



## HIPAA Research Tutorial

Health Insurance Portability and Accountability Act

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### HIPAA Overview

HIPAA is an acronym for Health Insurance Portability and Accountability Act. This federal law is best known for allowing individuals to maintain health insurance when they change employers. HIPAA establishes privacy standards in order to protect an individual's health information. This Act is designed to enable a person to go from one health insurance plan to another with continuity of care and not be denied coverage for a pre-existing condition (portability) and places protections for confidentiality of protected health information (PHI) that is collected (accountability). The privacy section of HIPAA, called the *Privacy Rule*, imposes restrictions on the use and disclosure of patient information by health care organizations and their employees.

The compliance date for health care facilities and providers was April 14, 2003. These regulations are administered by the Department of Health and Human Services, Office of Civil Rights. The University of South Alabama is committed to ensuring that PHI is collected, handled, transmitted and stored in a manner which preserves its confidentiality and privacy in accordance with the Privacy Rule.

### Who Needs to Comply With HIPAA Regulations?

HIPAA defines "covered entity" to mean a health plan; a health care clearinghouse; or a health care provider who transmits any health information in electronic form in connection with a transaction covered under the Act. "Protected health information" is defined as individually identifiable health information that is transmitted by electronic media; maintained in any medium meeting the definition of electronic media; or transmitted or maintained in any other form or medium. The University of South Alabama as a whole is a "Hybrid Entity" which consists of a single entity whose business includes covered and non-covered functions. The USA Health System has been designated as an Organized Health Care Arrangement (OHCA) which includes: USA Hospitals, USA Mitchell Cancer Institute, USA Physician's Group Clinics, USA Speech and Hearing Center, and USA Psychology Clinic. This means that within the OHCA different areas need to share protected health information about their patients, and that individuals who obtain services here expect that different areas share health information and are jointly managed. Anyone employed by a "covered entity" who uses PHI in the conduct of his/her research must comply.

### HIPAA Training Requirement

A covered entity (i.e., University of South Alabama) must train all members of its workforce on the policies and procedures with respect to protected health information required by the privacy rule, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity. These requirements must be fulfilled as outlined in [45 CFR 164.530(b)(1)] to ensure ongoing accountability for privacy and security of protected health information.

The University of South Alabama Hospitals HIPAA training is NOT interchangeable with HIPAA for

research purposes. The hospital based training program pertains to health care, while the Office of Research Compliance and Assurance requires that all researchers and key personnel complete HIPAA training as it pertains to research reviewed by the IRB.

This tutorial satisfies the training requirement set forth by the Privacy Rule as it pertains to research that utilizes protected health information during the course of a study

### **What Constitutes Research Activities?**

- Results are expected to be published or presented at a conference with attendees who are NOT faculty, staff or workforce of the University of South Alabama
- Activity intended to improve upon a medical device, pharmaceutical product, or diagnostic aid
- Activity intended to compare patient outcomes under two or more treatments, interventions or processes
- Activity which requires collection of information or imposes additional burdens beyond what is considered routine for clinical practice or patient care
- Class research project

### **When are Activities NOT Considered Research?**

- Public Health Disclosures - FDA and other government agencies
- Disclosures to government agencies in matters of national security
- Adverse event reporting
- Product recalls
- Post-marketing surveillance
- Related to tracking safety, quality or effectiveness of FDA-regulated projects

## **HIPAA Privacy Rule vs the Common Rule and FDA Regulations**

The Common Rule for the protection of human subjects and the FDA regulations acknowledge the importance of confidentiality, but the Privacy Rule goes beyond both these regulations to protect the privacy of the individuals, regardless of funding source.

The Privacy Rule builds upon existing federal protections and creates equal standards of privacy protection for research governed by existing federal human subjects regulations and research that is not. HIPAA adds additional points regarding privacy and PHI that need to be described to a research participant. The research participant must then authorize the use and disclosure of the PHI for the purposes described. More information on subject authorization will be discussed later in the tutorial.

Please remember that the Privacy Rule does not replace or modify the Common Rule [45 CFR 46] or the FDA regulations. When both HIPAA and human subjects regulations apply, both must be followed.

### **Privacy Rule Standards**

In general, the privacy rule:

- Limits the use and disclosure of health information
- Restricts the use and disclosure to the "minimum necessary" to conduct the research
- Establishes new requirements for access to medical records and the use and disclosure by

- researchers
- Establishes criminal and civil penalties for improper use and disclosure
- Gives the patient the right to: receive a Notice of Privacy Practice, list of possible disclosures, inspect / copy / amend their medical record, request alternate communications, and file a complaint about violations

## **Important Definitions**

**USE:** The "use" of PHI means the sharing, employment, application, utilization, examination or analysis of such information within an entity that maintains such information.

**DISCLOSURE:** A "disclosure" means the release, transfer, provision of access to or in any other manner of information outside the entity holding the information.

## **Minimum Necessary Rule**

HIPAA requires that the use and disclosure of a subject's PHI should be no more than minimum necessary to carry out the research. Specifically, the regulations acknowledge that "incidental uses and disclosures" inevitably occur and all that is required is "reasonable" effort by the institution's work force to achieve "minimum necessary" objective.

Both for healthcare and for research, HIPAA requires that PHI be communicated only on a "need to know" basis in the least or minimum amount necessary to adequately conduct the research. The minimum necessary rule does not apply to disclosures made for treatment or uses/disclosures made within the scope of a valid authorization obtained from the research participant.

## **Protected Health Information (PHI)**

### **What is Protected Health Information (PHI)?**

Protected health information is individually identifiable health information that is collected for treatment, diagnosis or research purposes. HIPAA details eighteen items that render PHI identifiable:

*Names*

*Account numbers*

*All geographic subdivisions smaller than a state*

*Certificate/license numbers*

*All elements of dates*

*Vehicle identifiers/serial numbers (license plates numbers) Telephone numbers*

*Device identifiers and serial numbers*

*Fax numbers*

*Web universal resource locators (URLs) Email addresses*

*IP address*

*Social security numbers Biometric identifiers Medical record numbers*

*Full face photographic images and comparable images*

*Health plan, beneficiary numbers*

*Any other unique identifying number, characteristic or code*

Research that is stripped of all eighteen identifiers is not regulated by HIPAA, as it is considered "de-identified". PHI can be de-identified for research purposes by removing the 18 identifiers and using a linked code for which access is extremely limited and protected. PHI may be released for treatment, payment and healthcare operations but NOT for research purposes without obtaining authorization in advance.

### **Privacy Rule Stipulates**

The Use or Disclosure of PHI for research requires either:

A written Authorization from the research participant

--OR--

A Waiver approved by the IRB

--OR--

Verification that the research involves:

- De-identified data
- Limited Data Sets
- Reviews Preparatory to Research
- Decedents' Information

## **Obtaining Authorization for the Use and Disclosure of PHI**

The HIPAA Privacy Rules characterize two basic types of written agreement that are utilized to secure the permission of an individual for the use and disclosure of his/her PHI. The first type is a general written consent by individuals for the use and disclosure of their PHI for treatment, payment and health care operations ("TPO") in the non-research setting. This written consent provides one-time blanket permission for a covered entity to use PHI for various purposes related to clinical care.

The second type of written agreement involves authorization for the use of PHI for specific purposes other than TPO. Specific written authorization is required for the use and disclosure of PHI in research studies. Under the regulations, this authorization may be incorporated into consent forms for clinical research or may be secured via a separate authorization form. The University of South Alabama IRB Office has adopted the option of including the authorization in the consent form for research studies.

### **Permitted Research Disclosures of PHI by the Privacy Rule**

The HIPAA Privacy Rule outlines the conditions under which health care data may lawfully be used for research purposes. The regulations apply to research if protected health information is used, created or disclosed during the study. A researcher's access to PHI must meet one of two conditions:

- 1) Permission is granted by the patient, through a written authorization form

--OR--

2) One of the following criteria must be met:

- IRB Waiver of Subject Authorization
- Review Preparatory to Research
- Use of Limited Data Set with Data Use Agreement
- Research using Decedents' Information (note: decedent research not covered by Common Rule)
- Use of De-identified Data and no longer governed by HIPAA

**All research projects that use PHI will fall into one of the categories listed above.** The remainder of this tutorial describes the various conditions for using PHI in research and information about how the rules are being applied at the University of South Alabama.

## **Research Use of PHI with Authorization**

Written authorization from the subject is the default requirement for use of protected health information in research. Prospective research, such as a clinical trial, generally requires prior authorization. The authorization differs from informed consent in that the authorization obtains specific permission to use and disclose protected health information for the research project. When written authorization is required, the Office of Civil Rights dictates very specific elements that must be contained in the authorization:

A valid authorization for the release of PHI for research purposes requested by or asked of a potential subject in a research study must be retained for at least six years from the date permission is granted and must contain the following required core elements:

- 1) a description of the information to be used or disclosed that identifies the information in a specific and meaningful manner
- 2) the name of the covered entity or person(s) authorized to make the requested use or disclosure
- 3) the name or other specific identification of the person(s) or entities which may include the covered entity itself to whom the covered entity may make the request for use or disclosure
- 4) an expiration date and a signature and date
- 5) the authorization must be written in plain language
- 6) if the authorization is executed by a legal representative authorized to act for the individual, a description of his/her authority to act for the individual must be specified as well as the relationship to the individual
- 7) a statement that the individual acknowledges that he/she has the right to revoke the authorization except to the extent that information has already been disclosed under the authorization
- 8) a statement that the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the federal privacy law
- 9) a description of the purpose(s) of the requested use or disclosure
- 10) a statement that the individual may inspect or copy the protected health information to be used or disclosed
- 11) a statement that the individual may refuse to sign the authorization.

The USA IRB has mandated that the authorization language be included in the written informed

consent within the confidentiality section. Although the authorization can be separate from the informed consent document per the HIPAA regulations, the IRB has adopted that these documents be combined as it simplifies the procedure for authorization.

The core elements listed above must be provided in writing to prospective subjects in securing authorization for the research use of their PHI. The USA HIPAA Subject Authorization template has been designed to incorporate standard language for the statements required above. This template is available in IRBNet in Forms and Template. Investigators will only need to specify to whom and where the PHI will be sent and what type of PHI will be used and disclosed.

## **Waiver of Authorization**

A covered entity is permitted to disclose PHI for research purposes without a written authorization when approval is obtained from the IRB. Generally, a waiver of authorization will be required if the investigator plans to access medical charts for a research purpose without obtaining consent from the subject. In most cases, if a protocol qualifies for a waiver of informed consent, it will be able to qualify for a waiver of authorization under HIPAA. Retrospective chart reviews and certain phone surveys are examples of research that may qualify for a privacy waiver. The investigator must provide information about the research study that enables the IRB to determine that three requirements are satisfied:

- 1) there must be no more than minimal risk to the privacy of the individual subjects based upon the presence of the following elements:
  - an adequate plan to protect the identifiers from improper use and disclosure;
  - an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law;
  - an adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure is permitted without authorization.
- 2) it must NOT be practicable to conduct the research without the waiver or alteration of the authorization requirement; and
- 3) it must NOT be practicable to conduct the research without access to and use of the PHI.

In planning a project that employs a waiver of authorization, researchers should consider their responsibility to comply with the "minimum necessary" standard of the Privacy Rule. Only the minimum amount of PHI should be used and disclosed, as necessary to accomplish the goals of the research. For example, date of birth should not be recorded if age will suffice.

To apply for a waiver of authorization, the USA Waiver of Authorization form should be completed for approval. This form is available in IRBNet in Forms and Template.

### **Waiver of Authorization: Review Process**

Generally, a request for a waiver of authorization will be assessed utilizing an expedited review

process. A full committee review will be required in those circumstances where a waiver has been requested by risk to the subject's privacy is considered to be greater than minimal. The IRB follows the Common Rule when reviewing the waiver request. Once the IRB has approved the waiver of authorization, the investigator must provide the covered entity maintaining the PHI with documentation from the IRB of approval. A waiver of authorization may be sought for three specific research uses of PHI to identify potential research subjects through:

- review of their PHI
- to contact potential subjects in order to determine their interest in research participation
- to receive or collect PHI during the conduct of research studies

## **Reviews Preparatory to Research**

The Privacy Rule recognizes the necessity of accessing PHI, without patient authorization, in order to prepare a research protocol. This "preparatory to research" provision may be useful for examining medical records in order to formulate hypotheses, assess feasibility of a project, or determine the availability of data or a patient base. Researchers may **review** identifiable data in order to make these determinations; however, HIPAA requires that any information recorded during the review must meet de-identification standards. Thus, the preparatory review may not be used for study recruitment because researchers may not record names and contact information from the charts.

In order to release records for a preparatory review, the holder of the medical record must receive certain documentation from the researcher. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

- The information is being sought solely to prepare a research protocol or for similar purposes
- Only de-identified data will be recorded during the review
- No protected health information will be removed from USA campuses.
- The information being sought is necessary for research purposes.

The Privacy Rule does not require IRB approval of activities preparatory to research. As a general rule, this pre-research activity will not require an IRB application because no formal protocol exists. Questions about the necessity of IRB review should be directed to the IRB office. Investigators may use PHI as preparatory to research if the investigator certifies the above provisions by completing Appendix D, Reviews Preparatory to Research form available in IRBNet in Forms and Template.

## **Research Involving Decedents and Limited Data Sets**

Research on decedents is not subject to human subject regulations; however, the Privacy Rule now requires that we oversee the use of decedent information for research purposes. In order to access medical records on decedents, the researcher must provide the holder of the medical record with assurances that:

- The information being sought is solely for research on decedents
- The information being sought is necessary for research purposes

The holder of the medical record has a right to require documentation of the death of the individuals.

Investigators may use PHI in research on decedent's information if the investigator certifies the above provisions by completing the Appendix E, Research Involving Decedent's form available in IRBNet in

Forms and Templates. This certification should be given to the holder of medical records for access to the information.

## **Research Involving the Use of Limited Data Sets**

Regulations permit covered entities to use or disclose PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

- Names
- postal address information, other than town or city, state and zip code
- telephone numbers
- fax numbers
- email addresses
- social security numbers
- health plan beneficiary numbers
- account numbers
- certificate/license numbers
- vehicle identifiers and serial numbers
- device identifiers and serial numbers
- web universal resources locators (URLs)
- Internet protocol (IP) address numbers
- biometric identifiers, including finger and voice prints
- full face photographic images and any comparable images

A limited data set may, however include other indirect identifiers such as:

- City, State, 5-digit zip code
- Dates of birth, admission / treatment, discharge, death, etc.

A Limited Data Set is considered to be protected health information under the Privacy Rule. For this reason, the researcher must negotiate a Data Use Agreement for the project. The agreement must contain the following elements:

- The permitted uses and disclosures by the recipient
- The approved users and recipients of the data
- Agreement by the recipient not to re-identify the data or contact the individuals
- Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the data use agreement
- Agreement that the researcher will report to the covered entity any uses or disclosures of the limited data set which were not specifically allowed
- Agreement to require that any agents and subcontractors adhere to the same safeguards

Investigators may use or disclose a limited data set without subject authorization for research purposes only if an assurance is obtained in the form of a Limited Data Use Agreement available in IRBNet Forms and Templates.



## **De-identified data, Subject's Rights, and Recruitment**

### **De-Identified Information**

The de-identified health information under HIPAA is much more specific than the general de-identification standard applied under the federal laws relating to human research subjects. PHI can be released freely if it does not contain "individually identifiable information." PHI is not individually identified if the subject is not identified, directly or indirectly, and has no reasonable basis to believe that the information can be used to identify the subject. For example, a de-identified data set might include age, gender, marital status, ethnicity, diagnosis codes, and other medical data or an unidentified tissue sample. It may be used in research without subject authorization or a waiver of authorization. The Privacy Rule refers to such health information as "de-identified data." Research which involves the use of "de-identified data" is exempt from the HIPAA requirements. To be exempt from HIPAA, none of the 18 subject identifiers can be reviewed or recorded by the research team. In order to de-identify PHI, the investigator will comply with one of the two following procedures:

A. *Use of a Statistician to include:*

- Obtain services of a person with appropriate experience and knowledge applying generally acceptable statistical and scientific principles and methods for determining that the information is not individually identifiable;
- Who makes a determination that there is a very small risk that the information could be used by itself or in combination with other available information by the anticipated recipient(s) to identify the subject with the information; and
- Who documents the methods and results in making such determination.

B. *Removal of all identifiers*

- Removal of all 18 identifiers listed above in the PHI section and have no actual knowledge that the information remaining could be used alone or in combination with other information to identify the patient who is the subject of the information.

## **Research subjects' rights under HIPAA**

### **Right to an accounting:**

When a research subject signs an authorization to disclose PHI, the covered entity is not required to account for the authorized disclosure. Nor is an accounting required when the disclosed PHI is contained in a limited data set or is released to the researcher as de-identified data. However, an accounting is required for research disclosures of identifiable information obtained under a waiver or altered authorization, reviews preparatory to research and research on decedents.

In addition to posting and providing a Notice of Privacy Practice, the covered entity must provide an accounting of all disclosures of an individual's PHI within the previous six years, upon request. It is anticipated that requests for an accounting of disclosure will come to the hospitals and the medical records department will respond in accordance with the policy on HIPAA: Accounting of Disclosures.

### **Right to revoke authorization:**

A research subject has the right to revoke his or her authorization unless the researcher has already

acted in reliance on the original authorization. Under the authorization revocation provision, covered entities may continue to use or disclose PHI collected prior to the revocation as necessary to maintain the integrity of the research study. Examples of permitted disclosures include submissions of marketing applications to the FDA, reporting of adverse events, accounting of the subject's withdrawal from the study and investigation of scientific misconduct.

## **Research Recruitment**

The Department of Health and Human Services states that covered entities may continue to discuss with patients the option of enrolling in a clinical trial. This can be done without subject authorization and without an IRB waiver of authorization. Similarly, direct care providers may communicate with their current or past patients about research opportunities without prior authorization of these patients. This permission does not extend, however, to disclosure of information to a third party for purposes of recruitment. In the latter case, the covered entity either has to obtain an authorization from the individual or secure a waiver of authorization as permitted by the Privacy Rule. The use of a partial waiver of authorization from the IRB would allow researchers to get specific information from other practitioners. The written permission or the waiver allows the researcher to view the patients PHI in order to make a determination about study eligibility.

Once a potential subject has been identified, research teams should follow appropriate ethical standards about contacting the patient. The initial contact should come from someone who is known to the patient as having knowledge of their health status, based on an established clinical relationship.

The need for a waiver of authorization for study recruitment should be assessed by the researcher at the time of submission of the IRB application.

### **Research Recruitment Practices**

After IRB approval has been granted, allowable recruitment practices for research include:

1. Health care providers who are conducting a study may talk with their own patients about the option of study enrollment.
2. Health care providers may use their own knowledge of the patient's condition and their knowledge about a colleague's study to inform their patients about a study. At that point, two possibilities exist:
  - a. the provider gives the researcher's contact information to the patient, and the patient initiates the contact
  - b. the patient signs a pre-approved authorization so that the provider can give the patient's name to the researcher.
3. Health care providers may release their patient records to a researcher, if the researcher obtains a waiver of authorization from the IRB office. Then the researcher can review the charts, determine eligibility, and work with the provider to contact potential subjects.
4. The researcher posts IRB approved flyers or advertisements, and eligible patients directly contact the researcher.

## **Pre-screening Logs**

Pre-screening logs which are used to document recruitment efforts in clinical trials often include PHI, such as initials, or dates of procedures. These logs should NOT be shared with a pharmaceutical sponsor without some form of privacy protection. In order to comply with the Privacy Rule, the data may be de-identified prior to sharing with the study sponsor. Alternately, if de-identified data is not feasible, the study sponsor can sign a Data Use Agreement and obtain the information in the form of a Limited Data Set.

## **Repositories and Databases**

### **Research Repositories:**

It may be necessary to create a repository that will support future research activities. The Privacy Rule specifies three ways in which PHI can be compiled for a research repository:

- individual, written authorization obtained from the subject
- waiver of the individual authorization requirement obtained from an IRB
- the PHI is obtained from a covered entity in a limited data set and accompanied by a data use agreement

If the repository is being created as new patients come to USA hospitals, the collection of data or tissue samples generally requires informed consent and authorization for the use and disclosure of PHI. Researchers should note that if approval is granted for the general purpose of constructing and maintaining the repository, then subsequent studies of the material also require IRB oversight. Depending on the nature of the subsequent study, the IRB will determine whether informed consent/HIPAA authorization is required or if the informed consent/HIPAA authorization requirement is waived.

### **Research Databases:**

If a researcher maintains a database containing PHI, then the investigator has an obligation to insure that the use and disclosure of PHI is in compliance with HIPAA policies.

- A. Maintaining applicable security for the database, including physical security and access control;
- B. Control and manage the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and
- C. Any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

Remember, HIPAA applies to uses of PHI. In order to use a research database containing PHI, one must have authorization or a waiver from the IRB. Another pathway to using PHI in a research database is by utilizing a limited data set and completion of a Limited Data Use Agreement, enabling certain identifiers to be used during the research study. The users of a tissue bank database would need to obtain individual authorization or a IRB waiver if he/she wanted to use and disclose the information in a research study.

## Security

### Computer Security for Research Records

HIPAA requires that privacy of PHI be maintained by limiting its use and maintaining appropriate computer security. Basic and well-established security principles will support our compliance efforts. These include:

- practicing "role-based access" to ensure that permissions for research files are commensurate with the employee's role in the project
- establishing password protections on electronic files
- storing records on secure networks and servers
- assuring that release of computerized research records conforms to HIPAA rules about allowable disclosures

### HIPAA Security Measures

HIPAA requires that we maintain the privacy of PHI by limiting its uses and disclosures and that reasonable steps be taken to ensure that PHI is secure. Typically, breeches in privacy can be traced to relaxed security, therefore some steps to secure data include:

- Access to paper files be limited by locking file cabinets or locking rooms with files
- Avoid sending PHI in email or as email attachments. Email attachments should be password protected and possibly may require encryption depending on the sensitivity of the data.
- Password protection on all computers maintaining PHI
- Databases containing PHI may need additional level of password protected in order to restrict access to the database itself

## Conclusion

The right to privacy in research has long been recognized as foundational to ethical conduct. Individuals wish to be asked about the use of their medical records for research and we must protect their privacy and dignity when using their medical information. As a result, the Privacy Rule creates expanded rights for research subjects and significant legal obligations when protected health information is used for research purposes. USA policies and procedures address these requirements as outlined in this tutorial and the HIPAA Compliance Plan for Clinical Research available at: <http://www.southalabama.edu/departments/research/compliance/humansubjects/hipaa.html>

## Questions?

If you have any questions regarding the content of this training material or it's applicability, please email Ms. Dusty Layton, Office of Research Compliance and Assurance at [dlayton@southalabama.edu](mailto:dlayton@southalabama.edu) or call 460-6625.

## **Additional Resources**

Additional information and resources regarding the HIPAA Privacy Rule are available at:

DHHS Office of Civil Rights HIPAA Website: <https://www.hhs.gov/hipaa/>

National Institutes of Health: HIPAA Privacy Rule- Information for Researchers  
[https://privacyruleandresearch.nih.gov/pr\\_02.asp](https://privacyruleandresearch.nih.gov/pr_02.asp)

### **Resources referenced to create this training module include:**

USA HIPAA Research Website (HIPAA Research Compliance Plan):  
<http://www.southalabama.edu/departments/research/compliance/humansubjects/hipaa.html>

Office for Civil Rights HIPAA Guidance, December 2002

University of Kansas Medical Center



## HIPAA Research Tutorial

H e a l t h i n s u r a n c e Portability and A c c o u n t a b i l i t y A c t

*Please save this page as your certificate of completion,  
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By selecting the checkbox and entering your name below, you confirm that you have received educational materials regarding the Privacy Rules and its impact on University of South Alabama (USA) Research. You understand that the Privacy Rules govern the manner in which protected health information (PHI) can be used and disclosed by USA, and that you are required to follow the policies and procedures set forth in the USA HIPAA Privacy Compliance Plan for Research.

As necessary, you will seek advice from you Supervisor or the Office of Research Compliance regarding any questions related to privacy compliance activities. You will also report to your Supervisor or the Office of Research Compliance any suspected violations of the USA HIPAA Privacy Compliance Plan for Research.

***You acknowledge understanding of the above information and agree to comply with the USA HIPAA Privacy Compliance Plan for Research.***

Name: \_\_\_\_\_ Date: \_\_\_\_\_

**If applicable, please enter your advisor's name below:**

Advisor's Name: \_\_\_\_\_

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