



Henry M. Jackson Foundation
for the Advancement of Military Medicine

HEALTH INFORMATION PRIVACY POLICY

PURPOSE

The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (the Foundation) frequently obtains and houses individual health information in the context of conducting and supporting medical research. The Foundation respects the privacy of an individual's health information and understands the importance of keeping this information confidential and secure. The Foundation seeks to maintain individual health information in a manner that is consistent with all local, state, and federal laws governing protection and disclosure of such health information, such as the Health Insurance Portability and Accountability Act of 1996, and its implementing Privacy Regulations ("HIPAA"). This policy describes how the Foundation protects health information that it generates from its own research activities or receives from other institutions.

DEFINITIONS

Data user means a person who has been granted explicit authorization by the Foundation to access health information data.

De-identified Information means health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.

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

Health Information means any information, whether oral or recorded in any form, that is created or received by the Foundation in the context of conducting and supporting medical research that relates to an individual's past, present, or future physical or mental health.

Individual means the person who is the subject of Protected Health Information.

Individually Identifiable Health Information means health information, including demographic information, that identifies an individual, or with respect to which there is a reasonable basis to believe the information can be used to identify an individual.

Limited Data Set means health information that has been de-identified except for dates directly related to an individual (e.g. DOB) and geographic information other than street address.

Protected Health Information (PHI) means individually identifiable health information that is transmitted by electronic media or transmitted or maintained in any other form or medium.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The development of research repositories and databases for future research and the recruitment of patients for research studies are considered research for purposes of this policy.

Use means sharing, employment, application, utilization, examination, or analysis of PHI within an entity that maintains such information.

POLICY ON USE AND DISCLOSURE OF PHI

It is the policy of the Foundation that all personnel must preserve the integrity and confidentiality of PHI to the highest degree reasonably possible so that individuals have confidence that the confidentiality of such information will be maintained by the Foundation. To that end, the Foundation, its officers, employees, and agents will

- Treat all PHI and related financial, demographic, and lifestyle information as sensitive and confidential;
- Collect and use PHI only for the purpose for which it was obtained;
- Not use or further disclose PHI, other than as permitted or required by governing contracts or laws;
- Reasonably safeguard PHI from misuse;
- Limit who within the Foundation has access to PHI so that PHI is shared or disclosed only to the minimum amount necessary for the purpose of the disclosure (see Access Authorization Procedure Below);
- Unless required by law, not use or disclose PHI to third parties *unless* the use or disclosure is for research purposes or patient care-related purposes only *and*:
 - The information has been completely de-identified; *or*
 - Patient/study subject authorization has been obtained and provided to the Foundation that permits the intended use or disclosure; *or*
 - The individual is deceased; *or*

- The use or disclosure is preparatory to research; *or*
 - A full or partial waiver of a patient privacy board or IRB waiver has been obtained; *or*
 - The use or disclosure involves only a limited data set and a data use agreement has been signed.
- When disclosing PHI to third parties, take appropriate steps to prevent unauthorized re-disclosures, such as specifying in writing that the recipient may not further disclose the information without patient/study subject authorization or as authorized by law;
 - In accordance with the section of this policy entitled Accounting of Disclosures, track all disclosures of PHI to third parties and maintain records of such disclosures for a period of six (6) years;
 - Upon request, provide access to an individual's PHI to (i) the originator of the PHI, or (ii) the individual, if the originator contractually obligated the Foundation to provide the individual access to his/her PHI.
 - Upon request, provide an accounting of all third party disclosures of PHI to (i) the originator of the PHI, or (ii) the individual, if the originator contractually obligated the Foundation to provide to the individual an accounting of the disclosures of his/her PHI.
 - Amend the individual's PHI maintained by the Foundation upon request of (i) the originator of the PHI, or (ii) the individual, if the originator contractually obligated the Foundation to amend the individual's PHI.
 - Report to the originator any use or disclosure of the PHI of which the Foundation becomes aware that is not provided for by contract with the originator.
 - Destroy or return all PHI to its originator at the conclusion of the research if feasible. If such destruction or return is not feasible, extend the protections of the contract between the originator and the Foundation and limit further uses and disclosures to those purposes that make the return or destruction of the PHI infeasible;
 - Unless required by law, under no circumstances use or supply PHI for purposes that are not research or patient care-related, such as direct marketing, employment, or credit evaluation.

HIPAA COMPLIANCE OFFICER, PHI ADMINISTRATORS, AND ACCESS AUTHORIZATION PROCEDURE

Access authorization is the process of determining whether a prospective data user should be granted access to the Foundation's health information data. Access may be granted only in accordance with this policy. The Foundation's HIPAA Compliance Officer, in the Regulatory Affairs Department at the Foundation's headquarters, will be responsible for monitoring overall compliance with this policy and its access authorization procedure.

The HIPAA Compliance Officer will designate a PHI Administrator for each Foundation-administered program. PHI Administrators are responsible for determining which personnel gain access to health information data. In making such determinations, PHI Administrators must follow these guidelines:

- Prospective data users should not gain access unless they have a need for such access;
- Prospective data users should obtain only the minimum access necessary to perform duties requiring such access;
- Access should be limited to necessary tasks, such as read-only, read and copy, or read and edit.

PHI Administrators should submit names of personnel needing access with the recommended levels of access to the database manager, who may then provide access to the extent authorized by the PHI Administrator.

PHI Administrators must ensure that all prospective data users receive training on this policy. If access is needed before training can be completed, PHI Administrators should annotate such, the reason why, and the date such training will be completed. All training must be completed within 30 days of receipt of access.

Once access is granted, all data users must comply with the following requirements:

- Use the PHI only for purposes authorized by the Foundation;
- Comply with this policy, particularly with regard to the use and disclosure of PHI;
- Not disclose PHI unless authorized in writing to do so.

Upon request, PHI Administrators shall forward the above information to the HIPAA Compliance Officer.

ACCOUNTING OF DISCLOSURES

Upon request, the HIPAA Compliance Officer will provide an accounting of all third party disclosures of PHI to (i) the originator of the PHI, or (ii) the individual, if the originator contractually obligated the Foundation to provide to the individual an accounting of disclosures.

RECORDKEEPING PROCEDURES

In order to comply with a request for an accounting, PHI Administrators must ensure that the following relevant information regarding the disclosure of PHI are recorded and maintained.

- The name of the protocol or other research activity;
- A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
- A brief description of the type of PHI that was disclosed;
- The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
- The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
- A brief statement of the purpose of the disclosure

COMPLIANCE AND ENFORCEMENT

All officers, agents, and employees of the Foundation must adhere to this policy. The Foundation will not tolerate violations of this policy. Any violation of this policy is grounds for disciplinary action, up to and including termination.

The HIPAA Compliance Officer is responsible for enforcing this policy.

EFFECTIVE DATE

This policy is effective immediately and supercedes all prior policies governing the subject matter contained herein.

This policy does not constitute an express or implied employment contract, and does not create any right, privilege, entitlement, or cause of action in any person or entity (other than the Foundation), where such right, privilege, entitlement, or cause of action would not otherwise exist. All managerial and administrative functions, responsibilities and prerogatives entrusted to and conferred upon employers inherently and by law are retained and vested exclusively with the Foundation, including but not limited to the right to exercise its judgment to administer policies, practices and procedures, and to change them. This policy can be changed at any time by the Foundation in its discretion without notice.

August 12, 2004
Date

John W. Lowe
John W. Lowe, President and CEO