

DRAFT 3/3/03

References

Federal Register, Vol. 65, No. 250, December 28, 2000, pages 82798 to 82829
Federal Register, Vol. 67, No. 157, August 14, 2002, pages 53181 to 53273

Related Documents

All related documents are contained in the SHC, LPCH, and Stanford University Administrative Manuals.

I. Purpose

The purpose of this policy is to describe the process and procedure for conducting human subjects research using protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) within the Stanford HIPAA covered entity (i.e., those portions of the University covered by HIPAA), Stanford Hospital and Clinics (SHC), and Lucile Salter Packard Children's Hospital (LPCH).

II. Definitions

III. Policy

The Stanford HIPAA covered entity is committed to protecting the privacy of patients and research subjects, while carrying out their research mission. The PHI of patients and subjects may be used (i.e., within the Stanford HIPAA covered entity) or disclosed (i.e., to those outside within the Stanford HIPAA covered entity) for research purposes only in accordance with this policy and applicable law.

IV. Principles

- A. A researcher is obligated to identify when the intended use or disclosure of PHI is for research.
- B. Individual authorization generally is required to request, access, review, use or disclose PHI for research purposes. In most cases, authorization will be combined with informed consent, and reviewed and approved by SU's Institutional Review Board (IRB).
- C. In those circumstances where individual authorization is excepted, other processes and requirements must be satisfied.
- D. The Stanford HIPAA covered entity administrative and management infrastructures and processes support this policy. Investigators conducting

research within the Stanford HIPAA covered entity will abide with the administrative processes described in this policy.

- E. The Stanford HIPAA covered entity must be able to account for disclosures of PHI on Individual request.
- V. Procedures
- A. ***A researcher is obligated to identify when the intended use or disclosure of PHI is for research.***
 - 1. The researcher must be aware of the HIPAA definition of research as well as its definitions for other types of activities.
 - a. HIPAA defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Any project involving PHI where one of the primary goals is generalizable knowledge, with or without publication or public presentation, is considered research.
 - b. In contrast, requests for, use and disclosure of PHI for purposes of treatment, payment, or healthcare operations (e.g., quality assurance, education within The Stanford HIPAA covered entity) are governed by other policies (see the Administrative manuals of SU, SHC, and LPCH for policies).
 - c. In some cases, a project that was initiated for a non-research purpose, e.g., a quality assurance study, may produce information that the author subsequently decides to generalize (e.g., publish). At that point, it becomes research, and the requirements of this policy apply.
 - d. A case study may or may not be considered research, but generally will require the researcher to obtain individual patient authorization (Refer to HIPAA: External Disclosure of PHI Policy).
 - 2. A researcher is obligated:
 - a. To know the requirements of this policy;
 - b. To be aware of other applicable privacy laws, e.g., local, State, and Federal laws relating to human subjects that are more restrictive than HIPAA;

- c. To conduct research in compliance with all requirements and processes;
 - d. To understand and comply with the concept of limiting use and disclosure of PHI to the minimum necessary (Refer to HIPAA: Minimum Necessary Policy).
 - e. When required, to obtain IRB approval prior to beginning the research project, the researcher is required:
 - f. To maintain PHI accessed and used for research separately from PHI maintained for other purposes (i.e., treatment, payment, and health care operations purposes), to comply with requirements for research documentation;
 - g. With limited exceptions, to obtain patient authorization prior to requesting, accessing, using, or disclosing PHI;
 - h. To satisfy the other processes (Refer to Section C), documentation (Refer to Sections D and E), and requirements for use or disclosure of PHI for research purposes for those exceptions when patient authorization is not required.
3. If a researcher maintains a database containing PHI, the researcher is obligated to ensure that use and disclosure of PHI is compliant with HIPAA policies.
- a. The researcher must provide and maintain database security, including physical security and access control (Refer to HIPAA: Physical Security Policy).
 - b. The researcher must control and manage the access, use and disclosure of PHI. The researcher is required to verify applicable IRB approval documentation and patient authorizations.
 - c. ***All original records must be maintained in the patient's legal medical record.*** PHI in the database that is relied upon to make treatment decisions should be a copy of what is in the Medical Record.
- B. Individual Authorization.
Individual authorization generally is required to request, access, review, use, or disclose PHI for research purposes. In most cases, authorization

will be combined with informed consent, and must be reviewed and approved by the IRB.

1. A researcher shall submit a research protocol to the IRB that includes:
 - a. A description of the PHI required to accomplish the research;
 - b. A research consent form that incorporates the legally required elements of individual authorization (Refer to Appendix A), and
 - c. An authorization form separate from the informed consent form when the PHI involves psychotherapy notes (Refer to Appendix A).
2. The IRB shall:
 - a. Confirm that individual authorization is necessary;
 - b. Review the submitted form to ensure inclusion of legally required elements, and
 - c. If the submission is satisfactory, issue documentation to the researcher confirming review and approval of the research protocol with individual authorization.
3. With satisfactory completion of Steps 1 and 2 above, the researcher may use the IRB approval notice in conjunction with a signed research informed consent/authorization form to access, use, and disclose PHI following the documentation rules outlined below (Refer to Sections D and E of this policy).
4. If subsequently the individual revokes the authorization to use the PHI, the researcher should consult with the IRB. HIPAA permits continued inclusion of the PHI obtained prior to the revocation, if the IRB agrees this is necessary to preserve the integrity of the research.

C. Individual Authorization Exceptions.

In some circumstances, individual authorization is excepted. However, the researcher is obligated to satisfy other processes and requirements.

1. Waiver of Authorization

The IRB may grant a waiver of authorization for some research activities, e.g., in order to obtain names of patients to recruit them into a clinical trial (Refer to Appendix B).

- a. The researcher shall submit a research protocol to the IRB that includes:
 - 1) A description of the minimum necessary PHI required to accomplish the research;
 - 2) A request for waiver of individual authorization, and
 - 3) Substantiation of the legal basis for the waiver (Refer to Appendix B).
- b. The IRB shall:
 - 1) Review and accept or deny the description of the Minimum Necessary PHI;
 - 2) Determine if a waiver of authorization is appropriate, and
 - 3) When the requirements above are met, issue documentation to the researcher confirming review and approval of the research protocol with the waiver of individual authorization.
- c. The researcher then may use the IRB approval notice to access, use, and disclose PHI following the documentation rules of this policy (Refer to Sections D and E).

2. Preparatory to Research (Refer to Appendix C):

- a. PHI requested as preparatory to research cannot include patient names, medical record numbers, social security numbers, or account numbers or be used to contact or recruit patients. **Neither recruitment nor patient contact is considered preparatory to research.**
- b. The researcher should determine if this phase of the project requires review under Federal laws relating to human subject research. The researcher should contact the IRB if further assistance is needed to make this determination.

- 1) If IRB review is necessary, the researcher shall submit a protocol to the IRB.
 - 2) If IRB review is not necessary, the researcher may proceed with the steps below.
- c. If access, use or disclosure of PHI is not required, no additional steps are necessary. For example, aggregate data, such as a request for the number of cases of a particular diagnosis in the last three years, does not contain PHI.
- d. Researchers may use PHI during preparatory to research activities if the researcher certifies in writing the elements specified in Appendix C (Form on HIMS website). Once these elements have been certified by the researcher, the researcher must complete a preparatory to research form, and in some cases a form for each patient, following the documentation rules. (Refer to Sections D and E of this policy).
3. Deceased Individuals (Refer to Appendix D):
- a. A researcher is not required to submit research involving deceased individuals to the IRB for review, ***unless other living individuals such as family members could be affected (e.g., genetic markers of certain diseases)***. The researcher should contact the IRB if assistance is needed to make this determination.
 - 1) If IRB review is necessary, the researcher shall submit a protocol to the IRB.
 - 2) If IRB approval is not necessary, the researcher:
 - a) May use PHI of deceased individuals without authorization from the decedent's estate if the researcher certifies in writing the elements specified in Appendix D (Form on HIMS website); and
 - b) must complete a deceased individual form, and in some cases a form for each patient, following the documentation rules outlined

below (Refer to Sections D and E of this policy).

4. De-identified Health Information (Refer to Appendix E):
 - a. When research data has been de-identified prior to receipt by the researcher (Refer to Appendix E), no further action is required to meet HIPAA compliance. However, the IRB still may need to review the protocol. The researcher should contact the IRB if further assistance is required.
 - b. When the researcher will de-identify the data:
 - 1) The researcher must submit a research protocol to the IRB that includes a description of the health information sought and an explanation of how the data will be de-identified (Refer to Appendix E).
 - 2) The IRB shall review the protocol to determine if the PHI will be adequately de-identified in accordance with the privacy laws.
 - a) Once satisfied, the IRB will issue documentation to the researcher confirming that the protocol and plan for de-identification have been approved.
 - b) The researcher may use the IRB approval notice to access PHI and create a de-identified database following the documentation rules outlined below (Refer to Sections D and E of this policy).
 - 3) It is inappropriate for the researcher to maintain a code linking the data to individuals. The researcher should contact the IRB for further assistance regarding the maintenance of keys by a trusted third party within the Stanford HIPAA covered entity
5. Limited Data Set (Refer to Appendix F):
 - a. The researcher shall submit a research protocol to the IRB that includes a description of the PHI required to accomplish the research and certify that PHI will include only those identifiers allowed for a limited data set as defined by the privacy laws (Refer to Appendix F).

- b. The IRB shall determine if the PHI is limited to the identifiers legally permitted in a limited data set and if so, issue documentation to the researcher confirming that the protocol using a limited data set has been approved.
- c. In addition, the researcher must complete a limited data set agreement form (Refer to Appendix G; Form on HIMS website).
- d. The researcher may use the limited data set agreement and the IRB approval notice to access, use, and disclose PHI following the documentation rules outlined below (Refer to Sections D and E of this policy).

6. Grandfathering

Grandfathering refers to research involving PHI and carried out according to a protocol reviewed and approved by the IRB prior to April 14, 2003:

- a. Protocols conducted under informed consent or a waiver of informed consent:

- 1) The researcher may continue to use or disclose the PHI created or received **prior** to April 14, 2003.

- 2) The researcher operating under a waiver of informed consent may continue to enroll new subjects and create, receive, use and disclose PHI after April 14, 2003, with no further action until the next scheduled IRB review.

- 3) If the protocol required informed consent and subjects will be enrolled after April 14, 2003, the researcher must submit a protocol revision to the IRB amending the informed consent to include individual authorization for subjects enrolled after April 14, 2003.

- b. Exempt Protocols Reviewed Before April 14, 2003

If the protocol reviewed prior to April 14, 2003 was approved as an exempt protocol without documentation of a waiver of consent, the researcher must contact the IRB for revision of the protocol. ***Until that occurs, PHI created***

or received prior to April 14, 2003 may not be used or disclosed after April 14, 2003.

- 1) Once IRB requirements are met (and if informed consent was not waived) the researcher may use the IRB approval notice in conjunction with informed consent forms to access, use and disclose PHI following the documentation rules outlined in this policy (Refer to Sections D and E).
- D. SU, SHC, and LPCH will establish administrative processes to implement this policy.

1. Privacy Questions

The privacy officers or their designees for SHC, LPCH, the School of Medicine (SoM), or SU as a whole, shall answer questions concerning this policy and questions regarding requests for PHI from the Stanford HIPAA covered entity databases.

2. Researchers must obtain IRB approval for protocols involving:

- a. Individual authorization
- b. A waiver of individual authorization
- c. De-identified health information
- d. Limited data sets
- e. Some preparatory to research activities

3. The researcher must present to the person who maintains the records containing PHI the following

- a. IRB Approval: A copy of the applicable IRB approval notice including:
 - 1) Approvals prior to April 14, 2003.
 - 2) Waivers of authorization, de-identified health information, limited data set, or a preparatory to research project submitted to IRB, or
- b. Appropriate Individual Privacy Documentation:
 - 1) Documentation for each patient whose PHI will be accessed:

- a) Individual Authorization / Informed Consent certification: A copy of a signed individual authorization / research informed consent for each patient whose PHI will be accessed (see Appendix A), or
 - b) Waiver of Authorization, Preparatory to Research, and Deceased Patients: The applicable certification for each patient record where PHI is abstracted as described in the Appendix (B, C, and D), or
 - 2) Receipt for Lists or Queries of PHI Received: When PHI is generated as a list or data query, the researcher must provide the holder of the PHI a single, macro receipt for the information received (see Forms Appendix).
 - 3) Limited Database certification: Sign appropriate Data Use Agreement as described in Appendix F.
 - 4) De-identified Database Certification: Certification that the PHI will be de-identified as described in Appendix E(?).
 - 5) No Abstraction of PHI: If the researcher will record neither health information nor identifying information (e.g., name, medical record number, dates), no documentation is required.
- c. Validation: The person who maintains the records (paper or electronic) with PHI shall:
- 1) Ensure IRB approval when appropriate (all but some preparatory to research and research of deceased patients);
 - 2) Validate that the applicable forms or individual authorizations are correctly completed and provided, for each subject whose PHI is accessed (Refer to Subsection E.2 of this policy).
- d. Provide Access: Once documentation is provided and validated, the person who maintains the records (paper or electronic) with PHI may provide access to the researcher.

- e. Documentation: In order to comply with the HIPAA accountability requirement, the person who maintains the PHI must ensure that validated documentation is appropriately archived and that requests for accountability can be responded to easily:
 - 1) For access, use or disclosure of PHI, patient, a copy of all completed forms must be forwarded to the HIMS Department for inclusion in the patient's legal medical record.
 - 2) A copy of macro receipts should be sent to the appropriate Privacy Office for filing and the original retained by the person who provided access.

 - f. Databases: Provide a mechanism for documenting researchers' PHI use (i.e., within the Stanford HIPAA covered entity) and disclosure (i.e., to those outside the Stanford HIPAA covered entity) of PHI for research.
 - 1) SHC and LPCH require centralized filing (document imaging) of all researcher documented accesses, uses, and disclosures of PHI for research purposes.
 - 2) SU and SOM require centralized filing of all researcher documented disclosures of PHI for research purposes performed under a waiver of authorization or involving deceased individuals (Refer to Appendix H).

 - g. Auditing: The privacy officers of the hospitals, SOM and SU will conduct periodic audits of researchers' access to PHI to insure that access is appropriate and documented, and that disclosures are tracked.
- E. SU, SHC, and LPCH must be able to account for disclosures of PHI on request.
- 1. It is anticipated that most requests for an accounting of disclosure will be made to the hospitals. The Privacy Office will respond in accordance with the policy entitled HIPAA: Accounting of Disclosures.

2. Based on the documentation in the legal medical record (Refer to Section E.5 of this policy), the HIMS Department will know of any researcher accesses and uses of PHI for research purposes.
3. The HIMS Department will contact the applicable SU privacy officer to query and consolidate all research disclosures of PHI.
 - a. The applicable SU privacy officer should respond to an accounting request within two weeks.
 - b. The research disclosure accounting will be consolidated with the hospital accounting and a response provided to the requestor (Refer to SHC/LPCH policy: HIPAA: Accounting of Disclosures).
4. When a non-hospital Privacy Office receives an accounting request, coordination to comply with this policy will be initiated by that Privacy Office.

IV. DOCUMENT INFORMATION

- A. Author/Original Date
December 2002. The HIPAA Research Taskforce, chaired by D'Arcy Myjer, authored this policy.
- B. Gatekeeper of Document
Administrative Manual Coordinators and Editors
- C. Distribution and Training Requirements
 1. This policy resides in the Hospital and University Administrative Manual.
 2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/ clinic manager will be responsible for communicating this information to the applicable staff.
- D. Review and Renewal Requirements
This policy will be reviewed every three years and as required by change of law or practice. The same entities or persons who provided initial approval must approve any changes to the policy.

- E. Review and Revision
This is a new document.

- F. Approvals
 - ___ by Security Committee
 - ___ by HIPAA Steering Committee
 - ___ by Legal Counsel
 - ___ by SHC HIMS Committee
 - ___ by LPCH HIMS Committee

- G. Board Approvals
 - ___ by SHC Medical Board
 - ___ by SHC Hospital Board
 - ___ by LPCH Medical Board
 - ___ by LPCH Hospital Board

V. APPENDICES

- A. Individual Authorization
- B. Waiver of Authorization
- C. Preparatory To Research
- D. Research Involving Deceased Individuals
- E. De-Identified Health Information Under HIPAA
- F. A Limited Data Set Under HIPAA
- G. Researchers' Responsibility for Accounting of Disclosure of PHI to Subjects

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Stanford, CA 94305

Appendix A Individual Authorization

In most cases, when a research protocol requires informed consent, the researcher will need an individual authorization in order to satisfy HIPAA. The IRB has revised the informed consent template on its website to include the required elements of an individual authorization (except for research involving psychotherapy notes). These elements are:

- * A description of the information [PHI] to be used or disclosed in a specific and meaningful fashion;
- * The name or other specific identification of the person(s) or class of persons authorized to make the requested use or disclosure;
- * The name or other specific identification of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure;
- * A description of each purpose of the requested use or disclosure;
- * An expiration date / expiration event that relates to the purpose of the use or disclosure (e.g., "end of research study" or "none" is permissible);
- * A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;
- * A statement that information used may be subject to re-disclosure by the recipient and no longer be protected by this rule;
- * Signature of the individual and date, and if the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual;
- * A statement of the consequences to the individual of refusing to sign;
- * That the consent be written in plain language; and
- * That a signed copy of the consent be provided to the individual.

If the PHI desired includes psychotherapy notes, an authorization form that is **separate** from the research informed consent must be used. Psychotherapy notes means:

Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record;

But they EXCLUDE medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical test, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

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Appendix B Waiver of Individual Authorization

In most cases, a protocol that qualifies for a waiver of informed consent from the IRB, also will qualify for a waiver of individual authorization under HIPAA. The IRB application addresses the waiver of authorization under HIPAA. It solicits information that is required by the IRB to evaluate and make a decision on the request for a waiver.

Three findings are specified by the HIPAA regulations:

1. Disclosure [of PHI] involves no more than minimal risk to privacy for the individual based on:
 - a. a plan to protect an individuals' identifiers from improper use and disclosure;
 - b. a plan to destroy identifiers at the earliest opportunity unless there is health or research justification for retaining identifiers or is required by law; and
 - c. adequate written assurances that protected health information will not be reused or disclosed to others except as required by law, for oversight of the research, or for other research that would be permitted by HIPAA;
2. The research could not be practically conducted without the waiver;
3. The research could not be practically conducted without access to protected health information.

The regulations state that the IRB chair, or another member designated by the chair, must sign the waiver of authorization. The waiver of authorization also must name the IRB that granted it.

Appendix C Preparatory To Research

The preparatory to research category of HIPAA is meant for use in situations where the investigator is developing a research hypothesis or exploring the feasibility of research. Preparatory to research does not permit disclosure of any PHI outside of the parts of the Stanford HIPAA covered entity. A non-Stanford investigator is not permitted to remove PHI from the premises of the Stanford HIPAA covered entity; this includes any disclosures to others outside the Stanford HIPAA covered entity.

Preparatory to research allows access to PHI from SHC or LPCH enterprise information systems or one of SU/ SOM's research data banks as part of planning and moving toward the actual research stage. For example, the investigator may need to collect demographics for a grant proposal or determine if there is a sufficient population from a particular SHC or LPCH clinic to support a clinical trial. If the project requires submittal to the IRB, the HIPAA requirements will be addressed as part of that review. (If an investigator is unsure whether IRB review is necessary, the investigator should check the definition and examples of research on the IRB website or contact the IRB to discuss the project.) When the project does not have to be submitted to the IRB, the investigator must complete a HIPAA preparatory to research form, which can be obtained from HIMS or downloaded from [redacted].

Either through the form or the IRB submittal, the investigator is required to certify compliance with the legal requirements of HIPAA and the policies of the Stanford HIPAA covered entity. The researcher must certify that:

1. My review of this individual's PHI is for research purposes and **solely** to prepare a research protocol or for similar purposes preparatory to research and will not be used for any other purpose;
2. I am:
 - a. a student, faculty, employee or agent of the Stanford HIPAA privacy entity, (i.e., SOM, SU Other, SHC, LPCH), and this work preparatory to research is carried out as part of that position (*i.e.*, part of my Stanford responsibilities), or
 - b. from _____.
3. I will not remove either physically or through disclosure to a third party any of the PHI from the Stanford HIPAA covered entity (i.e., School of Medicine, Stanford Hospital and Clinics, Lucile Packard Children's Hospital), unless subsequent steps (e.g., authorization by subject, IRB waiver) are taken that allow such disclosure;
4. If I record PHI, it will not include names and contact information, medical record numbers, social security numbers, or patient account numbers;

5. I will not contact individuals as potential subjects as part of this preparatory work;
and
6. The minimum necessary PHI to accomplish my work is:
_____.
7. I will destroy all PHI after this preparatory use, unless it was incorporated into the
subsequent research project for which this preparatory to research data review
was performed.

If the investigator intends to review the medical records of individuals and to record either health information or identifying information (e.g., name, medical record number) for the research purpose, HIMS requires completion of one form per individual specifying the individual's name.

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Appendix D

Research Involving Deceased Individuals

Research involving deceased individuals does not normally require submission to the IRB, because deceased individuals are not considered human subjects under the Federal IRB regulations. For that reason, compliance with HIPAA will be accomplished through a separate, specific form. Before accessing PHI from a SHC or LPCH enterprise information system or one of SU/ SOM's research data banks, the investigator must complete that form. The form can be obtained from HIMS or downloaded from [redacted].

The investigator is required to certify the following to comply with HIPAA. The researcher must certify that:

1. My research requires the review of protected health information solely for research on deceased individuals.
2. The access sought to protected health information is necessary for research purposes.
3. If requested, I will provide documentation of the death of the individual(s) whose protected health information I will be accessing.
4. The minimum necessary PHI to accomplish my work is:
_____.

Submission to the IRB is required if

- the investigator intends to maintain health information linked to identifiers that could affect living family members of the deceased (e.g., genetic markers of certain diseases), or
- the research includes individuals who are living, then that portion of the research must be submitted to the IRB.

If the investigator intends to review the medical records of individuals and if the investigator intends to record either health information or identifying information (e.g., name, medical record number), HIMS requires one form per individual that specifies the individual's name.

Appendix E De-Identified Health Information Under HIPAA

De-Identification Under the IRB Rules vs. HIPAA.

The definition of de-identified health information under HIPAA is much more specific (and probably more limiting) than the general de-identification standard applied under Federal laws relating to human research subjects. It is possible that protocols previously submitted to the IRB as exempt because of de-identification will no longer qualify as de-identified under HIPAA. Instead, it may require submittal as an expedited protocol with a request for a waiver of individual authorization because the HIPAA definition of de-identification is not satisfied.]

HIPAA Definition of De-Identified.

An investigator who submits a protocol to the IRB with de-identified health information should specify if it meets the HIPAA de-identification definition.

Under HIPAA, health information may be considered de-identified if one of the following two standards is met.

Method 1: Deletion of the following 18 specific identifiers.

- Names
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes;
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;

- Account Numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code (except a code to allow re-identification under certain requirements).

AND neither the covered entity nor the researcher has a reasonable basis to believe that the information can be used alone or in combination with other information to identify an individual.

Method 2: The second method of de-identifying under HIPAA allows a person with appropriate knowledge and experience to apply generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable to make and document a determination that there is a very small risk that the information could be used by others to identify a subject of the information

De-identification by the Investigator.

The workforce of the Stanford HIPAA covered entity is considered to be those persons (e.g., faculty, employee, student, volunteer) who perform activities in SHC, LPCH, or the portion of SU covered by HIPAA (e.g., SOM). If the maintainer of the PHI (e.g., HIMS) is willing, the investigator may act as the agent for the maintainer, access the PHI, and record it in a de-identified form, with no additional HIPAA requirements. The data taken away and retained by the investigator can be only in de-identified form.

If the investigator is from outside the Stanford covered entity, prior to accessing the data, the investigator must first enter into a HIPAA business associate agreement with SU/SHC/LPCH for the purpose of de-identifying the data.

Under HIPAA, a trusted third party who is a member of the Stanford HIPAA covered entity also (but **not** the investigator) may maintain a key for re-identifying the data. However, if such a key is maintained, the research does not meet the definition of de-identification for IRB purposes (e.g., exempt protocol). Any investigator performing such a de-identification function must submit a certificate to HIMS. , (Form available from HIMS and may be downloaded from .)

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Appendix F Limited Data Set

Limited Data Set Definition


Under HIPAA, a limited data set is related to, but does not qualify as, de-identification (Refer to Appendix E). It allows several of the 18 identifiers to be utilized without requiring individual authorization or waiver of authorization.

Allowable Identifiers in a Limited Data Set

A limited data set of PHI may not include any of the identifiers required for “de-identification” (Refer to Appendix E) under HIPAA but the following identifiers are permitted:

- Town or city, State, and zip code;
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
- Any other unique identifying number, characteristic, or code;
- **AND** neither the covered entity nor the researcher has a reasonable basis to believe that the information can be used alone or in combination with other information to identify an individual.

Data Use Agreement

A data use agreement between SU/SHC/LPCH and the recipient investigator is required under HIPAA. This applies to members of the Stanford HIPAA covered entity and external researchers equally. (Available from HIMS or may be downloaded from )

The Data Use Agreement obligates the recipient to:

1. Use or disclose the limited data set only for the limited research purpose stated in the agreement;
2. Establish who is permitted to use or receive the limited data set;
3. Require appropriate safeguards for confidentiality

4. Report to SU/SHC/LPCH of any use or disclosure contrary to the agreement, and
5. Require all agents to whom the recipient provides the limited data set to abide by the same restrictions and conditions.

IRB Implications.

The IRB definition of de-identification is less restrictive than the HIPAA definition. Research using de-identified data, as defined by HIPAA, may qualify as exempt under the IRB criteria. However, if a key for re-identifying the data is maintained, the research does not meet the de-identification definition for IRB purposes.

Creation of a Limited Data Set by the Investigator.

The workforce of the Stanford HIPAA covered entity is considered to be those persons (e.g., faculty, employee, student, volunteer) who perform activities in SHC, LPCH, or the portion of SU covered by HIPAA (e.g., SOM). If the maintainer of the PHI (e.g., HIMS) is willing, the investigator may act as the agent for the maintainer, access the PHI, and record it in the form of a limited data set, with no additional HIPAA requirements. The data taken away and retained by the investigator can be only be in the form of a limited data set.

If the investigator is from outside the Stanford covered entity, prior to accessing the data, the investigator must first enter into a HIPAA business associate agreement with SU/SHC/LPCH for the purpose of creating the limited data set.

Appendix G

Researchers' Responsibilities For Accounting of Disclosures of PHI To Subjects

An individual has a right to receive a written accounting of some research disclosures of PHI to individuals or entities outside the Stanford HIPAA covered entity. This right applies to all disclosures during research performed under a waiver of authorization or involving deceased individuals. .) The right includes any such disclosures during the six years prior to the date on which the accounting is requested. The period of time may be shorter if the individual requests an accounting for a period of time less than six years, or the period requested includes dates prior to April 14, 2003 (the effective date of HIPAA).

There is not an obligation to account for disclosures occurring in research

- Pursuant to individual authorization (and informed consent),
- Involving a disclosure of de-identified health information (as defined by HIPAA), or
- Under a limited data set certification and agreement.

Disclosures of PHI reviewed preparatory to research are not permitted.

Required Information. SU, SHC and LPCH and the researcher must provide the individual with a written accounting for each disclosure of PHI [including disclosures to or by business associates] containing the following:

1. The date of the disclosure;
2. The name of the entity or person who received the PHI;
3. The address of such entity or person, if known;
4. A brief description of the PHI disclosed; and
5. A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure; or, in lieu of such statement a copy of the individual's written authorization.

Multiple Disclosures. If, during the period covered by the accounting, the researcher has made multiple disclosures of PHI to the same person or entity for a single purpose (e.g., a sponsored project), or pursuant to a single authorization, the accounting for such multiple disclosures may (instead of the above) provide:

1. The information required above for the first disclosure during the accounting period;
2. The frequency, periodicity, or number of the disclosures made during the accounting period; and
3. The date of the last such disclosure during the accounting period.

Research Disclosures Involving 50 or More Subjects.

If the research involved 50 or more subjects, the accounting for any disclosures may (instead of the above) provide:

1. The name of the protocol or other research activity;
2. A description, in plain language, of the research protocol or other research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
3. A brief description of the type of PHI disclosed;
4. 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;
5. The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
6. A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

If the accounting is provided under this provision (i.e., 50 or more subjects), and if it is reasonably likely that the PHI was disclosed for such research protocol or activity, the researcher must assist in contacting the entity that sponsored the research and any researchers outside the Stanford HIPAA covered entity at the request of the individual.

Timing Of Response.

The accounting of disclosures must be provided no later than 60 days after receipt of the request. If it cannot be provided within 60 days, one extension of no more than 30 days is permitted, if within 60 days, the individual is provided with a written statement of the reasons for the delay and the date by which the accounting will be provided.