April 14, 2003.

IV. Definitions

The definitions are included in the body of these policies.

V. Responsibilities

DHH's workforce and its business associates are responsible for assuring that DHH's HIPAA Privacy Policies are followed. The DHH Privacy Officer and the Program Privacy Officers are responsible for the implementation, resolution and enforcement of all aspects related to DHH HIPAA Privacy Policies.

VI. E x c e p t i o n s

The exceptions are listed in the policies.

VII. Policy: Uses and Disclosures for External Research Requests, Internal Research Needs and Waiver of Privacy Rights for Research Purposes

A. When DHH uses or discloses an individual's information for research purposes, it must consider the following:

1. DHH may use or disclose client or participant's Individual Identifiable Health Information for research purposes as specified in this policy. 'Research" means "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge."

2. All such research disclosures are subject to applicable requirements of State and Federal laws and regulations and to the specific requirements of this policy.

Note: This policy is intended to supplement existing research requirements of the Common Rule, 45 CFR Part 46. The Common Rule is the rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services, and adopted by other Federal governmental agencies, including the National Institutes for Health, for research funded by those agencies. In addition, some agencies have requirements that supplement the Common Rule that are applicable to a particular research contract or grant.

3. De-identified information may be used or disclosed for purposes of research, consistent with DHH Policy #20, "De-identification of Client Information and Use of Limited Data Sets."

4. A limited data set may be used or disclosed for purposes of research, consistent with the policies related to Limited Data Sets DHH HIPAA Privacy Policy #20, "De-identification of Client Information and Use of Limited Data Sets."

5. DHH may also conduct public health studies, studies that are required by law, and studies or analysis related to its health care operations. Such studies are discussed in HIPAA Policies 4 and 5.

B. Institutional Review Board (IRB) or Privacy Board Established by DHH

DHH may use an Internal Review Board (IRB) established in accordance with 45 CFR Part 46 or a Privacy Board that has been established by DHH pursuant to this policy, to perform the duties and functions specified in this policy regarding a research project being conducted, in whole or in part, by DHH or by a DHH office or program. The Secretary or his designee shall have the power to appoint members of any DHH IRB or Privacy Board. DHH's Privacy Officer shall be a member of any DHH IRB or Privacy Board.

C. Uses and Disclosures for Research Purposes - Specific Requirements

1. DHH may use or disclose client or participant information for research purposes with the client or participant's specific written authorization.

2. Such authorization must meet all the requirements described in DHH Policy #19, "Uses and Disclosures of Client or Participant Information," and may indicate as an expiration date such terms as "end of research study," or similar language.

3. An authorization for use and disclosure for a research study may be combined with any other type of written permission for the same research study.

4. If research includes treatment, the researcher may condition the provision of research related treatment on the provision of an authorization for use and disclosure of such treatment information.

D. DHH may use or disclose client or participant information for research purposes without the client or participant's written authorization provided that DHH obtains documentation that a waiver of an individual's authorization for release of information requirements has been approved by either:

1. An Institutional Review Board (IRB); or

2. A Privacy Board that:

a. Has members with varying backgrounds and appropriate professional competency as needed to review the effect of the research protocol on the individual's privacy rights and related concerns;

b. Includes at least one member who is not affiliated with DHH, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entity; and does not have any member participating in a review of any project in which the member has a conflict of interest.

E. Documentation required of IRB or Privacy Board when granting approval of a waiver of an individual's authorization for release of information must include:

1. A statement identifying the IRB or Privacy Board that approved the waiver of an individual's authorization, and the date of such approval;

2. A statement that the IRB or Privacy Board has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:

a. The use or disclosure of an individual's PHI involves no more than minimal risk to the privacy of individuals, based on at least the following elements:

1) An adequate plan to protect an individual's identifying information from improper use or disclosure;

2) An adequate plan to destroy an individual's identifying information at the earliest opportunity consistent with the 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

3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the protected information would be permitted under this policy;

b. The research could not practicably be conducted without the waiver; and

c. The research could not practicably be conducted without access to and use of the individual's PHI.

F. A brief description of the PHI for which use or disclosure has been determined to be necessary by the IRB or privacy board;

G. A statement that the waiver of an individual's authorization has been reviewed and approved under either normal or expedited review procedures, by either an IRB or a Privacy Board, pursuant to Federal regulations at 45 CFR 164.5 12(2); and

H. The Privacy Board Chair must sign documentation of the waiver of an individual's authorization, or other member as designated by the Chair of the IRB or the Privacy Board, as applicable.

I. In some cases, a researcher may request access to individual information maintained by DHH in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access to an individual's information, DHH should determine whether Federal or State laws otherwise permits such use or disclosure without individual authorization or use of an IRB. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA Privacy exception, review by an IRB or Privacy Board and formal waiver of authorization is required. If such access falls within this HIPAA Privacy exception to authorization and is otherwise permitted by other Federal or State laws, DHH will only provide such access if DHH obtains, from the researcher, written representations that:

1. Use or disclosure is sought solely to review an individual's PHI needed to prepare a research protocol or for similar purposes to prepare for the research project;

2. No client or participant information will be removed from DHH by the researcher in the course of the review;

3. The client information for which use or access is sought is necessary for the research purposes;

4. Researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;

5. Researcher and his or her agents agree not to publicly identify the information or contact the individual whose data is being disclosed; and

6. Applicable Federal or State laws may require such other terms or conditions.

J. In some cases, a researcher may request access to individual information maintained by DHH about individuals who are deceased. DHH should determine whether Federal or State laws otherwise permit such use or disclosure of information about decedents without individual authorization or use of an IRB. There may be instances where it would be inappropriate to disclose information, even where the individual subject of the information is dead. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA Privacy exception, review by an IRB or Privacy Board and formal waiver of authorization is required. If such access falls within this HIPAA Privacy exception to authorization and is otherwise permitted by other Federal or State laws, DHH will only provide such access if DHH obtains the following written representations from the researcher:

1. Representation that the use or disclosure is sought solely for research on the protected information of deceased persons;

2. Documentation, if DHH so requests, of the death of such persons; and

3. Representation that the individual's protected information for which use or disclosure is sought is necessary for the research purposes.

4. Agrees not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement.

5 Agrees not to publicly identify the information or contact the personal representative or family members of the decedent, and

6. Agrees to other applicable Federal or State laws that may require other terms or conditions.

K. DHH Public Health Studies and Studies Required by Law

When DHH is operating as a public health authority, DHH is authorized to obtain and use individual health information without authorization for the purpose of preventing injury or controlling disease and for the conduct of public health surveillance, investigations and interventions. In addition to these responsibilities, DHH may collect, use or disclose information, without individual authorization, to the extent that such collection, use or disclosure is required by law. When DHH uses information to conduct studies pursuant to such authority, no additional individual authorization is required nor does this policy require IRB or Privacy Board waiver of authorization based on the HIPAA Privacy rules. Other applicable laws and protocols continue to apply to such studies.

L. DHH Studies Related to Health Care Operations

Studies and data analyses conducted for DHH's own quality assurance purposes and to comply with reporting requirements applicable to Federal or State funding, including but not limited to budgeting projections and program analysis requirements, fall within the uses and disclosures that may be made without individual authorization as DHH health care operations. Neither individual authorization nor IRB or Privacy Board waiver of authorization is required for studies or data analyses conducted by or on behalf of DHH for purposes of health care operations, including any studies or analyses conducted to comply with reporting requirements applicable to Federal or State funding requirements. "Health care operations" as defined in 45 CFR 164.5 12 includes:

1. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities;

2. Conducting population-based activities related to improving health care or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

3. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs, and accreditation, certification, licensing or credentialing activities;

4. Underwriting, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits;

5. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

6. Business planning and development, such as conducting cost-management and planning related analyses related to managing and operating DHH, including

improvement of administration or development or improvement of methods of payment or coverage policies;

7. Business management and general administrative activities of DHH, including management activities related to HIPAA implementation and compliance; customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers; resolution of internal grievances; and

8. Creating de-identified information or a limited data set consistent with DHH Policy #20, "De-identification of Client Information and Use of Limited Data Sets."

Policies:

DHH Policy #17 - "General Privacy Policy"

DHH Policy #18 - "Client and Participant Privacy Rights"

DHH Policy #19 - "Use and Disclosures of Client or Participant Information"

DHH Policy #20 - "De-identification of Client and Participant Information and Use of Limited Data Sets"

DHH Policy #22 - "Minimum Necessary Information"

DHH Policy #23 - "DHH Business Associate Relationships"

DHH Policy #24 - "Administrative, Technical, and Physical Safeguards"

DHH Policy #25 - "Enforcement, Sanctions, and Penalties for Violations of DHH HIPAA Privacy Policies"

Reference(s):

45 CFR Part 64

45 CFR 164.512

Louisiana Register, Vol. 24, No. 3 (March 20, 1998), pp. 449-454.

Contact(s):

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