

APPLICATION OF HIPAA TO RESEARCH ACTIVITIES



St. Barnabas Hospital

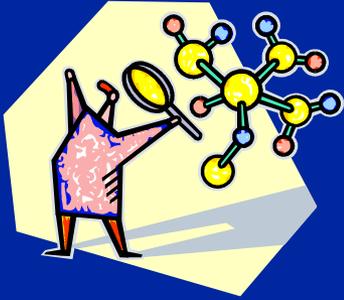
Definitions

- **HIPAA Definition of Research**: systematic investigation, including research development, testing and evaluation, designed to develop or contribute to “generalizable knowledge”
 - This definition is from Federal Policy for the Protection of Human Subjects (45 CFR Part 46, Subpart A), called the “Common Rule.”
- **HIPAA Definition of Treatment**: the provision, coordination, or management of health care and related services by one or more health care providers, including:
 - Coordination or management of health care by a health care provider with a third party;
 - Consultation between health care providers relating to a patient;
or
 - The referral of a patient for health care from one health care provider to another.

USES AND DISCLOSURES FOR RESEARCH PURPOSES

- General Rule: A researcher must obtain a written and executed Hospital approved authorization to use a patient's PHI for research.
- PHI can be used for research without HIPAA authorization if the research:
 - Meets requirements for a waiver; or
 - Falls into an exception to authorization:
 - Preparatory to Research,
 - Deceased Patients,
 - De-identified Information, or
 - Limited Data Set With Data Use Agreement.





AUTHORIZATION FOR RESEARCH

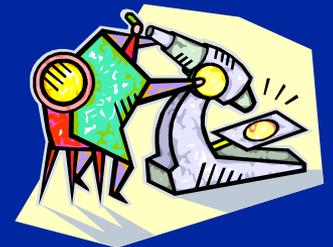
- Must utilize standard Hospital approved HIPAA-compliant authorization* for release of PHI.
- If research includes treatment, additional requirements may be included in the authorization:
 - Provision of research-related treatment may be conditioned on research participant executing an authorization, and/or
 - Research participant's access to research information in connection with a clinical trial may be conditional.
- Patient information used or disclosed pursuant to an authorization is not subject to minimum necessary requirements of HIPAA.

***Note:** If a researcher wishes to use a form of authorization other than the Hospital approved authorization, he/she must obtain permission from the Institutional Review Board.

DISCLOSURE OF PHI TO BUSINESS ASSOCIATES

- Authorization is *not* required for:
 - The Hospital to disclose PHI to a Business Associate (BA), or
 - A BA to create or receive PHI *on behalf of* the Hospital.
- The Hospital must have, however, “satisfactory assurances” that the BA will appropriately safeguard the PHI:
 - Assurance must be in writing, and
 - Business Associate Agreements must comply with HIPAA requirements.

Note: Business Associates do not include employees, volunteers, and other persons providing work for the Hospital, under its direct control.



WHO IS A BUSINESS ASSOCIATE?

A person who is not part of the Hospital's workforce, who:

- On behalf of the Hospital performs functions or activities involving the use/disclosure of PHI, including:
 - Data analysis, utilization review, quality assurance, claims processing
- For the Hospital, performs a function that involves:
 - Disclosure of PHI from the entity to the BA, and
 - Legal, actuarial, accounting, consulting, data aggregation*, management, administrative, accreditation, or financial services.

***Note:** Data aggregation: Combining PHI from multiple covered entities for health care operations, which does not include research.

EXAMPLES OF BUSINESS ASSOCIATES

- Private sponsors of research? No.
 - Sponsor is not performing a function on behalf of the Hospital.
 - Sponsor is not performing one of the specified services for the Hospital.
- Contract Research Organization? Yes, if:
 - CRO uses the Hospital's PHI to perform data analysis on behalf of the Hospital.



BUSINESS ASSOCIATE AGREEMENTS

Researchers should coordinate with the Purchasing Office to ensure a proper Business Associate Agreement is obtained from all BAs.



WAIVER OR ALTERATION OF AUTHORIZATION

PHI can be used for research (regardless of funding source) without individual authorization or under an altered authorization, provided the following 6 steps are taken *and* those actions are documented.

Note: For further information please refer to the Hospital's Policy Regarding the Use of Patient Information in the Conduct of Research.



STEP #1

The researcher must submit a request for waiver or alteration of the authorization to the institutional review board (IRB) designated by the Hospital to approve the alteration or waiver.



STEP #1 (continued)

- Voting Requirements:
 - IRB must follow voting requirements in Common Rule or expedited review procedures in Common Rule.
 - IRB must review research:
 - _ at convened meetings at which majority present, including at least one member not affiliated with the Hospital or research conductor or sponsor and not related to anyone who is affiliated with such entities and
 - _ waiver approved by majority present (unless expedited review procedure used).

STEP #1 (continued)

- Expedited review procedures: expedited review can be used if research involves no more than minimal risk to privacy of subject.
 - IRB - follow Common Rule for documentation.



STEP #2



The IRB must document its identity and the date of approval of alteration of waiver.

STEP #3

The IRB must determine that alteration or waiver satisfies the following criteria:

- Use or disclosure involves no more than “minimal risk” to privacy of individuals based on the following elements:
 - There is an adequate plan to protect identifiers from improper use and disclosure;
 - There is an adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research, unless health or research justification for retaining identifiers, or such retention is otherwise required by law;



STEP #3 (continued)



- The researcher receiving the PHI provides the IRB with a written agreement agreeing not to use or disclose to any other person or entity except as required by law, for authorized oversight of project, or for other research for which use or disclosure of PHI is permitted.
- Research could not practicably be conducted without waiver or alteration; and
- Research could not practicably be conducted without access to and use of PHI.

STEP #4



IRB must briefly describe PHI for which use or access has been determined to be necessary for research.

STEP #5



Chair of IRB (or members of IRB designated by chair) must sign all of the foregoing written documentation.

STEP #6



Documentation must state that the waiver has been reviewed under either normal or expedited review procedures.

USE OF DATABASES

- A researcher or the Hospital may use PHI to create database with IRB waiver.
- Database may be maintained indefinitely without seeking further authorizations.
- PHI in database can be used for future research studies if either:
 - Written authorization obtained; or
 - IRB waiver obtained.



USE OF INFORMATION PREPARATORY TO RESEARCH

- Can conduct research without authorization if the researcher represents in writing to the St. Barnabas IRB that:
 - sole purpose is to develop a research hypothesis or recruit research participants,
 - PHI is necessary for research purposes, and
 - PHI will not be removed from premises of the Hospital.
- Only de-identified PHI can be recorded by researchers.

Note: For further information, please refer to the Hospital's Policy Regarding the Use of Patient Information in the Conduct of Research.

DECEASED INDIVIDUALS

- Can use and disclose PHI of deceased person for research without authorization.
- Researcher must provide to the IRB of the Hospital representations that:
 - Use or disclosure is sought solely for research on PHI of deceased individuals
 - PHI is necessary for research purposes.
- The researcher must also provide to the IRB of the Hospital documentation of death of individual about whom PHI is being sought [optional].

Note: For further information, please refer to the Hospital's Policy regarding the Use of Patient Information in the Conduct of Research.

DE-IDENTIFICATION MOOTS HIPAA

The Hospital may determine that health information is not individually identifiable by:

- Retaining an entity experienced with generally accepted statistical and scientific principles and methods for masking identifying characteristics of information to opine that the information is not individually identifiable
- Removing specified identifiers of the individual or of relatives, employers, or household members of the individual



INFORMATION

IDENTIFYING AN INDIVIDUAL

- Names
- All geographic subdivisions (*i.e.*, address, zip code)
- All elements of dates (*i.e.*, birth date, admission date)
- Telephone/Fax numbers
- E-mail Addresses
- SSNs
- Medical record numbers
- Health plan numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifier/serial numbers
- Device identifier/serial numbers
- URLs
- IP addresses
- Biometric identifiers
- Photos
- Other unique characteristics, *e.g.*, tissue or DNA samples (excluding re-identification code)

LIMITS ON RE-IDENTIFICATION

The Hospital may create codes allowing re-identification of information, provided that:

- the code is not derived from or related to information about the individual
- the code is not capable of being translated so as to identify the individual
- the Hospital does not use or disclose the code or mechanism for re-identification for any other purpose



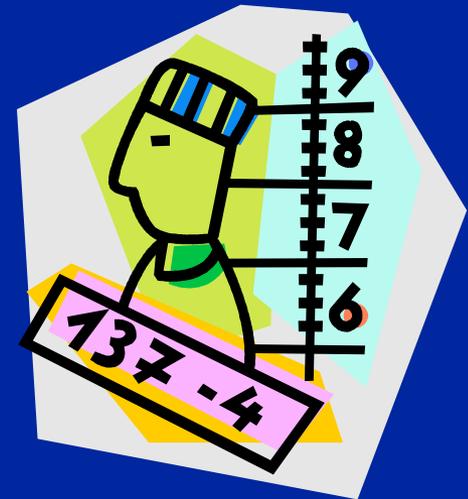
DE-IDENTIFICATION BY A RESEARCHER



A researcher can conduct research using de-identified information without obtaining an authorization if it follows the de-identification requirements in the Hospital's Policy Regarding the Use of Patient Information in the Conduct of Research.

Research Using De-identified Information

- If a researcher decides to conduct a research project using de-identified health information, the following three steps must be followed.



Step 1: De-identification

- All researchers must read and review the HIPAA self-directed training for researchers.
- For each researcher, a HIPAA Compliance Assurance form must be completed and signed.



Step 2: De-identification

- Present to the IRB a written request to conduct research. The request must detail three elements:
 - The nature and purpose of the research project.
 - The exact health information that will be used in the project.
 - Security plan for confidentiality of research information.
- All copies of the Compliance Assurance letter previously discussed must attached to the above request.

Step 3: De-identification

- After receiving affirmative response from an IRB member in writing, proceed to Medical Records to request the needed health information.
- Follow all procedures as given by the Medical Records Department.
- Medical Records will not begin work on the process of de-identification for any researcher until written approval is granted by the IRB.



USE OF LIMITED DATA SET MOOTS HIPAA

A researcher may create a limited data set for use and disclosure of patient information in connection with research if:

- Specified direct identifiers of the individual or of relatives, employers, or household members of the individual are removed and
- The intended recipient enters into a data use agreement regarding the limited allowable use or disclosure of the patient information in the limited data set.

DIRECT IDENTIFIERS

- Names
- Postal address information (except town, city, state or zip code)
- Telephone/Fax numbers
- E-mail addresses
- SSNs
- Medical record numbers
- Health Plan numbers
- Account Numbers
- Certificate/License numbers
- Vehicle identifier/serial numbers
- Device identifiers/serial number
- URLs
- IP address
- Biomedic identifiers
- Photos

DATA USE AGREEMENT

A data use agreement must provide the Hospital with satisfactory assurance that the limited data set will only be used or disclosed by recipient for specified purposes.

All data use agreements must be reviewed and approved by the IRB.



DATA USE AGREEMENT

The data use agreement must contain the following elements:

- A statement indicating whether the limited data set was created for research, public health or health care operations.
- A statement of the purposes for which the recipient can use or disclose the patient information being provided in the limited data set. These purposes must be consistent with the reason the data use set was originally created.

DATA USE AGREEMENT

- A list of the names of all individuals or entities being provided permission to receive the limited data set under the data use agreement.
- A statement that the recipient agrees not to use or further disclose the patient information in the limited data set other than as agreed to in the data use agreement or as requirement by the law.
- A statement that the recipient agrees to use appropriate safeguards to prevent the use or disclosure of the patient information in the limited data set in any manner other than as agreed to in the data use agreement.

DATA USE AGREEMENT

- A statement that the recipient agrees to report to the Hospital if it becomes aware of any use or disclosure of the patient information in the limited data set outside of the agreed upon uses in the limited data set.
- A statement that the recipient agrees to ensure any agents, including any subcontractors, who it provides the limited data set to will follow the same restrictions and conditions with respect to the use, disclosure and protection of the data use set.

DATA USE AGREEMENT

- A statement that the recipient agrees to not identify the information in the limited data set or attempt to contact the individuals.
- A statement that the Hospital can terminate the data use agreement and use of the limited data set by the recipient if it becomes aware of any pattern of behavior or activity or practice of the recipient which materially breaches or violates the data use agreement. The statement should further indicate the Hospital will report any such breach or violation to the Secretary of the Department of Health and Human Services.

RESEARCHER USING A LIMITED DATA SET



A researcher can conduct research using a limited data set and data use agreement without obtaining an authorization if it follows the limited data set requirements in the Hospital's Policy regarding the Use of Patient Information in the Conduct of Research.

INDIVIDUAL ACCESS TO RESEARCH INFORMATION

- Generally, an individual is allowed access to his/her research information that is used to make decisions about the individual. Please see the Hospital's Policy regarding Access to Patient Information.
- Where research includes treatment, there is an exception to access where:
 - PHI is obtained by the Hospital in course of clinical trial;
 - Individual agreed to denial of access when consenting to clinical trial; and
 - Clinical trial is still in progress.
- Individuals must be advised of their right to access once research is complete.

INTERACTION WITH COMMON RULE

- Where both sets of regulations apply to research conducted by the Hospital, both must be followed.
 - e.g., CR addresses informed consent to participate in research. HIPAA does not; it addresses the use or disclosure of PHI in connection with that research.
- FDA's human subjects regulations must also be followed, if applicable.
- Unlike Common Rule, HIPAA applies regardless of source of funding.

ETHICAL AND OTHER CONSIDERATIONS

- Must provide research information to individuals participating in clinical trial if threat to their welfare -- e.g., severe adverse reaction.
- Distinction from “Health Care Operations”: If activity starts out as a review for internal purposes and triggers a more generalized study, may become subject to these rules.



RESEARCH RECORDS



Researchers must secure all research records in locked file cabinets or other secured locations.

ANALYSIS OF NEED FOR AUTHORIZATION

- Step 1**: Is the information that is being collected “individually identifiable health information?”
- Step 2**: Is the source of the information a “covered entity” (e.g., hospital, nursing home, home health agency, rehab facility, individual provider)?
- Step 3**: Why is the PHI being collected (e.g., clinical trial that includes research, research without a clinical trial, preparatory to research)?
- Step 4**: What form will the information disclosed take (e.g., de-identified, identified)?
- Step 5**: Where is the information going (e.g., a business associate, a sponsor, another researcher, an oversight agency)?