LSU HEALTH COORDINATOR COMPETENCIES

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ADHERENCE TO ETHICAL STANDARDS

HIPAA Authorizations

Objectives

- Define HIPAA, protected health information, and covered entity
- Discuss HIPAA Authorizations and how they related to research
- Discuss Waivers to the HIPAA Authorization
- Provide tips for collecting HIPAA Authorization
- Identify how and when to report Privacy Violations

What is HIPAA?

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted on August 21, 1996.
- The resulting HIPAA Privacy Rule establishes, for the first time, a set of national standards for the protection of certain health information.
- The Privacy Rule addresses the use and disclosure of individuals' health information—called "**protected health information**" by organizations subject to the Privacy Rule — called "**covered entities**," as well as standards for individuals' privacy rights to understand and control how their health information is used.

What is Protected Health Information?

Protected Health Information (PHI) is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.

1. Names;
2. Street address, city, county, precinct, zip code
3. Dates, including birth date, admission date, discharge date, date of death; and all ages over 89
4. Phone numbers;
5. Fax numbers;
6. Email addresses
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. URLs;
15. IP address;
16. Biometric identifiers, including finger and voice prints;
17. Photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code

What is a Covered Entity?

Covered entities under HIPAA are individuals, institutions, or organizations that transmit protected health information electronically in transactions for which the Department of Health and Human Services (HHS) has published standards.

Three Main Covered Entities:

Healthcare Providers

Health Plans

Healthcare Clearinghouses

Covered Transactions:

- Transmissions of healthcare claims
- Payment and remittance advice
- Healthcare status
- Authorizations for treatment
- Coordination of benefits
- Enrollment and disenrollment
- Eligibility checks
- Healthcare electronic fund transfers
- Referral certification and authorization

HIPAA Authorizations

A HIPAA Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization.

HIPAA Authorizations or Waivers of Authorization are required for all research activities that involve the study team accessing, using, or disclosing PHI. HIPAA Authorizations are approved by a Privacy Board or Institutional Review Board.

A signed standard of care HIPAA Authorization ≠ permission to access, use or disclose PHI for research purposes

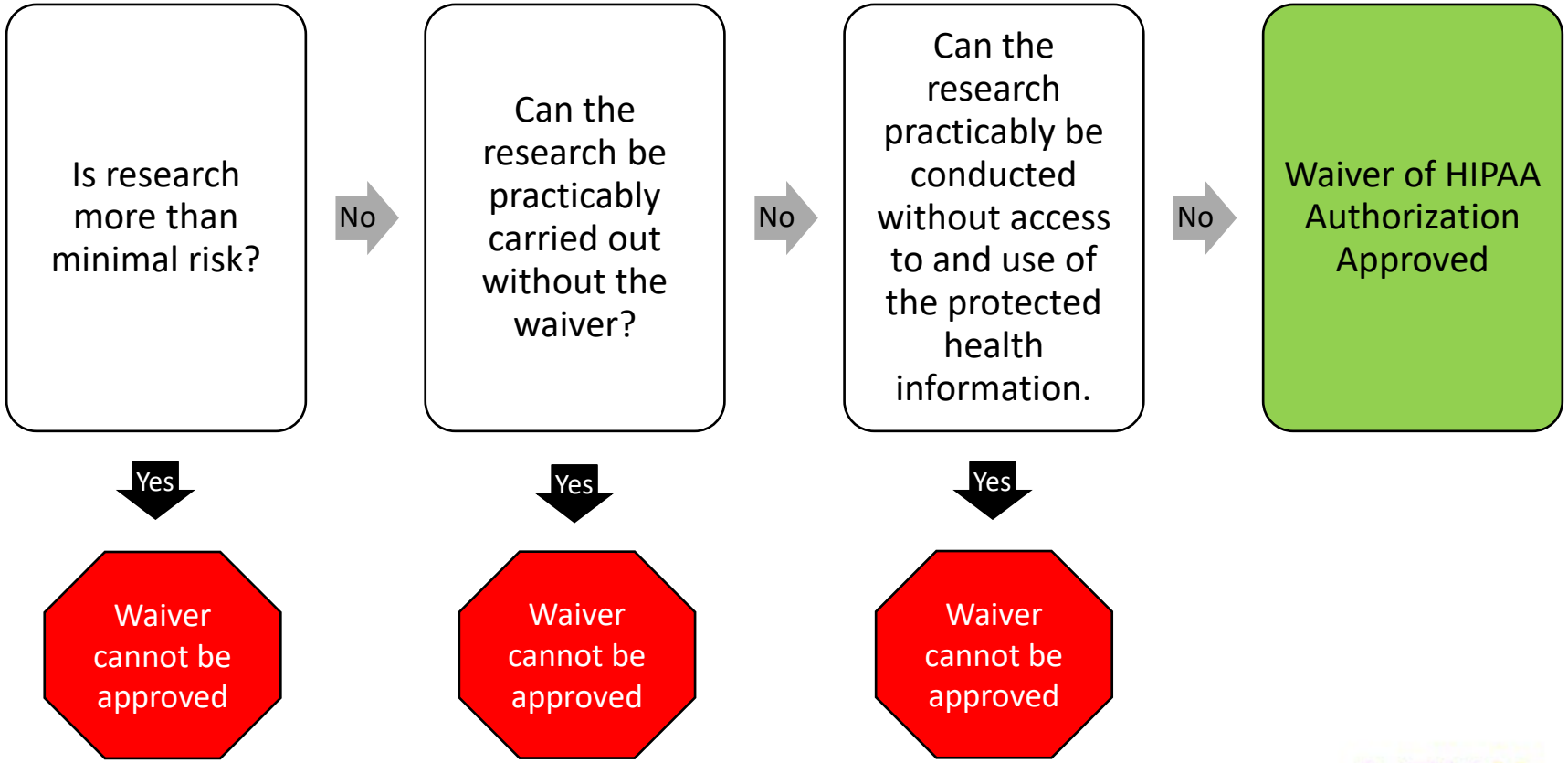
Research HIPAA Authorizations are separate from the HIPAA Authorization signed by a patient at a standard of care visit.

A signed research consent form ≠ permission to access, use, or disclose PHI

While collected at the same time, an informed consent form is separate from the HIPAA Authorization needed to access, use, or disclose PHI as part of research.

Waiver of HIPAA Authorizations

The IRB or Privacy Board may approve a waiver of the requirement to obtain HIPAA Authorizations provided that <u>all</u> of the following apply:



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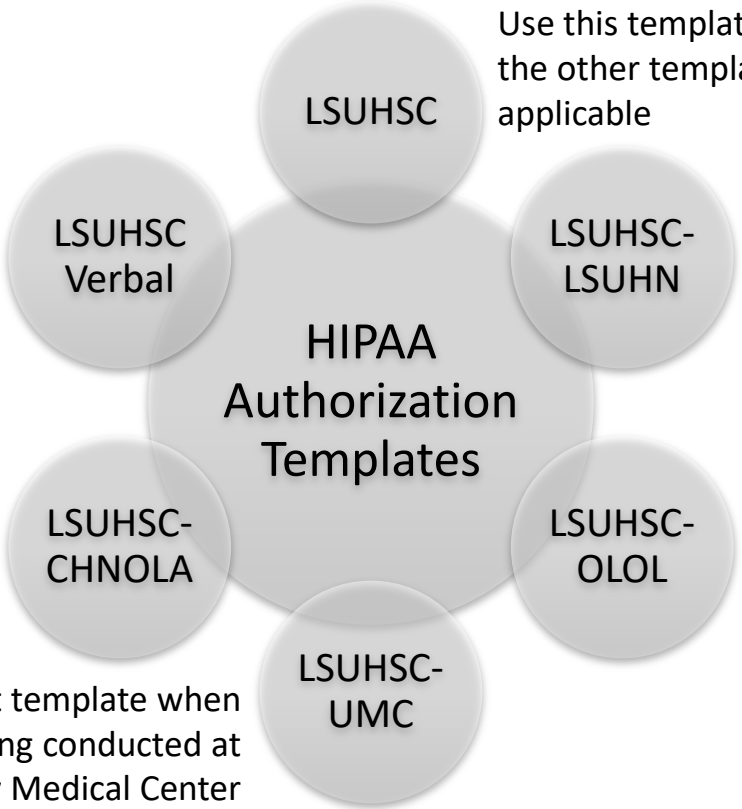
Collecting HIPAA Authorizations at LSU Health

LSUHSC has multiple HIPAA Authorization templates, each used in a certain circumstance as outlined below.

Note: If you conduct research at multiple sites with their own joint form, your study may have to draft and/or collect multiple HIPAA authorizations.



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Tips for Collecting HIPAA Authorizations

- When drafting the HIPAA Authorization, ensure you are completing all fillable sections (study information, Section 2, Section 8, Section 9) so that every subject is signing a consistent HIPAA Authorization.
- If you intend to enroll non-English speaking individuals, the HIPAA Authorization must be translated and match the English version in every way.
- Unlike the consent form, the person collecting consent and HIPAA Authorization does not need to sign the HIPAA Authorization after the subject does.
- All selections in Section 2 and 8 should be made electronically and IRB-approved. Do not alter these sections in wet ink.
- If the study undergoes a change in PI, make sure when amending the IRB application and consent form, that you also amend the PI name on the HIPAA Authorization.

Reporting Potential HIPAA Violations/Breaches

What constitutes a potential HIPAA violation or breach?

- Non-encrypted laptop/flash drive containing identifiable participant data was stolen
- Non-IRB approved person accessing, using, receiving or disclosing identifiable participant data
- Removal of identifiable participant data from campus
- Taking photos on a personal device of identifiable participant data

How would I report a potential violation or breach?

- Submit to the IRB a Reportable Event application outlining in specific detail what occurred.
- The IRB will alert the Office of Compliance Programs and begin an investigation into the potential violation or breach

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ❑ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development