HIPAA Privacy & Security Compliance for Research

Office of Research Compliance and Assurance
AD 240

HIPAA PRIVACY & SECURITY COMPLIANCE PLAN FOR RESEARCH

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- To effectively communicate the compliance standards, policies and procedures set forth in this Plan to all members who conduct clinical research;
- To take reasonable steps to achieve compliance with the standards, policies and procedures set for in this Plan by, for example, implementing, monitoring and auditing systems reasonably designed to detect the improper use and disclosure of PHI; and

- To respond appropriately to non-compliance after detection and to prevent recurrence, which may require modifications to this Plan.

The regulations impose three core requirements on health care providers and facilities (called "covered entities" in the regulatory text) that hold or maintain PHI. First, covered entities must obtain the agreement of patients to use or disclose their PHI unless specified exceptions are applicable. Secondly, persons must be notified by covered entities of their rights under the privacy regulations. Lastly, use and disclosure of PHI by covered entities must generally be restricted to the minimum necessary to accomplish the intended purpose. The HIPAA Rule exercises four basic rights of persons with respect to their PHI to include: to agree to the use and disclosure of PHI, to inspect and copy their records, to amend their records and to obtain certain limited audits of the disclosures of their records that have been made by covered entities.

C. Conditions when PHI may be utilized for Research Purposes

- Individual Subject's Authorization: After obtaining the individual subject's (or legally authorized representative's) authorization using the USAHS IRB HIPAA Authorization template located in IRBNet;

- Waiver of Authorization: After obtaining a waiver of Authorization from IRB R10a4

II. ResearchUseof PHI With

9. a description of the purpose(s) of the requested use or disclosure;

10. a statement that the individual may inspect or copy the protected health information to be used or disclosed; and

11. a statement that the individual may refuse to sign the authorization.

A. Research

Once the IRB has approved the Waiver of Authorization, the investigator must provide the covered entity maintaining the PHI with documentation from the IRB of approval. The IRB approval letter will include the following elements:

(1) identification of the IRB and provide the date on which the Waiver of Authorization was approved, (2) a statement that the IRB has determined that the waiver satisfies the criteria explained above, (3) provide a brief description of the PHI for which use or access has been determined to be necessary by the IRB, and (4) the letter must describe whether the request for Waiver of the Authorization requirements was reviewed via full board or expedited review procedures.

A Waiver of Authorization may be sought for three specific research uses of PHI to identify potential research subjects through review of their PHI, to contact potential subjects in order to determine their interest in research participation and to receive or collect PHI during the conduct of research studies.

** The Waiver of Authorization form is located in IRBNet forms and templates.

2. Reviews Preparatory to Research**

Investigators may review PHI without authorization to prepare a research protocol or for similar purposes preparatory to research (i.e., limited to designing a study and/or determining the feasibility of completing a study). Neither recruitment nor patient contact is considered review preparatory to research. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

1. The investigator shall not remove any PHR from the covered entity;
2. The use/disclosure of PHI is sought solely for the purpose of preparing a research protocol; and
3. The PHI for which use or access is sought is necessary for research purposes.

In addition, reviews preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference.

** Investigators may use PHI as preparatory to research if the investigator certifies the above provisions by completing the form attached as Appendix D.

3. Research on Decedent's Information **

An investigator is not normally required to submit research involving deceased individuals to the IRB for review, unless other living individuals, such as family members, could be affected (i.e., genetic markers of certain diseases) and should contact the IRB if assistance is needed to make this determination. If IRB review is necessary, the investigator shall submit a protocol to the IRB. If not, the investigator may use PHI of deceased individuals without authorization from the decedent's estate.

Qualifications under this provision requires that the researcher provide the covered entity:

1. Assurance that the use or disclosure is being sought solely for research on the PHI of decedents;
2. Documentation, at the request of the covered entity, of the death of such individuals; and
3. Assurance that the PHI is necessary for research purposes.

** Investigators may use PHI in research on decedent's information if the investigator certifies the above provisions by completing the form entitled Research Involving Deceased Individuals.

4. Research Involving the Use of Limited Data Sets**

Regulations permit covered entities to use or disclosure PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

a) names

b) postal address information, other than town or city, state and zip code

c) telephone numbers

d) fax numbers

e) email addresses

f) social security numbers

g) health plan beneficiary numbers

h) account numbers

i) certificate/license numbers

j) vehicle identifiers and serial numbers

k) device identifiers and serial numbers

l) web universal resources locators (URLs)

m) Internet protocol (IP) address numbers

n) biometric identifiers, including finger and voice prints

o) full face photographic images and any comparable images

p) A limited data set may, however include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

** Investigators may use or disclose a limited data set without subject authorization for research purposes only if assurance is obtained in the form of a Limited Data Use Agreement.

information is created, collected or received, if, prior to April 14, 2003, the Principal Investigator obtained, and has written documentation of, any one of the following:

- An authorization or other express legal permission from the research subject to use or disclose the information for the research study;
- The research subject's informed consent to participate in the research study;
- An IRB waiver of informed consent for the research study.

If the investigator has such documentation for a research subject, he/she may create, collect, or receive information after April 14, 2003. However, for subjects without such written documentation prior to April 14, 2003, the investigator must obtain a specific authorization or other appropriate documentation required by this policy. For subjects who enroll in studies on or after April 14, 2003, the regulations of the Privacy Rule described above must be followed.

E. Research subjects' rights under HIPAA

1. Right to an accounting

When a research subject signs an authorization to disclose PHI, the covered entity is not required to account for the authorized disclosure. Nor is an accounting required when the disclosed PHI is contained in a limited data set or is released to the researcher as de-identified data. However, an accounting is required for research disclosures of identifiable information obtained under a waiver or altered authorization, reviews preparatory to research and research on decedents. In general, the Privacy Rule requires that individuals have a right to receive an accounting of disclosures of PHI made by covered entities over a six year period. It is anticipated that requests for an accounting of disclosure will come to the hospitals and the medical records department will respond in accordance with the policy on HIPAA: Accounting of Disclosures.

2. Right to revoke authorization -

A research subject has the right to revoke his or her authorization unless the researcher has already acted in reliance on the original authorization. Under the authorization revocation provision, covered entities may continue to use or disclose PHI collected prior to the revocation as necessary to maintain the integrity of the research study. Examples of permitted disclosures include submissions of marketing applications to the FDA, reporting of adverse events, accounting of the subject's withdrawal from the study and investigation of scientific misconduct. (s) 2 6 . 7 1 0 8 2 0 e [(T i) -

3. Approved Tools for Storing ePHI

The following are licensed tools used by USA and USA Health and are expected to be used by employees, students and other agents of the University for storing ePHI of research subjects in accordance with HIPAA.

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