Flagler Hospital, Inc., Privacy, Confidentiality and HIPAA/PHI in Research

by

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Objectives

At the conclusion of this CME activity, participants will be able to:

- Define how the three principles of the Belmont Report are reflected in maintaining confidentiality and privacy in research.
- Describe the HIPAA Privacy Rule as applied to research.
- Explain the importance of maintaining the integrity of protected health information in research.

Historical Background: Belmont Report

- According to HHS Office for Human Research Protection (45 CFR 46.111(a)(7)) and FDA (21 CFR 56.111(a)(7)), in order to approve human research, the Institutional Review Board (IRB) is required to determine adequate provisions to protect the privacy of research participants and to maintain confidentiality of data.

- Privacy and confidentiality in human research are supported by the following three principles of the Belmont Report
  1. Respect for Persons
  2. Beneficence
  3. Justice

Barrow, J. M. & Khandhar, P. B. (2019). Research Ethics. *NCBI*. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK459281/

Belmont Report: Respect for Persons

Respect for Persons Definition:

Treat individuals as ***autonomous agents***; don't use people as a means to an end; allow people to ***choose for themselves***; provide ***extra protections*** for those with diminished autonomy (prisoners, children, individuals with impaired decision-making ability)

Implications for Privacy and Confidentiality in Research

The principle of respect for persons, also known as the principle of human dignity, implies respect for the privacy and confidentiality of individuals participating in human research.

Barrow, J. M. & Khandhar, P. B. (2019). Research Ethics. *NCBI*. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK459281/

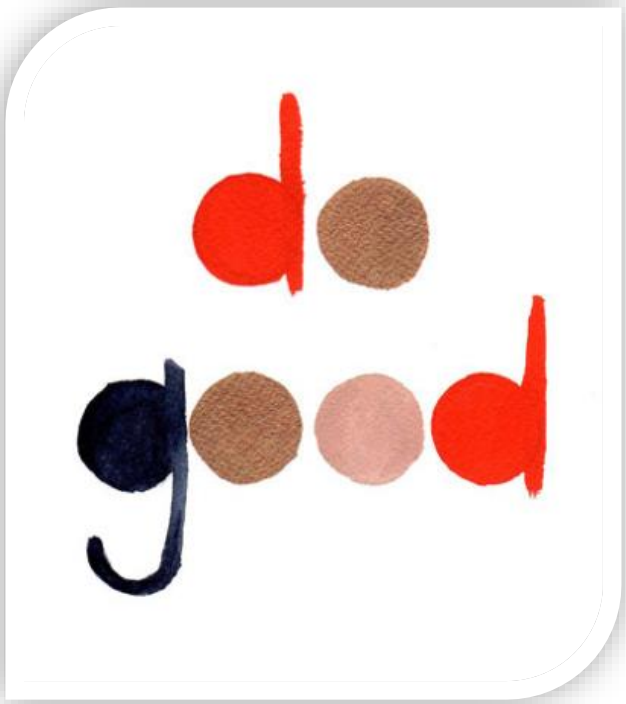
Belmont Report: Beneficence

Beneficence Definition:

Do good; maximize possible benefits and minimize risks

Implications for Beneficence in Research:

- Principle Investigators must identify potential risks and benefits to research participants prior to seeking IRB approval.
- In maintaining privacy and confidentiality, Principle Investigators protect research participants from potential harms including:
  - physical harm
    - injury
  - psychological harm
    - embarrassment or distress
  - social harms
    - loss of employment or damage to one's financial standing
  - legal harm
    - criminal or civil liability.
- In social/behavioral research the primary risk to research participants is invasion of privacy or breach of confidentiality.



UCI Office of Research. (n.d.) Privacy and Confidentiality. Retrieved from https://www.research.uci.edu/compliance/human-research-protections/researchers/privacy-and-confidentiality.html

Belmont Report: Justice

Justice Definition:
Treat people fairly; fair sharing of burdens and benefits of research

Implications for Justice in Research:

- The principle of justice in research implies research participants' right to privacy.

- Principal Investigators protect research participants' right to privacy by:
  - Using various methods to ensure confidentiality, such as substituting code numbers instead of names
  - Establishing anonymity by ensuring that the Principle Investigator does not have the ability to connect research participants to their data

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Privacy in Research

Privacy in Research:

- A concept in research ethics emphasizing research participants' right to privacy
- Refers to control over the extent, timing, and circumstances that research participant's share themselves with others

Examples-

- choosing whether or not to enter places that may be stigmatizing, i.e. mental health, family counseling, pregnancy counseling clinics
- Determining specifically to whom research participants' share their personal, private information

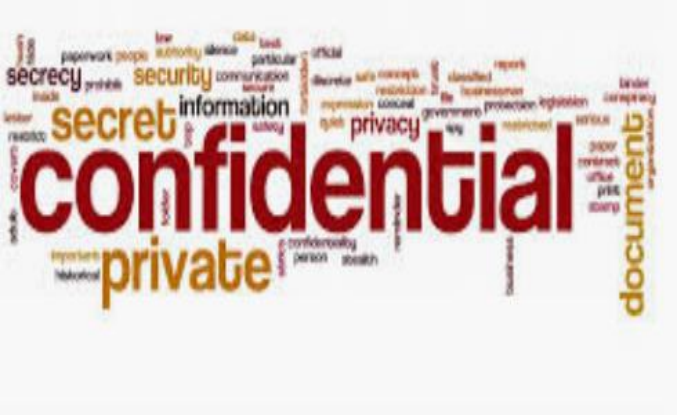
NOTE: IRB members must evaluate privacy elements in research applications by considering strategies proposed by Principal Investigators to:

- maintain privacy in recruiting potential research participants
- protect privacy interests and access to private information of research participants

Confidentiality in Research

Confidentiality in Research:

- A concept in research ethics where the Principal Investigator has the obligation to safeguard research participants' entrusted information essential to:
  - trust building between Principal Investigator and research participants
  - maintain integrity of research studies
- Involves methods Principal Investigator's use to maintain security in safeguarding entrusted research data. Examples:
  - Properly disposing of data sheets and paper records
  - Limiting access to identified data (de-identifying data can be completed by coding and anonymizing)
  - Storing research records in locked cabinets, secured databases, password protected computer, firewalls, anti-virus,
  - Protecting research participants' information from unauthorized access, use, disclosure, modification, loss or theft
- Certificates of Confidentiality (COC) are required in government funded research (i.e. National Institute of Health (NIH)) to protect the privacy and confidentiality of research participants (issued automatically for any NIH-funded research studies using identifiable sensitive information)



REMINDER: IRB members must consider confidentiality in research applications by evaluating strategies of Principal Investigators to protect confidentiality of research data.

Private Information in Research

Private information: includes information about research participants collected in a research study, about which the research participants can reasonably expect no observation or recording is taking place and that the participants' data will not be made public (e.g., a medical record).

Identifiable private information: private information for which the identity of research participants is or may readily be ascertained by the principal investigator and/or the identity of a participant is directly associated with the information.

Identifiable biospecimen: a biospecimen for which the identity of research participants is or may readily be ascertained by the principal investigator and/or the identity of the participant is directly associated with the biospecimen.

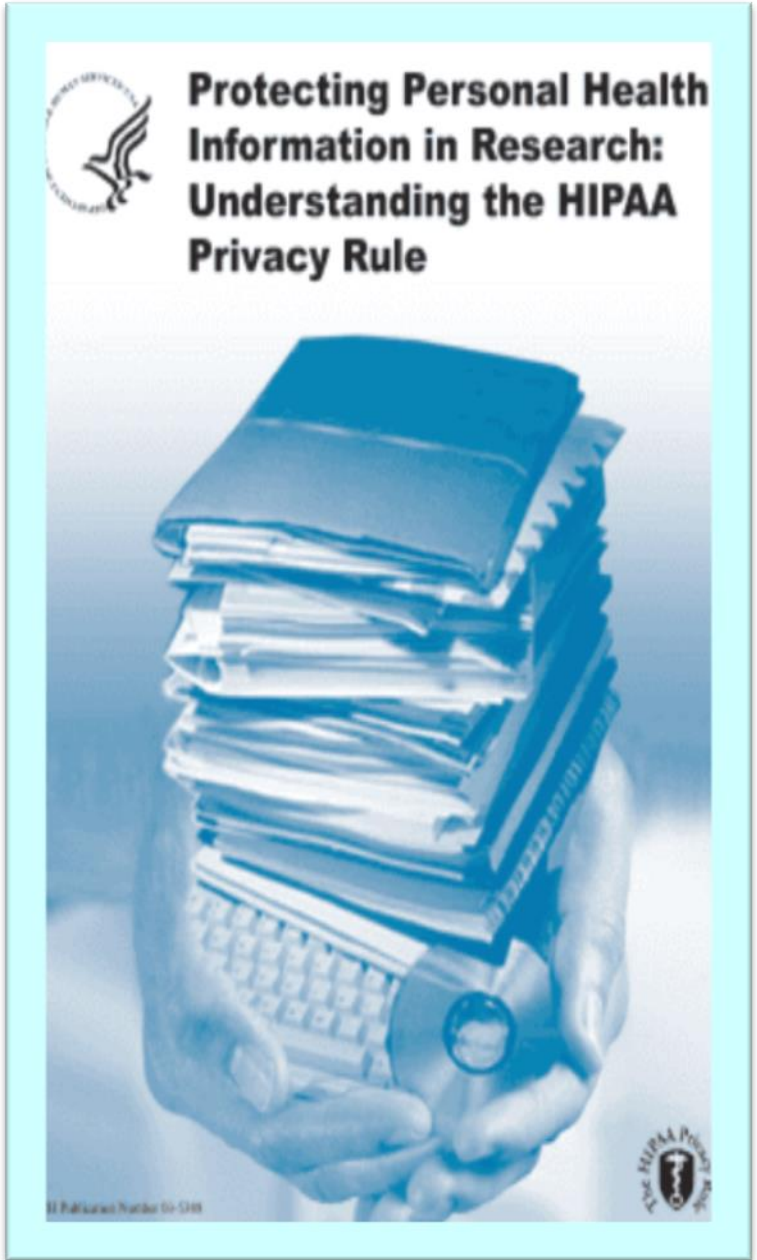
OHRP (2018, October 5). Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

Private Information and HIPAA in Research

- **Research** is defined in the Privacy Rule as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (See 45 CFR 46.102(d)).

- The **HIPAA Privacy Rule** establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

- A **covered entity** (health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions) may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d) and 164.514(a)-(c) of the Rule).

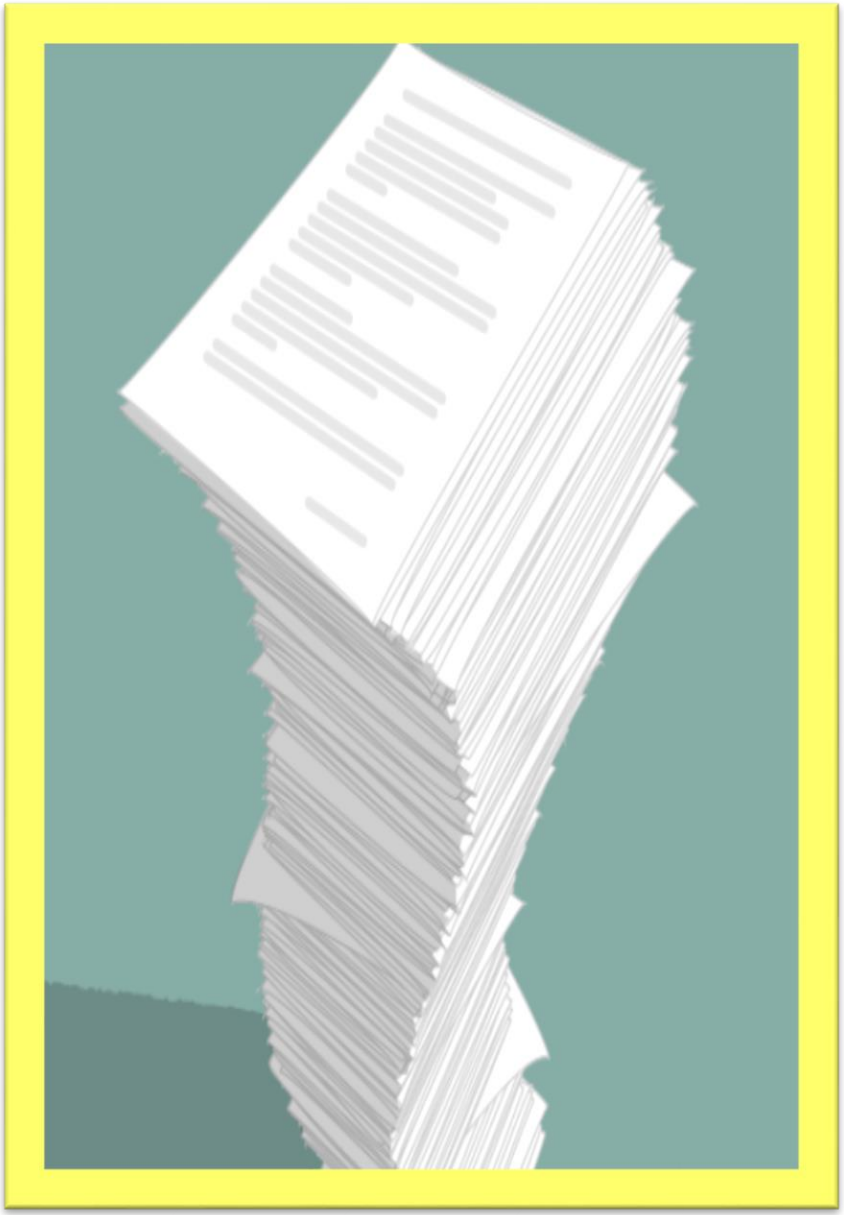


HIPAA Privacy Rule and Research

The HIPAA Privacy Rule:

- Builds upon existing federal protections, such as the Common Rule 45 CFR Part 46, Subpart A (OHRP implementation), and /or the Food and Drug Administration's (FDA) human subject protection regulations (21 CFR Parts 50 and 56). These human subject regulations include protections to help insure the privacy of research participants and the confidentiality of information.
- Defines the means by which research participants will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities.
- Protects the privacy of individually identifiable health information, while at the same time ensures that Principal Investigators continue to have access to medical information necessary to conduct research.

Key Terms



Covered entities: health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions.

De-identified Protected Health Information: Information that is no longer individually identifiable and cannot be used, alone or in combination with other reasonably available information, to identify the individual.

Disclosure: The release (transfer, provision of, access to, or divulging in any other manner) of information outside the entity holding the information.

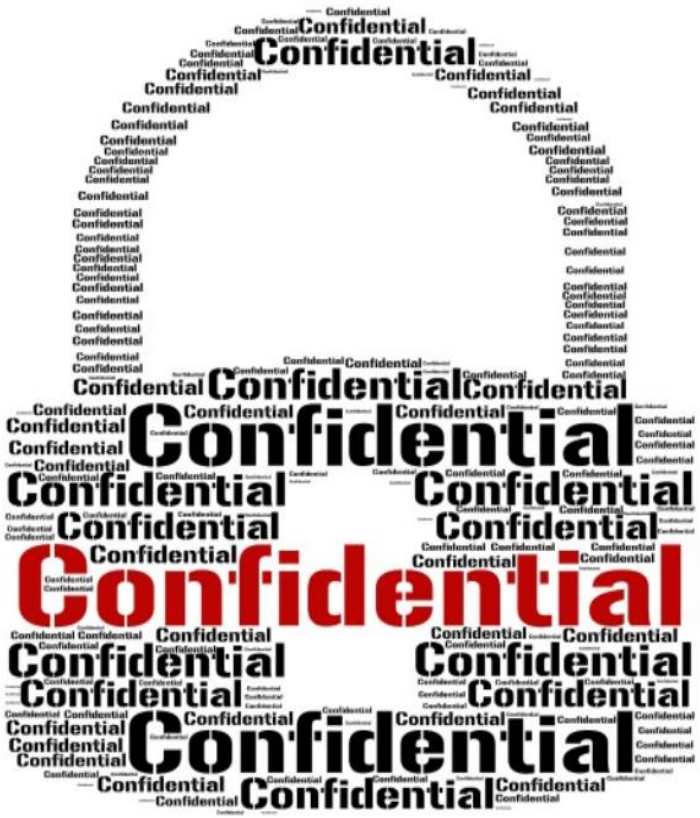
Limited Data Set: set of data that may be used for research, public health, or health care operations without an authorization or waiver of authorization. The limited data set is defined as PHI that excludes identifiers of the individuals, or their relatives, employers, or household members.

Key Terms continued

Protected Health Information (PHI):

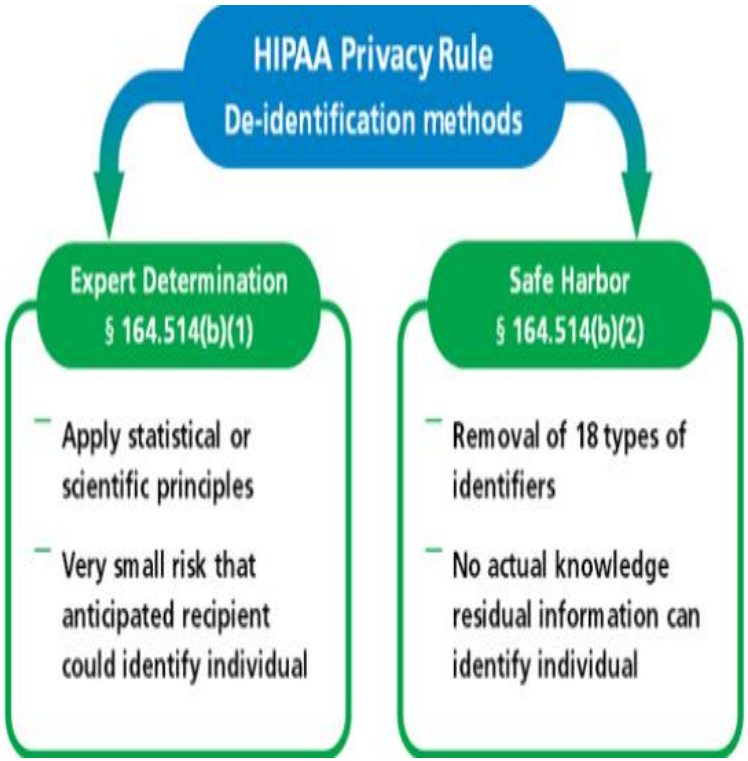
Defined in Code of Federal Regulation (CFR) (45 CFR 160.103), and referenced in Health Information Technology for Economic and Clinical Health (HITECH) Act Section 13400 of Subtitle D ('Privacy') as:

- Individually identifiable health information held or transmitted in any form or medium, including information created or received by a health care provider, health plan, employer or health care clearinghouse that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and that identifies the individual or for which there is a reasonable basis for believing that the information could be used to identify the individual. Protected Health Information includes medical, scheduling, and billing information.



Protected Health Information and HIPAA

- The HIPAA Privacy Rule defines "individually identifiable" information broadly, to include information such as name, address, or SSN, as well as "indirect identifiers" such as zip codes or date of birth, when attached to any health information.
- Covered entities and their employees must not use or disclose individually identifiable health information (called "protected health information", or "PHI") for research, except in any one of the following circumstances:
  - Research participants have signed a written authorization containing all elements specified in the Privacy Rule, or
  - An IRB has altered or waived the requirement for HIPAA authorization, or
  - Covered entities and their employees have "de-identified" data prior to its use and disclosure for research, or
  - Data are in the form of a "limited data set" containing no HIPAA "identifiers," and the Principal Investigator has signed a data use agreement.



Protected Health Information Identifiers

1. Names	**2. Telephone numbers**
3. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census: **(1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and** **(2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000**	
4. Dates- all elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	
5. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)	
6. Biometric identifiers, including finger and voice prints	
7. Social security numbers	**13. Certificate/license numbers**
8. Vehicle identifiers and serial numbers	**14. Full-face photos and other comparable images**
9. Fax numbers	**15. Internet Protocol (IP) addresses**
10. Device identifiers and serial numbers	**16. Medical record numbers**
11. Email addresses	**17. Account numbers**
12. Uniform Resource Locator (URL)	**18. Health plan beneficiary numbers**

Protected Health Information in Research

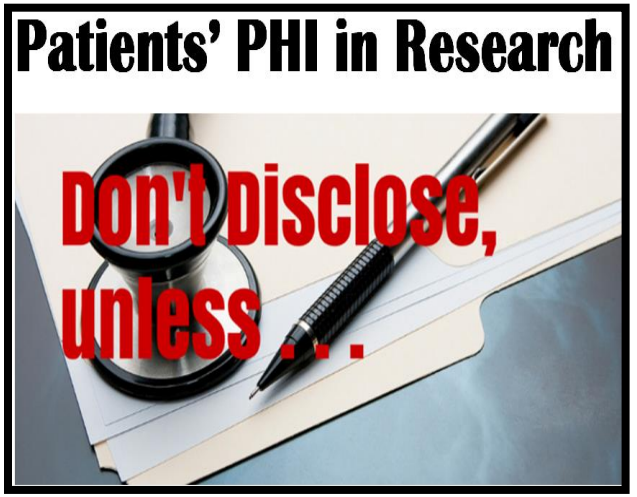
- In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the HIPAA Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the HIPAA Privacy Rule
- Research Use/Disclosure Without Authorization: to use or disclose protected health information without authorization by the research participant, a covered entity must obtain one of the following:
    - Documented IRB or Privacy Board Approval: documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an IRB or Privacy Board. For example, to conduct records research, a waiver may be appropriate when researchers are unable to use de-identified information, and the research can not practicably be conducted without waiver of consent.

Flagler Hospital, Inc. IRB and Privacy Board

- Flagler Hospital, Inc. IRB serves as the Privacy Board for research conducted at Flagler Hospital and external sites as applicable and may grant approval of authorization documentation or waive the requirement of HIPAA authorization as Federal regulations allow. The Flagler Hospital, Inc. IRB will consult with Flagler Hospital's Privacy Officer for HIPAA and PHI compliance- related matters, as needed.

Research Use/Disclosure of PHI with Authorization

- A legally effective research authorization for use/disclosure of PHI includes the following elements:
  - Description of information to be used or disclosed identifying the information in specific and meaningful way
  - Name or other specific identification of person(s), or class of persons, authorized to make requested use of disclosure
  - Name or other specific identification of person(s), or class of persons, to whom the Principal Investigator may make the requested use or disclosure
  - Description of each purpose of requested use or disclosure
  - Expiration date or expiration event relating to the individual or purpose of use/disclosure
  - Statement that the individual may revoke authorization if requested in writing. However, the PI may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual, pursuant to such authorization before it was revoked
  - Statement that either: the institution may not condition treatment, payment or eligibility for benefits on whether the individual signs authorization (for non-treatment studies) or the institution may condition the individual's research-related treatment on the provision of the authorization (for treatment studies)
  - Statement that information disclosed pursuant to the authorization could potentially be subject to re-disclosure by the recipient and no longer be protected under HIPAA and individual's signature (or that of his/her legally authorized representative) and date.
  - Authorization for use/disclosure of PHI for research may be combined with written informed consent for the same research.
- A signed copy of authorization for use/disclosure of PHI may be received by facsimile or electronically transmitted to an IRB.



Flagler Hospital, Inc. Institutional Review Board (IRB) Policy: I-LIB/CME-009

Alteration or Waiver of Authorization for PHI Use/Disclosure in Research

- PHI Authorizations in research may be altered or waived by an IRB, provided the following criteria are satisfied and documented:

  1. A statement that the IRB or Privacy Board determined that the alteration or waiver of authorization satisfies Privacy Rule requirements. Use/disclosure of PHI involves no more than minimal risk to privacy of individuals, based on the presence of at least the following elements:

     - Adequate plan to protect identifiers from improper use/disclosure
     - Adequate plan to destroy identifiers at earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining identifiers or if such retention is otherwise required by law
     - Adequate written assurances that the PHI will not be reused/disclosed to any other person or entity, except as required by law, for authorized oversight of research

  2. Research could not practicably be conducted without alteration or waiver of authorization.

  3. Research could not practicably be conducted without access to and use of PHI.

NOTE: When uses/disclosures of PHI are made pursuant to a waiver, the Principal Investigator must make reasonable efforts to limit PHI to the minimum necessary to accomplish purpose of use/disclosure.

Research Use or Disclosure of PHI with Waiver of Authorization Outside of Flagler Hospital, Inc.

If Flagler Hospital, Inc. IRB grants a waiver of authorization and the Principal Investigator discloses any PHI outside Flagler Hospital, Inc., the Principal Investigator must record the following information for any PHI disclosed and report this to Flagler Hospital, Inc. IRB as a **Reportable Event**:

- Date of PHI disclosure
- Name and address of entity or person that received PHI
- Brief description of PHI disclosed
- Brief statement of purpose and rationale for PHI disclosure

Use/Disclosure of Limited Data Set in Research

- A limited data set is protected health information that excludes identifiers of individuals or of relatives, employers, or household members of individuals
- Protected health information that may remain in disclosed information includes:
  - dates such as admission, discharge, service, DOB, DOD;
  - city, state, five digit or more zip code
  - ages in years, months or days or hours.

NOTE: Limited Data Set information is still protected health information under HIPAA. It is not de-identified information and is still subject to requirements of the HIPAA Privacy Rule.

Data Use Agreement in Research

Data use agreement: an agreement required under the Privacy Rule that must be entered into before there is any use or disclosure of a limited data set to an outside institution or party. A limited data set is still protected health information (PHI), and for that reason, covered entities, like Flagler Hospital, Inc., must enter into a data use agreement with any recipient of a limited data set from Flagler Hospital, Inc.

At a minimum, any data use agreement must contain provisions that:

- Establish permitted uses and disclosures of the limited data set
- Identify who may use or receive information
- Prohibit recipient(s) from using or further disclosing information, except as permitted by data use agreement or as otherwise permitted by law
- Require recipient(s) to use appropriate safeguards to prevent an unauthorized use/disclosure not defined by data use agreement and report to the covered entity any unauthorized use/disclosure
- Require recipient(s) to ensure that agents and their subcontractors) adhere to restrictions as provided in the data use agreement
- Prohibit recipient(s) from identifying PHI or contacting the individuals if their PHI is identified

NOTE: The Principal Investigator may use/disclose a limited data set for research purposes without authorization or waiver of authorization, if a data use agreement is completed and submitted to IRB. For example, a data use agreement is used when a PI shares a limited research data set with a colleague at another institution or private registry not involved in the research.

Breach of Data Use Agreement

- In the case of a data use agreement breach by a recipient, covered entities, such as Flagler Hospital, Inc., must take all reasonable steps to address and resolve all issues. For example:
  - If Flagler Hospital, Inc. learns that data provided to a recipient is being used in a manner not authorized under the data use agreement, Flagler Hospital, Inc. will work with the recipient(s) to correct the data use agreement breach.
  - If efforts to correct the breach are unsuccessful, Flagler Hospital, Inc. is required to cease any further disclosures of protected health information to the recipient under the data use agreement **and** report the situation to the Federal Department of Health and Human Services Office for Civil Rights.

Use/Disclosure of Decedents' Protected Health Information in Research

- The HIPAA Privacy Rule protects the identifiable health information about a decedent for 50 years after the date of death.
- For use/disclosure of a decedent's health information in research, a covered entity must obtain written HIPAA authorization from the decedent's personal legal representative who can authorize the disclosure. For example:
  - an executor, administrator, or other person who has authority under applicable State or other law to act on behalf of the decedent or the decedent's estate.

(See 45 CFR 164.502(g)(4), as well as guidance on personal representatives available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/personalreps.html, for more information.)

NOTE: Information about decedents who have been deceased for more than 50 years is NOT considered PHI.

Review of PHI Preparatory to Research

- A Principal Investigator may use PHI for activities considered preparatory to research without full IRB review, if all of the following criteria are satisfied:

  1. PHI use is sought solely to assess the PHI for appropriateness to:
     - determine feasibility of conducting research
     - design research
     - identify prospective research participants

  2. PHI is not removed from research site.

  3. A "Certificate for Use of Protected Health Information Reviews Preparatory to Research" document is submitted by Principal Investigator to the research site IRB

- When accessing PHI for activities preparatory to research, the Principal Investigator must make reasonable efforts to limit use and recording of PHI, maintaining minimum PHI necessary to accomplish purpose(s).

- IRB approval is required prior to analysis of PHI data abstracted during the Reviews Preparatory to Research process.

NOTE: If an IRB approved protocol is not submitted after the Reviews Preparatory to Research process, the abstracted PHI data *must not* be analyzed or disseminated in any form.

Research Participants' Access to Their PHI

Research participants have a right to access their PHI maintained in a designated research record set, EXCEPT when:

- Protected health information created or obtained in the research process is temporarily suspended during the research process and research participants have previously agreed to the temporary suspension of access to their PHI in their original informed consent.
- During the informed consent process, the Principal Investigator also informs research participants that the participants' right of access to their PHI will be reinstated upon completion of the research study

Participant's Request to Revoke Research Authorization

- Research participants may revoke in writing their PHI research authorization at any time during the research process, EXCEPT to the extent that the Principal Investigator has ***collected and/or analyzed*** the participants' PHI research data.
- In the case of research participants' revocation of their PHI research authorization, the Principal Investigator may ***use/disclose*** PHI data collected prior to the revocation.

Privacy, Confidentiality, HIPAA/PHI and Revised Common Rule Requirements

- According to the revised Common Rule, one of the basic elements of informed consent involves explaining how identifiable private information or identifiable biospecimens are protected in research.
- As stated in the Federal Register 46.116(b)(9):
  - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens must be included within the informed consent:
    - Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility;

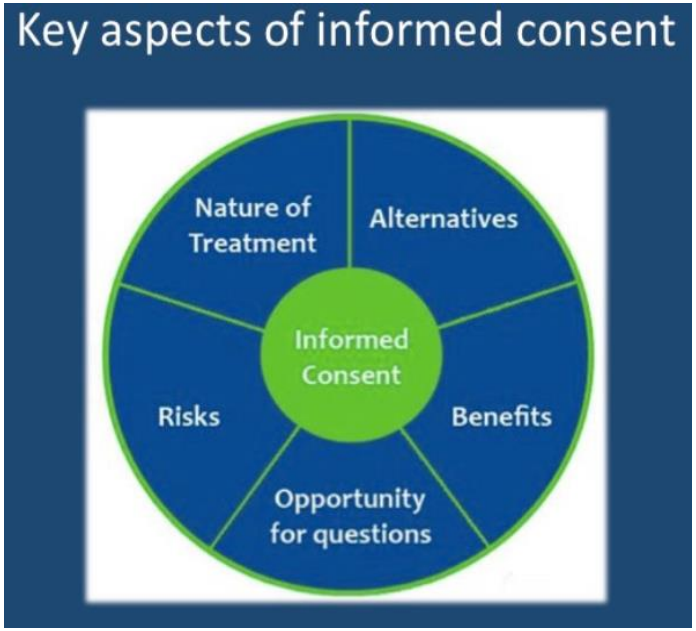
      or

    - The subject's (research participants) information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Federal Register 46.116(b)(9): Basic Elements of Informed Consent. Retrieved from https://www.ecfr.gov

Privacy, Confidentiality, HIPAA/PHI and Informed Consent

- Principal Investigators use the Informed Consent process to communicate how they will protect research participants' privacy, confidentiality, and/or HIPAA/PHI throughout the research process
- Questions that must be answered through the Informed Consent process are the following:
  - 1. What will happen with my protected health information (PHI) and/or biospecimens used in this study?
  - 2. What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
  - 3. What happens to information about me after the study is over or if I cancel my permission to use my personal health information (PHI)?
  - 4. When does my permission to use my PHI expire?
  - 5. How will the researchers protect my information?



Federal Register 46.116(b)(9): Basic Elements of Informed Consent. Retrieved from https://www.ecfr.gov

Maintaining Privacy, Confidentiality, HIPAA/PHI in Research Through IRB Oversight

Remember, according to HHS Office for Human Research Protection(45 CFR 46.111(a)(7)) and FDA (21 CFR 56.111(a)(7)), in order to approve human research, the Institutional Review Board (IRB) is required to determine adequate provisions to protect the privacy of research participants and to maintain confidentiality of data.

Accordingly, Flagler Hospital, Inc. IRB, as per policy (I-LIB/CME-009), ensures that privacy and confidentiality of research participants is maintained following the three key principles of the Belmont Report, which are respect for persons, beneficence, and justice.