

Impact of HIPAA on Research

HIPAA and Research at AMCs

- Goal: Protect Privacy without hindering or disrupting research
- Has proper balance been struck?
 - Final Rule
 - July 6, 2001 Guidance
 - Notice of Proposed Rulemaking (March 27, 2002)
 - Solicitation of Comments

Approval for Research Use

- Four Pathways for permission to use PHI for research related purposes:
 - Consent (for healthcare operations)
 - Authorization
 - Waiver of Authorization by IRB/Privacy Board
 - De-Identification

Approval for Research Use

- Consent for AMC to use for health care operations
 - “Health care operations” include protocol development; quality assurance, clinical guidelines and outcomes studies; and population-based activities relating to improving health or reducing health care costs

Research

Final Rule defines “Research” as “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to general reliable knowledge”

Approval for Research Use

- Authorization - research involving treatment of human subjects
 - In addition to IRB/Common Rule informed consent
 - Authorization exceptions for protocol development and decedents
- Waiver of Authorization -- for retrospective medical record or identifiable database research where Authorization is impracticable

Approval For Research Use

- Waiver by IRB/Privacy Board pursuant to 8 Waiver criteria (3 criteria under NPRM)
- Need Privacy Board for privately funded human subjects research/most records research
- IRB can assume Privacy Board functions

De-identified Data

- Database research involving de-identified PHI is permitted if the information does not identify an individual and there is no reasonable basis to believe the information can be used to identify an individual
- Adequate de-identification of PHI in one of two ways:
 - determination and documentation by a statistical expert that risk is very small that the information could be used to identify individual

De-identified Data

- Risk of identification is rarely very small
- Inherent identifiability of genetic materials?
- Removal of 18 specified identifiers (“safe harbor”)
- Identifiers include: name; birth date, admission date, discharge date, date of death (except year); ages over 89; social security numbers; e-mail addresses; medical record numbers; license plate numbers;

De-identified Data

telephone numbers; medical device identifiers/serial numbers; and for geographic region, identifiers other than state or the initial three digits of the zip code

- Any other unique, identifying number, characteristic or code
 - Clarification regarding reidentification code
 - Clarification regarding age expressed in days, weeks or months

De-identified Data

- Issues
 - Not useful for relational databases (e.g., comparison of genetic database with clinical database)
 - May not be useful for certain longitudinal studies (e.g., add new data on identifiable individuals)
 - May not be useful for certain outcomes studies (e.g., inability to use date of event (other than year) may undermine study)

De-identified Data

- May not be useful for epidemiological studies (e.g., dates needed to track disease), studies involving infants (e.g., need DOB), studies of environmental factors of disease (e.g., need zip codes)
- Paradoxically may cause researchers to seek more PHI through waiver than if de-identification standards were more reasonable
- NPRM - Limited dataset of facially identifiable information for research, public health and healthcare operations purposes

De-identified Data

- Excludes “facial identifiers” --name, address, phone and fax numbers, e-mail address, URL, IP address, social security number, certificate and license numbers, vehicle ID numbers, serial numbers, face photo or similar images
- Includes admission/discharge dates, service dates, date of birth, date of death, age, zip codes
- Data use agreement from recipient
 - limit use to specified purpose
 - No reidentification/no contact of subject

Open Research Issues

Research Permission

How many documents may be required under the Final Rule to conduct research?

Open Research Issues

Research Permission

- Authorization for research use of post-compliance date PHI
- Authorization for research use of pre-existing PHI (except if researcher obtained prior consent for research involving treatment)
- Common Rule Consent
- Consent to TPO
- Notice of Privacy Practices

Comparison of and Common Rule Consent and HIPAA Authorization

Common Rule

- Understandable language
- No exculpatory language or release of investigator, sponsor or institution
- Statement that study involves research, explanation of purposes of research, expected duration of subject's participation, description of procedures, identification of experimental procedures
- Description of reasonably foreseeable risks and discomforts to subject
- Description of benefits to subject or others reasonably expected from research
- Disclosure of appropriate alternative treatment that might be advantageous
- Statement of extent to which confidentiality will be maintained
- Explanation of whether compensation will be paid and if injury occurs, whether treatment is available and where further information may be obtained
- Explanation of whom to contact about the research, the subject's rights, and any research related injury
- Statement that participation is voluntary; refusal to participate or discontinuance carries no penalty or loss of benefits
- Statement that the treatment or procedure may involve risks to the subject which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the study
- The consequences of the subject's decision to withdraw from the research and procedures for orderly termination
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
- The approximate number of subjects involved in the study

HIPAA Authorization

- Description of information in specific and meaningful fashion in plain language
- Name of person(s) authorized to make the requested use/disclosure
- Name of person(s) authorized to receive request
- Individual's right to revoke
- Information may be subject to redisclosure and not protected by the federal privacy regulations
- Statement that will not condition treatment on providing Authorization, except as permitted
- Description of each purpose of the use or disclosure
- Right to inspect or copy PHI disclosed
- Right to refuse to authorize
- Disclose if direct or indirect remuneration to the Covered Entity will result
- Expiration date or event
- Signature (or authorized representative's signature), date
- Right to signed copy of Authorization

Open Research Issues

Research Permission

How many documents may be required to conduct research under the NPRM?

Open Research Issues

Research Permission

- Authorization for research use
- Common Rule Consent
- Notice of Privacy Practices
- Written acknowledgement of receipt of Notice
- Can documents be combined?

Open Research Issues

Research Permission

- Treatment related research Authorization can be combined with Common Rule Consent, TPO Consent for use of post-compliance date PHI, and/or Notice of Privacy Practices; but not with another Authorization
 - Other research Authorizations cannot be combined with other Authorizations
- Consent for TPO and Notice of Privacy Practices (otherwise) must be separate

Open Research Issues

Research Permission

- Consent for TPO can be combined with any other form of legal permission (e.g., Common Rule Consent, Research Authorization)
 - Consent for TPO must be visually and organizationally separate and separately signed and dated
- Authorization for use of pre-existing PHI must be separate from Authorization for post-compliance date research related treatment, Common Rule Consent and/or Consent for TPO

Open Research Issues

Research Permission

- NPRM - Can combine any research Authorization (including for use of pre-existing PHI) with any other form of permission
 - Elimination of requirement of Consent for TPO

Open Research Issues

Transitional Issues

Can a researcher rely on a pre-existing Common Rule Consent or IRB Waiver to conduct research after the HIPAA compliance date (April 14, 2003)?

Open Research Issues

Transitional Issues

- Can use before and after PHI based on pre-existing legal permission to conduct research related treatment
- Distinction between research that involves treatment and research that does not
 - Consent effective for research related treatment
 - Consent not effective for other research

Open Research Issues

Transitional Issues

- Distinction between Common Rule Consent and IRB Waiver -- IRB Waiver not effective to permit use of pre-existing PHI
- Does not address ongoing research with no pre-existing consent
- NPRM -- Eliminates distinctions; permits before and after PHI to be used if pre-existing permission (e.g., Common Rule Consent) or IRB Waiver was obtained
 - If never obtained informed consent or IRB waiver, before compliance date, still need to do so

Open Research Issues

Transitional Issues

- No use of pre-existing PHI if pre-existing permission or IRB Waiver was not obtained -- need to obtain Authorization or Waiver of Authorization
- Must obtain research Authorization after compliance date if subject of IRB Waiver gives Common Rule Consent after compliance date

Open Research Issues

Transitional Issues

Can an AMC condition research on the patient's Authorization to use pre-existing PHI?

Open Research Issues

Transitional Issues

- Currently limited to Authorizations under §164.508(f) (i.e., for treatment related research use of PHI created after the compliance date); not for use of pre-existing PHI
 - May need two separate Authorizations
- NPRM -- A subject's participation in any research can be conditioned on the subject's permission to use PHI (including pre-existing PHI) for purposes of the research study

Open Research Issues

Data Compilations

Will AMCs be able to develop clinical databases and tissue banks for research purposes?

Open Research Issues

Data Compilations

- Requires Authorization/Waiver of Authorization -- Does not constitute treatment, payment or healthcare operations

Open Research Issues

Data Compilations

Will researchers be able to access and use clinical data compilations?

Open Research Issues

Data Compilations

- Will need Waiver of Authorization from IRB/Privacy Board if database includes PHI

Open Research Issues

Data Compilations

- Problems with reliance on Authorizations
 - Impractical to obtain from all data subjects
 - Specification requirement -- the problem of unanticipated, future research
 - Expiration date or event
 - Revocation/reliance
 - Continuing integrity and scientific validity of database

Open Research Issues

Data Compilations

- NPRM -- If expiration date or event is listed as “none”, Authorization permits creation and maintenance of database in perpetuity
 - Expiration event can be “end of research study” (or similar language) - - allows researcher to meet record retention requirements
 - Does not authorize use for other research purposes

Open Research Issues Research Protocols

Where does the Authorization exception for development of a research protocol end and the need for Authorization for research begin?

Open Research Issues

Research Protocols

- Disclosure permitted without an Authorization/Waiver of Authorization for review of PHI necessary to prepare a research protocol or for similar purposes preparatory to research
 - Researcher must represent in writing:
 - Use or disclosure of PHI is sought solely for protocol/research purposes
 - The PHI for which access is sought is necessary for research purposes
 - PHI cannot be removed from premises during review
 - Develop hypothesis, protocol, characteristics of research cohort

Open Research Issues

Research Protocols

Under the research protocol exception, can a researcher comb through medical records of a CE to identify potential research subjects?

Open Research Issues

Research Protocols

- No -- clarified by NPRM
- Need Authorization/partial Waiver of Authorization to identify research candidates
 - Pre-existing knowledge of provider conducting treatment related research
 - Pre-existing PHI in hands of researchers who are not part of covered entity/component

Authorization Exceptions: Research Protocols

- Treating physician otherwise not authorized to discuss clinical trial enrollment with patient unless for treatment purposes
- Treating physician otherwise not authorized to discuss patient with research colleagues for potential enrollment purposes
- AMC physician can apply for partial Waiver to AMC's IRB or Privacy Board, but not to an independent IRB/Privacy Board

Open Research Issues

Revocation Issues

If an Authorization is revoked or expires after data derived from the study has been included in an identifiable database, can the database continue to be used for research purposes?

Open Research Issues

Revocation Issues

- Revocation not effective to extent of reasonable reliance by AMC/researcher
 - Not required to remove PHI from completed database
 - Completed research, but uncompiled data?
 - Uncompleted research -- to the extent of compiled data?
 - NPRM - reliance exception allows for continued appropriate use to preserve the integrity of the research study, e.g., "to account for the individual's withdrawal from the study"
 - No use for other research purposes without Waiver of Authorization

Open Research Issues

Revocation Issues

If a research subject revokes Authorization during the course of “blinded” research, can the research subject gain access to his or her medical records to determine whether he or she is in a placebo group?

Open Research Issues

Revocation Issues

- Potentially yes
 - General right of patient to access his/her PHI upon (written) request
 - Special research exception -- temporary suspension of right of access until research is complete
 - Revocation during course of research appears to reinstate right of access (research is “complete” with respect to revoking patient)
 - May invalidate blinded study if patient is matched to PHI for access purposes

Open Research Issues Waiver Criteria

- What are the criteria by which an IRB/ Privacy Board may approve a Waiver of the Authorization requirement for research use of PHI?
- How do the HIPAA waiver criteria compare with the Common Rule Consent waiver criteria?

Comparison of Waiver of Common Rule Consent/HIPAA Authorization Requirements

HIPAA

- 164.512(i)(2): IRB/Privacy Board must find:
 - Research could not practicably be conducted without PHI or waiver
 - Research could not practicably be conducted without access to the PHI sought
 - Disclosure involves no more than minimal privacy risk to the individual
 - Adequate plan to protect PHI from improper use and disclosure
 - Plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research
 - Adequate written assurances that PHI will not be reused or disclosed to any other person (except as required or permitted by law)
 - [Waiver or alteration will not adversely affect privacy rights and welfare of the individual]
 - [Privacy risks are reasonable in relation to anticipated benefits to individuals and the importance of the knowledge that may reasonably be expected to

OHRP

- IRB must find:
- 46.116(c):
 - Research conducted or subject to approval by state or local government officials to study public benefit or service programs, or changes to procedures or payment methodology, if research could not practically be carried out without waiver or alteration
 - 46.116(d)
 - Research involves no more than minimal risk to subjects
 - Waiver or alteration will not adversely affect the rights and welfare of the subjects
 - Research could not practically be carried out without the waiver or alteration
 - Whenever appropriate, subjects will be provided with additional pertinent information after participation

FDA

- No comparable waiver of informed consent to clinical trials

Open Research Issues

Waiver Criteria

- Are any of the Waiver criteria mutually inconsistent?
 - No adverse affect on privacy rights vs. minimal privacy right; corrected by NPRM
- What is the practicability standard and how will it be applied?
 - Untested standard/uncertain, non-uniform results
 - Is “impracticality” a scaleable concept?

Open Research Issues Waiver Criteria

- What is adequate research justification for not destroying identifiers?
 - General requirement to destroy identifiers at end of research
 - FDA/OHRP retrospective audits and investigations
 - NPRM - “lookback” provision for notifying recipients of tainted blood and plasma products

Open Research Issues

IRBs/Privacy Boards

Will an IRB/Privacy Board Waiver approved by one CE site be effective for purposes of conducting multi-site research?

Open Research Issues

IRBs/Privacy Boards

- Not necessarily:
 - Can obtain Waiver from any IRB or Privacy Board (no sponsorship or location requirement)
 - Cannot disclose PHI to an unaffiliated IRB/Privacy Board, absent (1) business associate contract/TPO Consent, or (2) Authorization/Waiver of Authorization
 - Can reasonably rely on decision of any IRB/Privacy Board; but can accept or reject decision

Open Research Issues

IRBs/Privacy Boards

- Waiver does not assure access to PHI of other CEs
- Need for joint research cooperation agreements

Open Research Issues

IRBs/Privacy Boards

Should a lawyer be a member of an AMC's
Privacy Board?

Open Research Issues

IRBs/Privacy Boards

- Privacy Board must be composed of members with appropriate competency to review the effect of the research protocol on privacy rights and related interests
 - Legal knowledge would be useful
- Should not be a lawyer who represents the AMC or IRB
 - Conflicts of interest
 - Potential waiver of attorney-client privilege

Open Research Issues Tissues/Organs

- Are tissues/organs PHI? Does it matter if the donor is living or dead?
 - Potentially yes and yes; Authorization exception for decedents only
- Are organ/tissue banks covered entities?
 - Not if they do not conduct standardized transactions
 - May be covered component of AMC (business associate-type functions)

Open Research Issues Tissues/Organs

- If an organ from a live donor proves unsuitable for transplant, can the transplant team transfer the organ to researchers without Authorization/Waiver of Authorization?
 - Not if the donor is alive

Open Research Issues: Patient Registries

- Can AMCs make reports containing PHI to privately sponsored patient registries? Can AMCs maintain patient registries?

Open Research Issues Patient Registries

- Authorization exception for making state and federally mandated reports
 - No Authorization exception for voluntary reports
 - No Authorization exception for reports to privately sponsored patient registries
 - Reports to “a person subject to the FDA” - - includes manufacturer representatives
 - Some patient registries may qualify as business associates to whom PHI may be disclosed with patient Consent for TPO purposes (without patient Authorization)

Open Research Issues Patient Registries

- Patient registries can receive de-identified data
- NPRM - reporting to a person subject to the FDA with respect to an FDA regulated product or activity for purposes related to quality, safety or effectiveness

Other HIPAA Research Issues

- Certificates of Confidentiality
 - Inconsistency with HHS access provision
- Researchers are generally workforce and not business associates
 - May be business associate if the researcher is not part of workforce and contracts to provide treatment in connection with research

Other HIPAA Research Issues

- Business associates include persons who provide data aggregation services on behalf of covered entity for TPO purposes (e.g., QA, population-based activities)
- Satisfactory assurance that PHI will be appropriately safeguarded
- Requires written contract
- Business associate contracts for reimbursement/patient assistance programs

Other HIPAA Research Issues

- Accounting for research disclosures
 - NPRM - No accounting required for research conducted pursuant to an Authorization; accounting required if research conducted pursuant to a Waiver

Minimum Information Necessary

- Minimum Necessary Standard - Currently no exception for PHI used for research that includes treatment
 - Employee access policies for routine uses
 - Individualized determinations for non-routine uses
 - NPRM - Exception for research conducted pursuant to an Authorization; not if conducted pursuant to a Waiver

What to Do? What to Do?

- Develop research Authorization forms
 - Research related treatment
 - Other research
 - Pre-existing PHI
- Obtain Authorization for research from patients when possible
 - Require contractual affiliates to obtain Authorizations

What to Do? What to Do?

- Combine with Common Rule Consent and Consent for TPO to extent permitted
- Appoint Privacy Board/Assign Privacy Board functions to IRB for privately funded research
 - Adopt Privacy Board policies and procedures
- Develop Waiver application form
- Develop Waiver approval form

What to Do? What to Do?

- Seek IRB/Privacy Board Waiver if patient is not available or obtaining Authorization is impractical
- Use joint research cooperation agreements for multi-site projects
- Consider feasibility of de-identification
 - Consider obtaining opinion of statistical expert
- Hope that NPRM amendments are adopted