

STATE OF UTAH DEPARTMENT OF HEALTH	Number: 12.41	Page 1 of 2
	Original Issue Date: 10/09/2012	Revision Date:
POLICIES & PROCEDURES	Authorized By: W. David Patton	
Section: Privacy Policies	Subject: Access, Use, Disclosure and Safeguarding PHI in the Conduct of Research Policy	

Effective Date: October 9, 2012

Policy:

1. DEPARTMENT and its staff engage in the conduct of research which may involve access to, and use of, PHI. Consistent with its mission, it is DEPARTMENT's policy to safeguard PHI and to afford it the utmost privacy and confidentiality.
2. In addition to the policies specific to research activities presented below, the corporate policies on Security of Health Information and Confidentiality and Privacy of Health Information apply to research activities. The corporate policies address Access to Information, Safeguarding Information, Minimum Necessary Information, Disclosure of PHI, Storage and Disposal of PHI, and Compliance applies to research activities.
3. Staff involved in research activities will receive additional training regarding the Health Insurance Portability and Accountability Act requirements (HIPAA) related to both the provisions of the Standards for Privacy of *Protected Health Information* (45 CFR Parts 160 and 164) and the HIPAA Security Rule (45 CFR Parts 160 and 164, subparts A and C) as they relate to research. The lead staff person for the project (such as the principal investigator) involving research is responsible for assuring that all staff involved in research, which involves the use of PHI, receive training or have been trained within the past two years.

Use of Protected Health Information

PHI may be used in research if appropriate authorization from research participants is obtained, or if the PHI is obtained through one of the following alternatives:

1. Certified de-identified data sets;
2. Limited data sets (when accompanied by an appropriate Data Use Agreement);
3. Waiver or alteration of the authorization requirement by an Institutional Review Board (IRB) or Privacy Board;
4. Research involving decedents' PHI (when appropriate representations are made by the researcher to the covered entity that the PHI is necessary and sought solely for research on decedents); or
5. Reviews preparatory to research when the covered entity receives representations from the researcher that access to the PHI is necessary and will not be removed from the covered entity.

PHI may only be used for the specific purposes for which it was obtained.

Access to Protected Health Information:

1. PHI may be used in research only by those individuals authorized to access the information by the person(s) responsible for the project (principal investigator, project director, project coordinator) or the department head. The person(s) responsible must protect the information from unauthorized access and must maintain and regularly update a list of staff that is authorized to have access to the PHI.

2. The person(s) responsible should ensure that access to PHI received through the accreditation process is provided for research purposes only when certified as de-identified or appropriate authorization is obtained.

Disclosure:

PHI received under a data use agreement shall be disclosed only as outlined in such agreement. Disclosure of PHI received under individual authorization is limited as outlined in the authorization. Data that is certified as de-identified may be disclosed.