

HIPAA Privacy Rule and Research

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Healthcare/Privacy



Research Pre-January 2013

- Under HIPAA, may use PHI for research with:
 - an individual's written authorization
 - **Must be study-specific**
 - **No compound authorizations**
 - **May not authorize future unspecified research**
 - a waiver of authorization by an Institutional Review Board (“IRB”) or privacy board,
 - a data use agreement regarding a limited data set,
 - de-identified information
 - a certification for data reviews preparatory to research, or
 - special provisions for research using decedent's information.

Major changes in the HITECH final rule

- Study-specific limitation/future unspecified research
- Compound authorizations

Research: Study-Specific Limitation

- HHS prior position = research authorizations may not authorize future unspecified research
- The Privacy Rule requires authorizations to describe the “purpose” of the requested use and disclosure. *Historically, HHS has interpreted this as requiring study-specific descriptions of the purpose, and prohibiting authorization for use or disclosure of PHI for future, unspecified research.*

New approach to describing future research

- HITECH Final Rule modifies HHS's prior position:
 - As of March 26, 2013, a HIPAA authorization may permit future research if the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his/her PHI could be used or disclosed for that purpose.
 - Certain ongoing studies grandfathered

Research: Compound Authorization

- The Privacy Rule prohibits compound authorization for use/disclosure of PHI that authorizes (i) research activities for which treatment is conditioned on signing the authorization (“conditioned”) and (ii) research activities for which treatment is not conditioned on signing the authorization (“unconditioned”).
- *Under old interpretation, a clinical trial associated with corollary research activities (e.g. biospecimen banking), required separate authorizations for the clinical trial participation (conditioned authorization) and participation in the corollary activity (unconditioned authorization).*

New approach to compound authorizations

- The Final Rule permits such compound authorizations for research purposes provided:
 - (1) the authorization clearly differentiates between the conditioned and unconditioned research components;
 - (2) the authorization provides a clear opportunity for individuals to opt-in to the unconditioned component; and
 - (3) the research does not involve psychotherapy notes

What does this mean for research?

- Significant change in interpretation provides greater flexibility to conduct research
- Removes some of the road blocks for research
 - Important for researchers, study sponsors
 - C-Change advocated for these changes to the authorization process

What are covered entities doing now?

- Revising template HIPAA research authorizations to permit future research
- Considering compound authorizations for protocols involving multiple research activities (e.g., investigational treatment and tissue banking of specimens)
- Amending policies and procedures for implementing requests to revoke authorization
- Reviewing ongoing studies that involve the possibility of future research to determine eligibility for grandfather status

Looking at de-identification

There are two methods of de-identifying PHI in accordance with the HIPAA Privacy Rule

1. Statistician Certification

- A statistician must determine that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information.
- The statistician must document the methods and results of the analysis that justify the determination.
- A similar determination by a non-statistician would not satisfy the HIPAA standard. See 45 C.F.R. § 164.514(b)(1)

HIPAA De-Identification Requirements

2. **Safe Harbor**: (a) The following 18 identifiers of the individual or of relatives, employers, or household members of the individual must be removed:

1. Name	7. Social security number	13. URLs
2. Geographic subdivisions smaller than a state	8. Health plan beneficiary number	14. Device identifiers/serial number
3. All elements of dates (except year) for dates directly related to an individual (e.g., DOB, admission date)	9. Medical record number	15. Biometric identifiers including finger and voice prints
4. Telephone number	10. Account numbers	16. Full face photo and comparable image
5. Fax number	11. Certificate/license numbers	17. IP address numbers
6. E-mail	12. Vehicle identifiers/serial numbers	18. Unique identifying number, characteristic or code

(b) and the covered entity must not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

HIPAA De-Identification Requirements

- Once PHI is de-identified in accordance with the HIPAA Privacy Rule, it:
 - Is no longer PHI
 - Is not subject to HIPAA
 - May be used for any purpose (subject to other applicable law)

Sale of PHI

- Sale of PHI: disclosure of PHI by a covered entity (CE) or business associate (BA), where the CE or BA directly or indirectly receives remuneration from or on behalf of the recipient of the PHI in exchange for the PHI
- Several exceptions, including disclosures for:
 - Research (allows a reasonable cost-based fee to cover the cost to prepare and transmit data)
 - Public Health (costs not limited to cost-based fee)
 - Grants, contracts, other similar arrangements
 - Example: Grant funding from government that requires CE to report PHI for program oversight ≠ Sale of PHI

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