

A Bag of HIPAA Tricks

For Moving Your Research Forward Consistent with Federal Law

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Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

- Governs the uses and disclosures of “protected health information” or PHI
- Defines and limits the circumstances in which an individual’s PHI may be used or disclosed

HIPAA

- Contains privacy and security provisions
 - There can be no privacy without security
- Substantially amended in February, 2009 under the HITECH provisions of the American Recovery and Reinvestment Act of 2009 (ARRA)

PHI may be used and disclosed for research only if permissible under some provision of the Privacy Rule

- De-identified information
- Participant's written authorization
- IRB/Privacy Board waiver of authorization
- Data Use agreement
- Preparatory to research
- Decedent information

De-identified PHI

- May be used for research without restriction
- It is *not* PHI provided that it is de-identified in accordance with HIPAA

Two options for de-identifying PHI

Option 1: Removal of identifiers

- Names
- All geographic subdivisions smaller than state (street address, city, county, zip)
- All elements of dates, except for year, for dates directly related to an individual, including birth date, admission date, discharge, date of death, and all ages over 89
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vin and license plate numbers
- Device identifiers and serial numbers
- URLs
- IP address
- Biometric identifiers (voice and fingerprints)
- Full face photographic images
- Any other unique identifying number, characteristic or code

Option 2. Statistical Method

A covered entity may obtain certification from “a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable” that the risk is “very small” that information could be used to identify the subject of the information

Authorization

- A patient's written permission for uses and disclosures of PHI that are not otherwise permitted by the Privacy Rule (such as research)
 - A separate permission, distinct from informed consent for research participation

Authorization

- Must be specific to a research study (not valid for future, unspecified projects)
 - May obtain authorization for the creation of an information repository or database, but subsequent use of that repository or database requires a separate authorization

Authorization Core Elements

- A description of the PHI to be used
- The person or class of persons authorized to make the requested use or disclosure
- The names or identification of the persons to whom PHI may be disclosed
- The purpose of the disclosure
- Expiration date or event (“none” or “end of research” are permissible)
- Signature of the patient and date

Authorization Required Statements

- The right to revoke and instructions for revoking
- Disclosure of benefits that may be conditioned on the authorization and consequences of not signing
- Potential risk that PHI may be re-disclosed by the recipient

Authorization

- May be a stand-alone document
- May be combined with a consent form

Waiver of Authorization

- When an authorization is required, but infeasible to obtain, a researcher may seek a waiver of the authorization requirement from an IRB or “privacy board”
- Waiver may be partial or complete

Waiver of Authorization continued

- **Complete Waiver**
 - May be granted if an IRB or Privacy Board determines that the research may proceed with no authorization
- **Partial Waiver**
 - May be granted if an IRB or Privacy Board determines that no authorization is needed for *some* research uses of PHI (such as recruitment)

Waiver of Authorization continued

- IRB may review a waiver request under normal or expedited procedures
- The process and criteria is similar to a request for waiver of informed consent under the Common Rule

Waiver of Authorization continued

- The use or disclosure of PHI must involve no more than minimal risk to privacy based on:
 - An adequate plan to protect identifiers
 - An adequate plan to destroy identifiers
 - Adequate written assurances that the PHI will not be reused or disclosed except as required by law, for authorized research oversight, or for other research as permissible under the Privacy Rule
- The research could not practicably be conducted without the waiver or alteration
- The research could not practicably be conducted without access to or use of the PHI

Limited Data Set - Data Use Agreement

A covered entity may use and disclose PHI in a “Limited Data Set”

- Limited Data Set: Refers to PHI that excludes 16 categories of direct identifiers
 - may include city, state, zip code, elements of dates, and other numbers, characteristics and codes
- Data Use Agreement: Establishes the ways in which the limited data set may be used and how it will be protected

Limited Data Set

- Has a new role under ARRA, 2009
- It is presently the “minimum necessary” standard

Activities Preparatory to Research

- A researcher may use PHI to prepare a research protocol or for a similar purpose preparatory to research if the researcher represents that:
 - The PHI will not be removed from the covered entity in the course of review
 - The PHI to be accessed is necessary for the research

Decedents

- Authorization (by next of kin) for the use or disclosure of a decedent's PHI is not required if the researcher provides assurances that:
 - The research involves only the PHI of decedents;
 - The PHI is necessary for the research; and
 - Documentation of the death of the individuals whose PHI is being sought (optional).

HIPAA Trick

- Use different provisions of the privacy rule for a single study

HIPAA Trick

- Use a business associate to create de-identified information
- The business associate may be the intended recipient of the de-identified PHI

HIPAA Trick

- From NIH Guidance on HIPAA and Research:
- ...“A covered entity is permitted to de-identify PHI or engage a business associate to de-identify PHI. For example, a researcher may be a covered entity himself/herself performing, or may be hired as a business associate to perform, the de-identification...”

HIPAA Trick

- Your researcher may de-identify the information for his or her own use as a permissible “health care operation”
 - HIPAA permits the use of PHI without authorization for treatment, payment or health care operations

HIPAA Trick

- The same researcher may:
 - Use the preparatory to research exception to identify PHI valuable for a study
 - De-identify PHI himself/herself as a permissible health care operation
 - Use the de-identified PHI without authorization

HIPAA Trick

- The same researcher may also send the de-identified PHI outside of his or her institution in connection with the research
 - No authorization is required

HIPAA Trick

- A researcher may be able to extend uses of PHI “preparatory to research” by either of the following:
 - For recruitment as a permissible health care operation
 - For recruitment through the use of a business associate (who can be another researcher)
 - For recruitment under the treatment exception

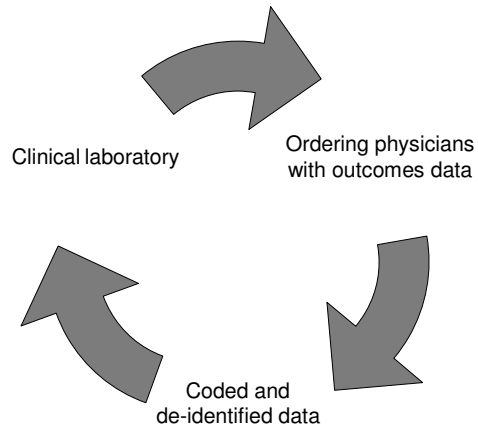
HIPAA Trick

- Multiple institutions may use these “tricks” to direct PHI to a central repository of information which serves as a business associate of each of the study participants

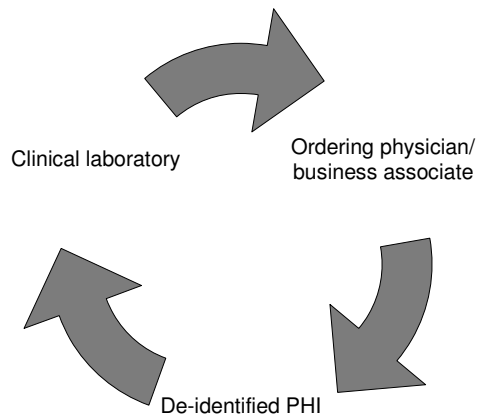
IMPORTANT CAVEAT

- HITECH Provisions of ARRA, 2009 have significantly changed the compliance obligations of business associates
 - Directly liable for security compliance
 - Directly liable for compliance with certain privacy provisions
 - Subject to federal audit
 - Subject to state and federal enforcement

Registry Study Example (prospective)



Registry Study Example (retrospective)



Questions?

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Thank You!