HIPAA and Human Subjects Research Training

Revised 09/29/2015.
Introduction

• Anyone who conducts Human Subjects Research at LSUHSC-NO is required to complete this training module on an annual basis.
What is Considered “Research” under HIPAA?

• Research is defined in the regulations as:
  – The systematic investigation, designed to develop or contribute to generalizable knowledge including development, testing, and evaluation.
  – This includes research that may be conducted as part of a treatment plan.
Is it Research or Not?

• When in doubt as to whether the activity you are undertaking is human subjects research, you must have the LSUHSC-NO IRB make a determination of whether the activity is human subjects research under the Common Rule, and therefore, the Privacy Rule.
Is it Research or Not? (cont.)

• Not all kinds of “Research-Like” activities are included in the definition of research. The following are NOT research:
  – Quality assessment and improvement activities, including outcomes evaluation, and development of clinical guidelines or protocols, fall under the category of “health care operations” - - provided the primary aim is not obtaining generalizable knowledge.
  – Activities that aim primarily for generalizable knowledge of population health may fall into the category of “public health” activity.

➢ More information on “Research-Like” activities will be discussed later in this presentation.
HIPAA’s Authorization Requirement for Research

• The general rule is that LSUHSC-NO must obtain an individual’s authorization before using or disclosing protected health information (PHI) for RESEARCH purposes.
IRB Review

• A Principal Investigator (PI) must comply with the HIPAA Privacy Rule as well as the Common Rule when submitting a research protocol for review by the Institutional Review Board (IRB).

• A Principal Investigator (PI) must submit a HIPAA Authorization form template for research in addition to any other documents the IRB may require.
Failure To Obtain HIPAA Authorization From Each Research Subject

• All data collected from the subject for the research must be **DESTROYED** and may **NOT** be used!

• Additional penalties that can occur:
  – Loss of research privileges.
  – Repayment of grants/awards.
  – Penalties/fines from regulatory agencies.
  – Loss of your job or student status.
Enrollment in a Research Study

• For a person to be enrolled in the research study, the HIPAA Authorization form **MUST** be completed.

• This authorization allows the PHI of the person signing the authorization to be:
  
  – Used by employees of LSUHSC-NO including treatment providers, and/or other members of its workforce.
  
  – Disclosed to government officials or government agencies, study sponsors, study monitors, or others responsible for oversight of the research project.
  
  – Sent to collaborating researchers outside LSUHSC-NO, if indicated in the Informed Consent document(s).
  
  – Used for subsequent research.
Where to find LSUHSC-NO’s HIPAA Research Authorization

- LSUHSC-NO’s HIPAA Authorization form for research is attached to **Chancellor’s Memorandum (CM) 53** and may be found at:
  - **Policy S: Human Subject/Patient Policy: Use and Disclosure of Protected Health Information for Research**
  - Policy S Attachment A: Authorization for Use and Disclosure of Protected Health Information for Research Purposes - - There are two versions:
    - **with HIV/Substance Abuse language**
    - **without HIV/Substance Abuse language**
LSUHSC-NO HIPAA Research Authorization Forms

with HIV/Substance Abuse language

without HIV/Substance Abuse language

Double Click on Picture to Access full form
ABSOLUTLEY
NO SUBSTITUTION OF FORMS!!!

• The forms on the CM-53 website are the ONLY forms that may be used for purposes described in this training.

• Researchers and their staff members are NOT permitted to create or use any other form for these purposes.
  – To do so violates CM-53 and may violate HIPAA, subjecting the researchers and LSUHSC-NO to the penalties described later in this training.
Defective Authorizations

• An Authorization is not valid if the form signed by the subject has any of the following defects:
  – The authorization has been revoked in writing.
  – Any material information in the authorization is known by LSUHSC-NO to be false.
  – If the authorization is signed by a personal representative of the individual and a description of such representative’s authority to act for the individual is not attached.
Defective Authorizations (cont.)

• The Authorization lacks:
  – The signature of the individual and date.
  – A description of each purpose of the requested use or disclosure.
  – A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
  – The name or other specific identification of the person(s), or class of persons, to whom LSUHSC-NO may make the requested use or disclosure.
  – An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure.
Defective Authorizations (cont.)

- The expiration date has passed or the expiration event is known by LSUHSC-NO to have occurred.
  - For example, the authorization is valid for the duration of the pregnancy. Once the pregnancy has ended, the authorization is no longer valid and disclosures of PHI must not occur, unless a new authorization has been signed by the patient.
  - The statement “end of the research study”, “none” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including the creation and maintenance of a research database or research repository.
Revocation of Authorizations

• Research Authorizations may be revoked by the subject at any time, provided the revocation is in writing.

• Revocation is not valid to the extent LSUHSC-NO has relied on the Authorization.
  - For example, if a patient revokes an authorization, but LSUHSC-NO has already disclosed the information to the sponsor or a government agency based upon that authorization, the disclosure is permissible. However, from the date of the revocation, any further disclosures are not allowed.
Minimum Necessary Standard

• Research information that is obtained using an authorization IS NOT subject to the minimum necessary standard, but bound by the scope of the signed HIPAA Authorization.

• Information uses and disclosures for research that do not require an authorization ARE subject to the minimum necessary standard. (CM-53 Section D)
Recruitment of Human Subjects

• HIPAA does not prevent a healthcare provider from discussing with his/her patient recruitment into a research study for whom involvement might be appropriate.

• A patient’s information may not be disclosed to a third party (even another healthcare provider) for the purposes of recruitment into a research study without an authorization from the individual or an approved waiver of authorization from the IRB.
Treatment Studies

• When an investigator is involved in a Treatment Study of patients, the investigator must:
  – Provide a copy of LSUHSC-NO’s Notice of Privacy Practices; and
  – Obtain an acknowledgement of that Notice or document a good faith attempt to obtain the Notice.

• This documentation should be kept along with the informed consent and HIPAA Research Authorization.
Notice of Privacy Practices

• LSUHSC-NO’s Notice of Privacy Practices can be obtained at the following address:
  http://www.lsuhsc.edu/administration/cm/cm-53/AttachmentA-NoticeofPrivacyPractices.pdf

• LSUHSC-NO’s Acknowledgement of Notice of Privacy Practices can be obtained at the following address:
  http://www.lsuhsc.edu/administration/cm/cm-53/AttachmentB-NoticeofPrivacyPractices.pdf
Notice of Privacy Practices

This Notice Describes How Medical/Dental Information About You May Be Used and Disclosed and How You Can Get Access to this Information. Please Review it CAREFULLY.

The law requires us to make sure your medical information is kept private. It also requires us to give you this notice of our legal duties and privacy practices to tell you what we can do with the medical information about you. To better understand this law, you may want to read it. It is in Title 45 of the Code of Federal Regulations, Part 164. In the unlikely event that the information we have about you should be obtained by someone who is not supposed to have it, the law requires us to notify you. We are required to follow the practices outlined in this notice. We have the right to change this notice and our privacy practices in the future. Any changes made will apply to all of the medical information we have about you at this time. If we make a change, we will put a notice in our building. We will also give you a copy of the new notice if you ask for it. You can also read about these changes on the computer at this website: www.lsuhealth.edu

HOW YOUR MEDICAL/DENTAL INFORMATION MAY BE USED: In general, we may use your medical information in a number of ways:

To provide patient care to you. Your medical information may be used by the doctors, nurses and other professionals who are treating you. For example, your medical information is used to help them find out your problems or condition, and to decide the best way to treat you.

Appointment reminders. We may use your medical information to contact you to remind you of appointments, and to give you information about other treatment options or other health-related benefits and services that may be of interest to you.

To obtain payment. Your medical information may also be used by our business office to prepare your bill and process payments from you as well as from any insurance company, government program or other person who is responsible for payment.

For our health care operations. Your medical information may be used to review the quality and appropriateness of the care you receive. We may also use your medical information to put together information to see how we are doing and to make improvements in the services and care we give you. In some cases we may have students, trainee, or other health care personnel, as well as some non-health care personnel, who come to our facility to learn under the guidance of faculty to practice or improve their skills.

To create de-identified databases. We may use your medical information for the purpose of removing your personal information that tells anyone who you are, and putting it into a computer program. Your information may be completely de-identified where all identifying information is removed or partially de-identified but includes information such as gender and zip codes. This information is often used for research purposes. If your information is partially de-identified, it is called a "limited data set."

Fundraising. We may use your medical information to raise funds for our organization directly or to raise funds for our organization through an institutionally-related foundation or business associate. You may receive

Acknowledgement Form

ATTACHMENT B

ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES

I, __________________________, acknowledge that I have received a copy of the Notice of Privacy Practices of LSUHSC NO on this date.

(____________________________)   (________________________)
(Patient’s Signature)           Date:

**********************************************************************************************************

Health Care Provider’s Documentation of Good Faith Effort to Obtain Acknowledgement of Receipt

If the Acknowledgement could not be obtained prior to the date of first service to the patient, or, in an emergency situation, as soon as reasonably practicable after the emergency has resolved, describe below the efforts made to obtain the written Acknowledgement and the reasons why the written Acknowledgement could not be obtained. If the patient refused to provide the written Acknowledgement, please state.

Efforts to obtain written Acknowledgement

(________________________________________________________)

Reasons written Acknowledgement could not be obtained:

(________________________________________________________)

(________________________________________________________)

(Signature of health care provider)   (________________________)

(Printed name of health care provider)
Other Ways to Utilize Health Information in Research

• De-identification
• Limited Data Sets
• HIPAA waiver of authorization
De-identified Information

• A researcher may take PHI and remove all direct and indirect identifiers to eliminate or make highly improbable, re-identification using statistical techniques in accordance with CM-53 Section O.

• Once the PHI is de-identified, the information is no longer subject to the Privacy Rule and may be disclosed freely.
Direct Identifiers

- Names
- Postal address information, other than town or city, state, and zip code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical records numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Device identifiers and serial numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code.
Indirect Identifiers

• All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent, except for the initial three digits of zip code, if according to the current publicly available data from the Bureau of Census;
  – the geographical unit formed by combining all zip codes with the same initial three digits contains more than 20,000 people; and
  – the initial three digits of a zip code for all such geographical units containing 20,000 or fewer people is changed to 000.
Indirect Identifiers (cont.)

• All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of age, except that such ages and elements may be aggregated into a single category of age 90 or older.
Statistical Standard Option

HIPAA provides that LSUHSC-NO may determine that health information is not individually identifiable if:

- A person with appropriate knowledge of, and experience with, generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is the subject of the information; and that person documents the methods and results of the analysis that justify such determination.
Statistical Standard Option (cont.)

- If you feel you need to utilize this option, you must contact the LSUHSC-NO Privacy Officer BEFORE any disclosure of information occurs.
Re-identification of Data

• LSUHSC-NO may assign a code or other means of record identification to allow de-identified information to be re-identified.

• The code may not be derived from, or related to any of the removed identifiers.

• Any tables linking the code to patient identifiers must be kept confidential.

• If the data is re-identified, the information once again becomes subject to the Privacy Rule.
Where to find LSUHSC-NO Policy and Procedures on De-identification of PHI

- LSUHSC-NO’s HIPAA Policies and Procedures on De-identification of PHI are contained in Chancellor’s Memorandum (CM) 53 and may be found at:
  - Policy O: De-identification of Protected Health Information
  - Policy O Attachment A: Request for De-identified Information
  - Policy S Attachment D: Principal Investigator’s Request De-identification form for Approved Exempt Research
Limited Data Sets

• LSUHSC-NO may disclose PHI in a limited data set (LDS) to a researcher who has entered into an appropriate “data use agreement” in accordance with CM-53 Section N.

• LDS must have all direct identifiers removed; they may still include information that could “indirectly” identify the subject using statistical methods.
Data Use Agreement

• LSUHSC-NO must condition the disclosure of the LDS on execution of a “data use agreement.”

• Data use agreement must establish:
  – the permitted uses and disclosures of such information by the recipient, consistent with the purposes of research;
  – limit who can use or receive the data;
  – require the recipient to agree not to re-identify the data or contact the individuals.
Where to find LSUHSC-NO’s HIPAA Policies and Procedures on Limited Data Sets and Data Use Agreements

• LSUHSC-NO’s HIPAA Policies and Procedures on Limited Data Sets and Data Use Agreements are contained in Chancellor’s Memorandum (CM) 53 and may be found at:
  – Policy N: Limited Data Set
  – Policy N Attachment A: Limited Data Set Request and Data Use Agreement
Privacy Board/IRB

• Under the Privacy Rule, the Privacy Board can determine or monitor the requirements to patient privacy in research.

• At LSUHSC-NO, the IRB functions as the Privacy Board.

• The Privacy Board or Chair may:
  – make an alteration to or waive, in whole or part, the authorization requirement.
  – approve the waiver of authorization if the researcher has made representations that the information is needed for reviews preparatory to research.

• The Privacy Board or Chair must receive a certification from a researcher who conducts research on decedents.
Reviews Preparatory to Research

• A researcher may use or disclose protected health information for reviews preparatory to research, regardless of the source of funding of the research, provided that the researcher certifies to the IRB that:
  – The PHI for which use or access is sought is necessary for research purposes
  – The use or disclosure sought is solely to review PHI to prepare a research protocol
  AND
  – No PHI is removed from the institution by the researcher in the course of the review
Where to find LSUHSC-NO’s Policies and Procedures for Reviews Preparatory to Research

• LSUHSC-NO’s HIPAA policies and procedures on Reviews Preparatory to Research are contained in Chancellor’s Memorandum (CM) 53 and may be found at:
  - Policy S: Human Subject/Patient Policy: Use and Disclosure of Protected Health Information for Research
  - Policy S Attachment C: Principal Investigator’s Certification of Review of Data Collection for Reviews Preparatory to Research
Research on Decedents’ Information

• A researcher may conduct research on decedents' information **IF:**
  – The use or disclosure is sought solely for the purpose of research on decedents’ PHI
  – The PHI for which the use or disclosure is sought is for research purposes only
  – Documentation is provided, at the request of LSUHSC-NO, of the death of such individuals.

• The researcher must provide certification of these requirements to the IRB/Privacy Board prior to conducting the research.
Where to find LSUHSC-NO’s Policy and Procedures on Research on Decedents’ Information

- LSUHSC-NO’s HIPAA policies and procedures on Research on Decedents’ Information is contained in Chancellor’s Memorandum (CM) 53 and may be found at:
  - Policy S: Human Subject/Patient Policy: Use and Disclosure of Protected Health Information for Research
  - Policy S Attachment B: Principal Investigator’s Certification of Requisition for Research on Decedent’s Information
Waiver of Authorization

• A patient’s authorization to use or disclose PHI for research purposes is not needed if the researcher obtains a Waiver of Authorization from the LSUHSC-NO IRB in accordance with CM-53 Section S Paragraph 3.4.
Authorization Waiver Criteria

• In order to approve a waiver of authorization request, the Board must determine that the use or disclosure of PHI involves:
  – A minimal risk to the privacy of the persons, based on the following elements:
    • An adequate plan to protect the identifiers from improper use and disclosure.
    • The research could not practically be conducted without the waiver or alteration
Authorization Waiver Criteria (cont.)

• An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or retention is required by law.

• The research could not practicably be conducted without the use or access to and use of the PHI.
Destruction of Unauthorized Data

• Any PHI obtained for research purposes without a VALID authorization or a waiver of authorization from the IRB must be removed from the research data set and destroyed.

• If any PHI obtained without a valid authorization or waiver of authorization, has been shared with a sponsor, publisher, or other external entity, that entity must be contacted and instructed to destroy the data.
Accounting of Disclosures

• Research disclosures pursuant to an authorization or disclosures pursuant to a limited data set are NOT subject to accounting requirements

• Research disclosures operating under a Privacy Board waiver to the authorization requirement ARE subject to accounting requirements.

• Contact the LSUHSC-NO Privacy Officer if you receive any requests for Accounting of Disclosures.
Where to find information on LSUHSC-NO’s Policy and Procedures on Accounting of Disclosures

• LSUHSC-NO’s HIPAA policies and procedures on Research on Accounting of Disclosures is contained in Chancellor’s Memorandum (CM) 53 and may be found at:
  – Policy C: Accounting of Disclosures of Protected Health Information
Research-Like Activities
Cadaveric Organ, Eye or Tissue Donation Purposes

- LSUHSC-NO may use or disclose PHI to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of organ, eye or tissue donation and transplantation.

- The disclosure of the PHI does not require a signed HIPAA Authorization form, but the disclosure IS subject to the minimum necessary standard.
Public Health Activities

• LSUHSC-NO is permitted to disclose to **public health authorities** or other agencies that are authorized by law to collect and receive data.
  – The disclosure of the PHI does not require a signed HIPAA authorization form;
  – The disclosure IS subject to the minimum necessary standard; however, LSUHSC-NO may rely on any representation of a public official who represents that the information requested is the minimum necessary for the stated purpose.
What is a Public Health Authority?

- A Public Health Authority is:
  - an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters, as part of its official mandate.

Contact the LSUHSC-NO Privacy Officer if you are unsure whether the entity requesting information is a public health authority.
Public Health Disclosures

• Disclosures may relate to:
  – The reporting of diseases or injuries;
  – “Vital events” such as births and deaths;
  – Reporting of child abuse and neglect; or
  – The conduct of public health surveillance, investigations, and interventions.
Public Health Disclosures (cont.)

• Disclosures to the FDA or to individuals or corporate persons subject to the jurisdiction of the FDA are permitted for the purposes related to quality, safety, and effectiveness of FDA-regulated products or activities. These include:
  – Collecting and reporting adverse events (or similar activities regarding food or dietary supplements), product defects or problems (including problems with the use or labeling of a product) or biological product deviations
Public Health Disclosures (cont.)

– Tracking FDA-regulated products
– Enabling product recalls, repairs, or replacement or for lookback (including locating and notifying persons who have received products that have been withdrawn, recalled, or are subject of lookback)
– Conducting post-marketing surveillance
Adverse Event Reporting

• LSUHSC-NO may disclose PHI to the FDA or any public health authority that is authorized to receive or collect a report on an adverse event, or to any agency if reporting such an event is required by law.
Role of Privacy Officer

• Responds to HIPAA privacy complaints
• Investigates reports of violations
• Implements policies and procedures
• Conducts educational programs
• Reviews LSUHSC’s privacy program
• Is available to answer any privacy questions or concerns
Reporting a HIPAA Violation

• If anyone suspects or knows of mishandling or misuse of patient PHI, a complaint can be made to:
  – The LSUHSC-NO Privacy Officer or the Office of Compliance Programs by:
  – Telephone at:
    • Office: (504)568-5135
    • Confidential reporting hotline: (504)568-2347
  – E-mail at: nocompliance@lsuhsc.edu
Penalties for HIPAA Violations

• There is a tiered system for assessing the level and penalty of each violation:
  
  – Tier A-violations that are accidental not intentional: fines of $100 per violation up to $25,000 for violations of an identical type per calendar year.
  
  – Tier B-violations due to reasonable cause and not willful neglect: fines of $1000 per violation up to $50,000 for violations of an identical type per calendar year.
Penalties for HIPAA Violations (cont.)

– Tier C- violations that the hospital corrected, but were due to willful neglect of the policies/procedures: fines $10,000 per violation up to $250,000 for violations of an identical type per calendar year.

– Tier D- violations due to willful neglect that the hospital did not correct: fines $50,000 per violation up to $1.5 million for violations of an identical type per calendar year.
Additional Penalties

- Loss of your job or student status.
- Individuals and health care providers (hospitals, etc.) also can face civil and criminal prosecution, depending on the facts of the case.
Questions?
We Are Here to Help!

Office of Compliance Programs
433 Bolivar St.
Suite 807
New Orleans, LA. 70112
Office: 568-5135
Hotline: nocompliance@lsuhsc.edu