

<b>Policy Title:</b>	<b>Uses and Disclosures for Research Purposes &amp; Waivers</b>				
<b>Policy Number:</b>	DHS-100-006	<b>Version:</b>	2.0	<b>Effective Date:</b>	Upon Approval

Signature on File in the office of the Chief Administrative Officer

**Approved:** Jeremy Emerson, Interim CAO

**Date:** July 20, 2009

## Overview

### Purpose/Rationale:

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

## Policy

### 1. General

When DHS uses or discloses an individual's information for research purposes, as specified in this policy, they must consider the following:

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

- a. All research disclosures are subject to applicable requirements of state and federal laws and regulations related to the conduct of research and the specific program using or disclosing the information for research.
- b. De-identified information and limited data sets may be used or disclosed for purposes of research, consistent with **DHS Policy DHS-100-007**, "De-identification of Client Information and Use of Limited Data Sets."
- c. DHS may also conduct public health studies, studies that are required by law, and studies or analysis related to its health care operations. Refer to sections (4) and (5) of this policy.

### 2. An Established Institutional Review Board (IRB)

DHS may accept the action of an IRB established in accordance with 45 CFR Part 46 with regard to the duties and functions specified in this policy regarding a research project being conducted in whole or in part by DHS. Any IRB reviewing genetic research under ORS 192.547 must be registered with the Department in accordance with OAR 333-025-0125.

3. Uses and disclosures for research purposes – specific requirements (except for genetic research).
  - a. DHS may use or disclose client or participant information for research purposes with the client's specific written authorization.
    - A. Such authorization must meet all the requirements described in **DHS Policy DHS-100-003**, "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.
    - B. An authorization for use and disclosure for a research study may be combined with other types of written permission for the same research study.
    - C. If research includes treatment, the researcher may condition the provision of research related treatment on the provision of an authorization for use and disclosure for such research.
  - b. DHS may use or disclose client or participant information for research purposes without the client's or participant's written authorization provided that:
    - A. DHS obtains documentation that a waiver of an individual's authorization for release of information requirements has been approved by an Institutional Review Board (IRB).
    - B. Documentation required of IRB when granting approval of a waiver of an individual's authorization for release of information must include:
      - i. A statement identifying the IRB that approved the waiver of an individual's authorization (pursuant to federal regulations at 45 CFR 164.512(2)), and the date of such approval;
      - ii. A statement that the IRB has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:
        - I. The use or disclosure of an individual's protected information involves no more than minimal risk to the privacy of individuals, based on at least the following elements:
          - An adequate plan to protect an individual's identifying information from improper use or disclosure;
          - 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

- 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 study, or for other research for which the use or disclosure of the protected information would be permitted under this policy;
- II. The research could not practicably be conducted without the waiver of authorization; and
  - III. The research could not practicably be conducted without access to and use of the individual's protected information;
- iii. A brief description of the protected health information for which use or disclosure has been determined to be necessary by the IRB;
  - iv. The IRB Chair or his or her designee must sign documentation of the waiver of an individual's authorization.
- C. In some cases, a researcher may request access to individual information maintained by DHS in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access to individual information, DHS should determine whether federal or state law 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 exception, review by an IRB and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, DHS will only provide such access if DHS obtains, from the researcher, written representations that:
- i. Use or disclosure is sought solely to review an individual's protected information needed to prepare a research protocol or for similar purposes to prepare for the research project;
  - ii. No client information will be removed from DHS by the researcher in the course of the review; the client information for which use or access is sought is necessary for the research purposes;
  - iii. 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 within a written agreement;
  - iv. Researcher and his or her agents agree not to publicly identify the information or contact the individual whose data is being disclosed; and
  - v. Applicable federal or state law may require such other terms or conditions.
- D. In some cases, a researcher may request access to individual information maintained by DHS about individuals who are deceased. DHS should determine

whether federal or state law otherwise permits 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 – for example, individuals who died of AIDS may not have wanted such information to be disclosed after their deaths. If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by an IRB and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, DHS will only provide such access if DHS obtains the following written representations from the researcher:

- i. Representation that the use or disclosure is sought solely for research on the protected information of deceased persons;
- ii. Documentation, if DHS so requests, of the death of such persons; and
- iii. Representation that the individual's protected information for which use or disclosure is sought is necessary for the research purposes.
- iv. Researcher and his or her agents agree not to use or further disclose the information other than as provided in a written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for within a written agreement;
- v. Researcher and his or her agents agree not to publicly identify the information or contact the personal representative or family members of the decedent; and
- vi. Applicable federal or state law may require such other terms or conditions.

#### 4. DHS Public Health Studies and Studies Required by Law

When DHS is operating as a Public Health Authority – through the Public Health Division – DHS is authorized to obtain and use individual 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, DHS may collect, use or disclose information, without individual authorization, to the extent that such collection, use or disclosure is required by law. When DHS uses information to conduct studies pursuant to such authority, no additional individual authorization is required nor does this policy require IRB waiver of authorization based on the HIPAA Privacy rules. Other applicable laws and protocols continue to apply to such studies.

#### 5. DHS Studies Related to Health Care Operations

Studies and data analyses conducted for DHS's own quality assurance purposes related to health care and to comply with reporting requirements applicable to federal or state

funding requirements fall within the uses and disclosures that may be made without individual authorization as related to DHS health care operations. Neither individual authorization nor IRB waiver of authorization is required for studies or data analyses conducted by or on behalf of DHS 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 164.501 include:

- a. 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;
- b. Conducting population-based activities relating 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;
- c. 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;
- d. Underwriting, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits;
- e. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
- f. Business planning and development, such as conducting cost-management and planning related analyses related to managing and operating DHS, including improvement of administration or development or improvement of methods of payment or coverage policies; and
- g. Business management and general administrative activities of DHS, 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
- h. Creating de-identified information or a limited data set consistent with the **DHS Policy DHS-100-007**, "De-identification of Client Information and Use of Limited Data Sets."
  - **Exception:** HIV-AIDS information may not be disclosed to anyone without the specific written authorization of the individual. Re-disclosure of HIV test information is prohibited, except in compliance with law or with written permission from the Individual.

## 6. Genetic research

In addition to the general research requirements of this Policy, genetic research has

specific and detailed requirements described in OAR 333-025-0100 to 333-025-0165. Any genetic research or genetic testing must comply with the requirements of the genetic privacy laws.

Genetic research means research using DNA samples, genetic testing or genetic information.

Genetic testing means a test for determining the presence or absence of genetic characteristics in an individual or the individual's blood relatives, in order to diagnose or determine a genetic characteristic.

Genetic information means information about an individual or the individual's blood relatives obtained from a genetic test.

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.

Note: To provide some additional background into the topic of research involving health information, the Department makes available a report by the National Institutes of Health called "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule". This report is available at the Health Division's web site: [http://www.oregon.gov/DHS/ph/irb/docs/HIPAA\\_Booklet\\_4-14-2003.pdf](http://www.oregon.gov/DHS/ph/irb/docs/HIPAA_Booklet_4-14-2003.pdf)

## References

- 45 CFR Part 64
- 45 CFR 164.501
- OAR 333-025-0100 to 333-025-0165
- [Privacy/Security Glossary of Common Terms](#)

## Policy(ies) that apply:

[DHS-100-003](#) Uses and Disclosures of Client or Participant Information

[DHS-100-007](#) De-identification of Client Information and Use of Limited Data Sets

## Contact(s):

- Jane Alm, DHS Privacy Officer, [jane.alm@state.or.us](mailto:jane.alm@state.or.us)
- Privacy Program Office, (503) 945-5780

## Policy History:

- **Version 2.0:**  
07/01/09: This policy originated in March 2003 in order to meet compliance with the federal HIPAA Privacy Rule. The 2009 revisions do not impact the policy's compliance with HIPAA. The revisions are implemented to improve clarity and to bring some of the language in line with other more familiar program-specific privacy language.
- **Version 1.0:**  
03/31/2003: Initial Release