

Operational Policy

Policy title:	Release & Waivers for Use and Disclosure for Research and Reporting		
Policy number:	DHS OHA-100-010		
Original date:	7/22/2014 (OHA only)	Last update:	10/03/2016 (Joint DHS OHA)
Approved:	Mark Fairbanks, CFO OHA Dr. Richardson, Deputy Director DHS		

Purpose

This policy is one of two that outline the Department of Human Services (DHS) and Oregon Health Authority (OHA) guidelines and expectations for protecting the privacy of information and maintaining reasonable safeguards when performing required or allowed research and reporting.

Description

This policy details the responsibility of DHS and OHA staff to maintain the privacy of an individual's identifiable or protected information by outlining the circumstances under which the agencies may use and disclose information for research purposes. All DHS and OHA staff should review their agencies privacy policies to be sure they understand how these policies work together to protect individual privacy.

Applicability

This policy applies to all DHS and OHA staff including employees, volunteers, trainees and interns.

As keepers of the public trust, all agency employees have a responsibility to comply with state and agency policies, administrative rule, and state and federal law. The agency takes this responsibility seriously and failure to fulfill this responsibility is not treated lightly. Employees who fail to comply with state or agency policy, administrative rule, or state and federal law may face progressive discipline, up to and including dismissal from state service.

Policy

1. Research means a systematic investigation, including research development, investigation, testing, and evaluation designed to develop or contribute to generalized knowledge.
2. When conducting activities that involve the use or disclosure of individually identifiable or protected information for research purposes, DHS and OHA staff shall comply with all applicable federal and state statutes and rules and DHS and OHA policies including:
 - a. The existing research requirements of the Common Rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services.
 - b. HIPAA and HITECH rules (Health Insurance Portability and Accountability Act and Health Information Technology for Economic and Clinical Health Act respectively) for the covered entity components of OHA and the business associate components of DHS.

- c. Requirements applicable to particular research contracts or grants, including those funded by the National Institutes for Health.
3. When DHS and OHA are using or disclosing individually identifiable or protected information for research purposes, the agencies shall:
 - a. Use or disclose information without authorization only as allowed or required by law;
 - b. Obtain an authorization for use or disclosure signed by the individual or the individual's personal representative; or
 - c. Obtain an Institutional Review Board (IRB) waiver.
4. OHA may obtain, use or disclose individually identifiable or protected information without authorization to conduct studies that are required by law.
5. DHS may use and disclose information without informed consent if allowed by law for research and demonstration projects related to public benefit or service programs, conducted by or subject to the approval of the federal funding agency to evaluate:
 - a. The program or service as a whole.
 - b. Procedures for obtaining benefits.
 - c. Changes or alternatives to the program.
 - d. Changes in methods or levels of payment for program benefits and services.
6. DHS and OHA may obtain, use or disclose individually identifiable or protected information without authorization to comply with reporting requirements applicable to federal or state funding requirements.
7. OHA, through the Public Health division, may obtain, use or disclose individually identifiable or protected information without authorization for the purpose of:
 - a. Preventing injury or controlling disease; or
 - b. Conducting public health surveillance, investigations and interventions.
8. OHA may obtain, use or disclose individually identifiable or protected information without authorization to conduct studies and data analyses for quality assurance purposes related to:
 - a. OHA's health care operations as that term is defined in 45 CFR 164.501; and
 - b. OHA's actions as a health care provider.
9. DHS and OHA shall maintain the confidentiality of protected health information for a period of 25 years following the death of an individual.
10. Without specific authorization from an individual or the individual's representative, DHS and OHA shall not disclose:
 - a. Information about an individual's infection with AIDS or HIV.
 - b. Psychotherapy notes.
 - c. Information related to alcohol and drug treatment.
11. When DHS or OHA uses or discloses de-identified information or limited data sets for research purposes, disclosure shall be made in compliance with federal and state statute and rule, including the federally required minimum necessary standard, and agency policy related to privacy, especially the de-identification of data and limited data sets policy.
12. When DHS or OHA uses or discloses an individual's information for research purposes based on a HIPAA compliant authorization from the individual or the individual's representative:
 - a. The authorization shall be study specific.
 - b. The expiration date of the authorization may be defined using terms such as "end of research study".

- c. The authorization may be combined with other types of written permission for the same research study.
13. If research includes treatment, the researcher may condition the provision of research related treatment on receiving an authorization for use and disclosure of information for the research project.
14. When DHS or OHA receive a request for use or disclosure of individually identifiable or protected information for research purposes, including preparing for research or developing a research protocol in anticipation of research, the agencies shall determine whether federal or state statute permits the use or disclosure without individual authorization or use of an IRB to authorize release.
15. When a request for use or disclosure of individually identifiable or protected information, including information about a deceased individual, can clearly be identified as a permitted release, DHS or OHA may provide access if the researcher enters into a data use agreement with the agency that provides specific written assurances:
 - a. The individual's protected information is necessary for research purposes.
 - b. The information shall not be used or disclosed in any way not provided for in the agreement.
 - c. The researcher and the researcher's agents shall use appropriate safeguards to prevent the use or disclosure of the information other than as provided for within the written agreement.
 - d. The researcher and the researcher's agents shall not publicly identify individuals whose protected information has been disclosed.
 - e. The researcher and the researcher's agents shall not contact the individual whose data is being disclosed.
 - f. The researcher and the researcher's agents agree to comply with any other terms or conditions required by law.
 - g. If the information being disclosed is being used to prepare for research or for the development of a research project the researcher also shall confirm that:
 - A. Use or disclosure is only sought to prepare for research or develop a research protocol.
 - B. No individually identifiable or protected information will be removed from OHA in the course of the researcher's review.
 - h. If the information sought is related to an individual who is deceased the researcher also shall confirm that:
 - A. Use or disclosure is solely for research related to deceased individuals.
 - B. The agency has documentation confirming the death of the individual whose information is being requested.
16. If a request for information for research purposes, including information about a deceased individual, cannot clearly be identified as a permitted release, DHS or OHA may use or disclose information without an individual's written authorization if the agency obtains a waiver of authorization from an IRB established in accordance with 45 CFR Part 46.
17. When DHS or OHA conducts research approved by an IRB, procedures or approvals designed by the IRB may create exceptions to this policy.
18. When using or disclosing information based on an IRB waiver, DHS and OHA shall maintain:
 - a. A statement identifying the IRB that approved the waiver and the date of the approval.
 - b. A brief description of the information to be used or disclosed under the IRB waiver.
 - c. Documentation of the waiver of an individual's authorization signed by the IRB chair or the chair's designee.

- d. A statement that the IRB 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 protected information involves no more than minimal risk to the privacy of the individual;
 - B. The research could not practically be conducted without the waiver of authorization; and
 - C. The research could not practically be conducted without access to and use of the individual's protected information.
19. An IRB's determination that use or disclosure of an individual's protected information involves no more than minimal risk to the privacy of individuals shall be based on a minimum assessment that:
- a. There is an adequate plan to protect an individual's identifying information from improper use or disclosure;
 - b. There is 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
 - c. There are adequate written assurances that the individual's information will not be reused or disclosed except:
 - A. As required by law;
 - B. For authorized oversight of the research study; or
 - C. For other research permitted under this policy.
20. Genetic research and testing shall comply with the specific requirements of state and federal law, including the genetic privacy laws, and the research standards of this policy.
- a. Genetic research means research using DNA samples, genetic testing or genetic information.
 - b. 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.
 - c. Genetic information means information about an individual or the individual's blood relatives obtained from a genetic test.
21. Any IRB reviewing genetic research under ORS 192.547 shall be registered with DHS or OHA in accordance with OAR 333-025-0125.
22. DHS and OHA shall not use or disclose genetic information for underwriting purposes, even if provided with an individual authorization.
23. If this policy conflicts with federal or state statute or rule that statute or rule supersedes unless this policy provides more protection.
24. DHS and OHA follow all applicable federal and state statutes and rules and all applicable Oregon Department of Administrative Services statewide policies.

References

[45 CFR Part 46](#)
[45 CFR Part 160](#)
[45 CFR Part 164](#)
[OAR 333-025-0100 – 333-025-0165](#)
[Privacy/Security Glossary of Common Terms](#)

Related policies

[OHA Privacy Policies 100-001 to 100-014](#)

Contact

Information Security and Privacy Office (ISPO)

Phone: 503-945-6812 (Security)

503-945-5780 (Privacy)

Fax: 503-947-5396

Email: dhsinfo.security@state.or.us

dhs.privacyhelp@state.or.us

Policy history

Version 1 OHA 100-010 Established 07/22/2014

Version 1 DHS|OHA 100-010 Established 10/03/2016

Keywords

IRB, Institutional Review Board, HIPAA, HITECH, Research, Waivers, Privacy, Genetic research

This document can be provided upon request in an alternate format for individuals with disabilities or in a language other than English for people with limited English skills. To request this document in another format or language, contact the Publications and Design Section at 503-378-3486, 7-1-1 for TTY, or email dhs-oha.publicationrequest@state.or.us.