PRIM&R Privacy Panel II "Privacy/Confidentiality Challenges in the HIPAA Era"

Pearl O'Rourke, Moderator
Bartley Barefoot
Oliver Johnson
Lora Kutkat

Assessments of HIPAA's Impact on Research

AAMC assessed the negative effects of HIPAA on research activities.

These effects include an impact on:

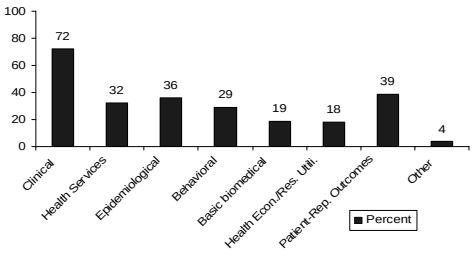
- Patient recruitment
- Multi-center, collaborative research
- Data quality/integrity

AAMC HIPAA Survey -- Purposes

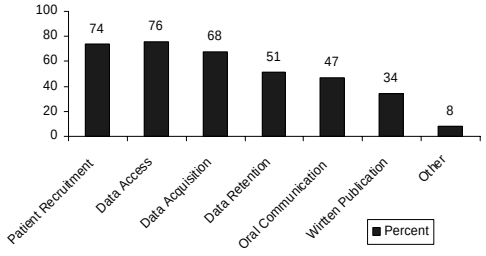
To document the effects of HIPAA on biomedical and health sciences research by

- Creating database of case reports
- Documenting research delayed, hindered, abandoned, foregone, or benefited
- Probing costs, broadly defined

Types of Research Affected by HIPAA (n = 331)



Research Functions Affected by HIPAA (n = 331)



Patient recruitment

- Negative impact on informed consent process
- Confusion of subjects
- Diminished access to patients
- Informed consent process burdened

Sample – Authorizations and Confusion/Distraction for Subjects

". . . additional consent form tends to confuse more than inform participants."

". . . the required HIPAA Authorization is confusing for participants to understand."

"Subjects are overwhelmed by added length to consent form and repetition of several points already made in body of main consent…."

Sample – Authorization Impact on Informed Consent process

"My greatest concern is that the requirement for all these various authorizations to be signed overshadows the importance of the research informed consent document and process."

"I am worried, actually, that subjects are now paying LESS attention to the consent process because they are given so many pages to read and sign."

Sample – Recruitment

"HIPAA has just about made it impossible to obtain research participants."

Recruitment of clinic patients has become a large issue that has yet to be resolved."

"Recruitment is more difficult and obtaining patient information from other providers has become more difficult."

"HIPAA has shut down our recruitment of subjects for a phase III chemoprevention study."

Sample – Informed Consent

". . . Instructions/information is laborious for a family to read when already needing to read a 4-6 page consent for emergency tx. in times of crisis/trauma . . . my fear is that they will not take the time to thoroughly read the consents as they are overwhelmed by the situation, all the pages to read and will just want to sign without being fully informed…."

Must a separate Authorization be obtained for each research use or disclosure of PHI?

No. As long as each use or disclosure is part of a specific research activity and the Authorization describes the types of uses or disclosures that will occur as part of that research activity, only one Authorization is required from each subject. That Authorization will generally be obtained at the time of enrollment in the trial itself, as part of the informed consent process. It is important, therefore, that researchers, research nurses, or others involved in informed consent discussions with subjects also understand the Authorization and its meaning so that subjects' questions and concerns can be answered accurately.

Example

"If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for the research study described below: [Provide a description of the research study, such as the title and purpose of the research.]

The health information that we may use or disclose (release) for this research includes [complete as appropriate]: Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

HHS Guidance on Authorization Matters

When a covered entity chooses to combine the Authorization with the informed consent document for a research study, can the compound document cross-reference required elements for both permissions (i.e., to minimize redundant language)?

Yes. The Privacy Rule permits the compound Authorization to cross-reference relevant sections of an informed consent document, so long as the compound document includes the core elements and statements required by section 164.508(c). In addition, under the HHS and FDA Protection of Human Subjects Regulations, all of the required elements for informed consent would need to be in included in the informed consent document, unless an IRB alters or waives the requirements.

HHS Guidance on Identifying Research Participants

Under the "preparatory to research" provision, covered entities may use or disclose PHI to researchers to aid in study recruitment. The covered entity may allow a researcher, either within or outside the covered entity, to identify, but not contact, potential study participants under the "preparatory to research" provision. However, before permitting this activity, a covered entity must receive proper representation, as described above, from the researcher. Under the "preparatory to research" provision, no PHI may leave the covered entity.

HHS Guidance on Contacting Research Participants

In order to contact potential study participants, a researcher may do so, without Authorization from the individual.

If the researcher is a workforce member of a covered entity, the researcher may contact the potential study participant:
(1) as part of the covered entity's health care operations.
(2) discuss treatment alternatives, which may include participating in a clinical trial, with the patient as part of the patient's treatment or the covered entity's health care operations.

If the researcher is NOT a workforce member of a covered entity, the researcher may contact the potential study participant:
(3) under contract with a business associate.
(4) Pursuant to a waiver of the Authorization requirement.

Q&A from Clinical Research Fact Sheet

May a covered entity obtain an individual's Authorization to include his or her PHI in a clinical research recruitment database of possible research participants, such as a pre-screening log?

Yes. The Privacy Rule permits a covered entity to include an individual's PHI in a clinical research recruitment database and permit researchers access to the recruitment database, provided the individual has given his or her permission through a written Authorization. The Authorization must inform the individual of the purpose for which (e.g., for the pre-screening log for one or more clinical trials) and what PHI will be used and meet the other requirements at section 164.508 of the Privacy Rule. Alternatively, a covered entity may provide a researcher access to the PHI for reviews preparatory to research, provided the required representations are obtained. See section 164.512(i) of the Privacy Rule. Unless otherwise permitted by the Privacy Rule, a subsequent Authorization must be obtained from the individual before a covered entity may use or disclose the individual's PHI for the clinical trial itself.

Multi-center, collaborative research

- Impaired ability to collaborate
- Impaired data access
- Differing interpretations
- Authorization form issues

Sample – Multiple Organizations and Collaborations

"The major difficulty for us has been establishing multi-site trials and getting everyone to collaborate in this newly derived, fear-of-litigation driven system. We have no solution and I fear good research will begin to die out soon."

Sample – Multiple Organizations and Collaborations

"Many health care providers no longer participate/submit data to several observational pregnancy exposure registries as a result of HIPAA."

". . . am now limited in my collaborations with researchers…."

"Multi-site trials used to be more feasible."

Sample – HIPAA Interpretations

"Solutions are just guesses."

". . . considerable heterogeneity in the interpretation of the HIPAA confidentiality rules, and in their implementation across covered entities…."

"higher level of uncertainty that the correct procedures are being followed."

HHS Guidance on Multi-site Matters

A waiver or an alteration of the Privacy Rule's Authorization requirements could be obtained from a single IRB in connection with a multisite research activity or where the PHI necessary for the research is to be used or disclosed by more than one covered entity.

A covered entity's ability reasonably to rely on documentation of an Authorization waiver or alteration may be especially important for research projects taking place at multiple sites and/or requiring the use and disclosure of PHI created or maintained by more than one covered entity (collectively, multisite projects).

Does the Privacy Rule specify who must develop the Authorization form?

No. The Privacy Rule does not specify who may draft the Authorization, so a researcher could draft it. However, in order to comply with the Privacy Rule, an Authorization must be written in plain language and contain the core elements and required statements specified at section 164.508 of the Privacy Rule. A covered entity may disclose PHI as specified in a valid Authorization that has been created by another covered entity or a third party, such as a researcher.

Data quality/integrity

- Errors due to use of de-identified information
- Possible increase in selection bias
- Reduced long-term follow-up

Sample -- Bias

"The complexity of the authorization form intimidates some potential participants. My concern is that by not including those people in the study, we are not including a 'true' cross-section of the population…. Will this lead to only including college-educated people in studies? . . . 'form comprehension' bias…."

Sample – De-identification and Quality of Research

". . . Increases errors when using only de-identified material…."

"It has severely limited my ability to obtain long term follow-up for patients participating in national registries…."

Can a covered entity use or disclose PHI to identify the whereabouts of a research participant (e.g., subjects who are "lost to follow-up")?

A covered entity is permitted to use or disclose PHI to identify or locate the whereabouts of a research participant during the study as long as the use or disclosure is not limited in the individual's Authorization (or "grandfathered" prior permission, if relevant) or waiver or alteration of Authorization. In addition, such use or disclosure is permissible if, for example, it is necessary for treatment of the individual or for a permissible public health purpose.

Sample – De-identification and Research Direction

"Increase in . . . time and money for redacting identifiable information for limited data sets and deidentified data, forced to make decisions about current need for data items when research is open ended and has unforeseen questions that will later arise…."

Does "Unique Identifier" Include a Re-identification Code?

- A covered entity may assign a code to allow information de-identified under the Privacy Rule to be re-identified by the covered entity, as long as:
  - The code is not derived from or related to information about the individual.
  - The code is not otherwise capable of being translated to identify the individual. And
  - The covered entity does not use or disclose the code for any other purpose, and does not disclose the mechanism for re-identification.
- Disclosure of a code or other means of record identification designed to enable coded (or otherwise de-identified information) to be re-identified is a disclosure of PHI. And
- If de-identified information is re-identified, a covered entity must use or disclose such re-identified information in accordance with the Privacy Rule.

Q&A from Repository/Database Fact Sheet

Are an individual's initials considered to be identifiers under the Privacy Rule?

Yes, because an individual's name is an identifier and initials are derived from the individual's name, initials are considered identifiers under the Privacy Rule. Thus, for information to be de-identified using the safe harbor method of the Privacy Rule, an individual's initials must be stripped from the information. However, it may be possible for initials to remain as part of de-identified information if the statistical method for de-identification at section 164.514(b)(1) allows it.

A researcher requests data that assigns a code derived from the last four digits of the social security number. This code is necessary to link individual records from different data sources. The data contain none of the other listed HIPAA identifiers at section 164.514(b)(2). Are the data de-identified under the Privacy Rule?

No. Under the Privacy Rule, a de-identified data set may not contain unique identifying codes, except for codes that have not been derived from or do not relate to information about the individual and that cannot be translated so as to identify the individual. A code derived from part of a social security number, medical record number, or other identifier would not meet this test.

Q&A from Repository/Database Fact Sheet

Does the Privacy Rule permit a covered entity to de-identify health information or create a limited data set without obtaining Authorization, waiver of the Authorization requirement from an IRB or Privacy Board, or representations for reviews preparatory to research?

Yes. In the Privacy Rule, creating de-identified health information or a limited data set is a health care operation of the covered entity, and thus, does not require the covered entity to obtain an individual's Authorization, a waiver of the Authorization requirement, or representations for reviews preparatory to research. If a business associate is hired by a covered entity to de-identify health information or create a limited data set, such activity must be conducted in accordance with the business associate requirements at sections 164.502(e) and 164.504(e).

Can a limited data set include the geographic subdivision code with the five-digit ZIP code (or a nine-digit ZIP code)?

Yes, the limited data set may include the five-digit or nine-digit ZIP code plus any other geographic subdivision, such as state, county, city, precinct, and their equivalent geocodes, except for street name or street address or post office box.

Limited Data Set with Data Use Agreement

- The Privacy Rule permits limited types of identifiers (e.g., city, state, zip, dates) to be released for research with health information (referred to as a Limited Data Set).
- Limited Data Sets can only be used and released in accordance with a Data Use Agreement between the covered entity and the recipient.

Types of Research Affected by HIPPA as Reported by Roles of Respondents

Type	Administrator	HIPAA Official	IRB Member	Investigator	Study Coord/Mgr	Unk	Total Percent
Clinical	8%	3%	2%	43%	22%	22%	100%
Health Services	10%	5%	4%	47%	12%	22%	100%
Epidemiological	9%	4%	3%	51%	9%	24%	100%
Behavioral	12%	5%	4%	47%	11%	21%	100%
Basic biomedical	13%	5%	5%	40%	13%	25%	100%
Health Econ./Res. Utili.	13%	5%	3%	46%	10%	23%	100%
Patient-Rep. Outcomes	9%	3%	3%	48%	17%	20%	100%
Other	15%	8%	8%	31%	23%	15%	100%