Corporate Policy
on
Research Privacy under HIPAA

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NOTE

The HIPAA Privacy Rule ensures protections for certain individually identifiable health information that qualifies as "Protected Health Information." The rule is complicated and interfaces with other research review and approval requirements. Institutions subject to HIPAA must be in compliance with the rule by April 14, 2003.

DISCLAIMER

Given the newness of the HIPAA regulation, additional interpretation and guidance will likely be forthcoming from the Department of Health and Human Services (HHS) on a regular basis. These new issuances may have an impact on the information contained in this manual. Therefore, the manual may become incomplete or inaccurate as a result of evolving government standards.

This manual only addresses the impact of the HIPAA regulations as they affect research involving human subjects.

Individuals should consult the website of the HHS Office of Civil Rights, which is managing questions relating to HIPAA. That website is located at http://www.hhs.gov/ocr/

Chapter 1.
Research Privacy: The Ethical Mandate

GOAL	**Protect Individual Privacy and Safeguard the Confidentiality of Identifiable Private Information**

Reference	***Declaration of Helsinki***

Patient and research subject privacy and confidentiality have long been recognized as an important global concern. The World Medical Association Declaration of Helsinki (updated October 2000) states: “It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.” For Institutional Review Boards (IRBs) that review and approve research subject to the Federal Policy for the Protection of Human Subjects, privacy and confidentiality have always been significant considerations under the regulations.

Concerns over the unauthorized disclosure of personal information affect everyone. Whether the information relates to finance, insurance, education, medical matters, clinical research, social situations, or medical secrets, control over who receives personal information, and how that information is used has a significant effect on all citizens. Today, technological advances make the transfer of information more expeditious and efficient and have complicated our ability to protect private information.

In biomedical and behavioral research, the use of private and confidential information is not only commonplace, but is an essential element of valuable research. However, there is a genuine possibility that the methods employed to gather information about research subjects might invade the privacy of the subject, or that use of clandestinely disclosed personal medical information could breach confidentiality. In both instances, the research institution has the responsibility to exercise control over the release and use of personal information.

Before research is approved and conducted, the institution is responsible for safeguarding how a patient or research subjects’ private medical information will be released for the development of research protocols or for research participation. Similarly, the institution’s responsibility to the subject continues during and after research to ensure that any sensitive information received during the conduct of the research remains confidential and protected.

Chapter 2.
Research Privacy: The Regulatory Mandate

Goal:	**Safeguard and Manage the Use and Disclosure of "Protected Health Information"**

General Rule:	**HIPAA permits the Use and Disclosure of "Protected Health Information" for routine treatment, payment and health care operations** • **Consent is not required to use or disclose Protected Health Information for treatment, payment, or health care operations** • **A "Notice of Privacy Practices" must be provided that describes such uses and disclosures**

Regulatory References:	
The HIPAA Privacy Regulations:	**45 CFR Parts 160 & 164**
Notice of Privacy Practices:	**45 CFR 164.520**
Organizational Requirements:	**45 CFR 164.530 & 164.532**
Compliance Deadline:	**45 CFR 164.532(c) & 164.534(a)**

In accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the Department of Health and Human Services (DHHS) published regulations on December 28, 2000 (65 FR 82462) establishing "Standards for Privacy of Individually Identifiable Health Information."

Commonly referred to as the "Privacy Rule, these regulations were subsequently amended on August 14, 2002 (67 FR 53182). For most affected organizations (so-called "covered entities"), compliance with the regulations was required no later than April 14, 2003.

The Privacy Rule governs the use and disclosure in research of "Protected Health Information" by "covered entities" (a term that includes almost all providers of healthcare services, healthcare organizations, and organizations that conduct research related to healthcare). In addition to information that is collected for clinical, diagnostic, or other purposes, the Rule also governs the use and disclosure of health information that is created or produced specifically for research.

Notably, the HIPAA privacy requirements apply to all research involving the use or disclosure of "Protected Health Information" by "covered entities," regardless of the funding source for the research. Thus, even privately-sponsored research, conducted by private physicians in their private offices, is subject to the Privacy Rule, as long as the physicians are considered "covered entities" under the regulatory definition that includes almost all providers of healthcare services.

A. Overall Effects of HIPAA

Fundamentally, the HIPAA Privacy Rule creates standards that:

- Give people more control over their health information.
- Establish safeguards to protect the privacy of health information.
- Set rules for the use and release of health information and records.
- Create civil and criminal penalties for violations of privacy standards.

For patients and research subjects, the Privacy Rule:

- Restricts the use and disclosure of their health information to particular situations, except as specifically authorized by the patient-subject.
- Limits the use and disclosure of their health information to the minimum reasonably needed, except as specifically authorized by patient-subject.
- Provides for an accounting of how their health information has been used and disclosed.
- Provides the right to examine and obtain a copy of their health records and request corrections.

For research investigators, the Privacy Rule:

- Requires either an Authorization from the patient-subject or a waiver by an Institutional Review Board (IRB) or a Privacy Board to use or disclose Protected Health Information.
- Requires methodical tracking of disclosures of Protected Health Information.

For covered healthcare organizations, the Privacy Rule:

- Requires appropriate administrative, technical, and physical safeguards to protect the privacy of Protected Health Information.
- Requires designation of a "Privacy Official" to be responsible for the development and implementation of the organization's Privacy Rule policies and procedures.
- Requires a process to receive and document complaints concerning its Privacy Rule protections.

- Requires a process to provide and document adequate and timely training of all members of its workforce on its policies and procedures for dealing with Protected Health Information.
- Requires a process to provide and document appropriate sanctions against members of its workforce who fail to comply with Privacy Rule requirements.
- Requires practicable mechanisms to mitigate any harmful effects of violations of Privacy Rule requirements.
- Requires that a "Notice of Privacy Practices" be provided to all research subjects.
- Prohibits action to intimidate, threaten, coerce, discriminate against, or retaliate against any individual for exercising the rights under the Privacy regulations.

B. Compliance Deadline

For most health care organizations and providers, including THR, compliance with the HIPAA Privacy requirements was required no later than April 14, 2003 [§164.534(a)].

Research Consents Obtained Prior to April 14, 2003. Protected Health Information may continue to be created, received, used, or disclosed for research after April 14, 2003 (the Privacy Rule compliance deadline), if one of the following has been obtained prior to the April 14, 2003 deadline:

1. Express legal permission or authorization from the individual to use or disclose Protected Health Information for the research.
   or
2. The informed consent of the individual to participate in the research.
   or
3. Approval by the relevant IRB of a waiver of informed consent requirements in accordance with the requirements of the Common Rule and DHHS regulations at 45 CFR 46.116(d).

Thus, Privacy Rule protections are not required for the use in research of Protected Health Information of subjects who have provided informed consent for the research prior to April 14, 2003. However, Privacy Rule protections are required for the use of Protected Health Information of any subject enrolled in the research on or after April 14, 2003 [§164.532(c)].

C. Penalties for Violation of HIPAA Requirements

The HIPAA statute sets substantial civil and criminal penalties for violations of HIPAA requirements.

Civil penalties. Violations of HIPAA privacy standards are subject to civil liability.

i. $100 per violation, with an annual cap of $25,000, for violations where the person did not know (and by exercising reasonable diligence would not have known) that such person committed a violation;

ii. $1,000 per violation, with an annual cap of $100,000, for violations due to reasonable cause and not to willful neglect;

iii. $10,000 per violation, with an annual cap of $250,000, for violations due to willful neglect that are corrected within thirty (30) days of the date the person knows (or should have known) that the violation occurred; and

iv. $50,000 per violation, with an annual cap of $1,500,000 for violations due to willful neglect that are not corrected within the thirty (30) day period. The$50,000 per violation/$1,500,000 per year penalties are the maximum penalty that may be imposed under any of the categories of violations.

The HHS Secretary has the discretion to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) that such person committed a violation.

Criminal penalties. Congress also established criminal penalties for certain actions, such as knowingly obtaining protected health information in violation of the law. Criminal penalties include:

- Up to $50,000 and one year in prison for certain offenses.
- Up to $100,000 and up to five years in prison if the offenses are committed under "false pretenses".
- Up to $250,000 and up to 10 years in prison if the offenses are committed with the intent to sell, transfer or use protected health information for commercial advantage, personal gain or malicious harm.

Chapter 3.
Basic Regulatory Definitions

Goal:	**Clarify Basic Definitions Found in the HIPAA Regulations**

Regulatory References:	
HIPAA Privacy Definitions:	**45 CFR 160.103 & 164.501**

The HIPAA Privacy Rule added requirements for the "use" and "disclosure" of "Protected Health Information" gathered or used by a "Covered Entity" in the course of "research" activities.

THR's Privacy Policy Standard Definitions are provided in Appendix B. Most HIPAA definitions are found in §160.103 and §164.501 of the HIPAA regulations, which are provided in Appendix C.

The following definitions directly affect the conduct of human subject research. All personnel involved in the conduct of human subject research should be familiar with these basic terms.

Authorization. Permission from an individual to use or disclose Protected Health Information for a purpose other than Treatment, Payment, or Health Care Operations. A valid authorization must be written in plain language and must include six core elements and three required statements. The individual must be given a signed copy of the authorization that she or he has provided [45 CFR 164.508(c)]. Authorization to use or disclose Protected Health Information for research purposes may be included in the research informed consent document. Sample language for authorization to use or disclose information for research is provided in Appendix A.

Breach. The acquisition, access, use or disclosure of PHI which compromises the security or privacy of the PHI. Breach excludes:

- Any unintentional acquisition, access or use of PHI by a Workforce member or person acting under the authority of the entity or a Business Associate, if such acquisition, access or use was made in good faith and within the scope of authority and does not result in further use or disclosure.
- Any inadvertent disclosure by a person who is authorized to access PHI at an entity or Business Associate to another person authorized to access PHI at the same entity or Business Associate, or Organized Health Care Arrangement in which the entity participates, and the information received as a result of such disclosure is not further used or disclosed.

- A disclosure of PHI where the entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain the information.

An acquisition, access, use or disclosure of PHI is presumed to be a breach unless the entity or business associate demonstrates that there is a low probability that the PHI has been compromised based upon a risk assessment of at least the following factors:

- The nature and extent of the PHI involved, included the types of identifiers and the likelihood of re-identification;
- The unauthorized person who used the PHI or to whom the disclosure was made;
- Whether the PHI was actually acquired or viewed; and
- The extent to which the risk to the PHI has been mitigated.

Business Associate. A person or Subcontractor of the Business Associate who performs, or assists in performing, a function or activity of a Covered Entity that involves the creation, receipt, maintenance, or transmission of protected health information [§160.103]. Such use or disclosure usually requires a formal Business Associate Contract/Agreement. However, use or disclosure of health information for research purposes does NOT require a Business Associate Contract/Agreement, even where the researcher has been hired by the Covered Entity to perform research on its own behalf. Research sponsors and collaborators are not considered Business Associates unless they also perform a function regulated by the Administrative Simplification Rules, such as payment , claims billing, or health care operations. Of course, the covered entity can require written agreements with research sponsors and collaborators as it deems necessary or desirable. The THR Business Associates Policy is provided in Appendix B.

Covered Entity. A health plan, health care clearinghouse, or a health care provider who transmits any health information in electronic form [§160.103]. THR is a Covered Entity under HIPAA.

Data Use Agreement. An agreement between a Covered Entity and the person or institution that will receive a Limited Data Set. The agreement must state that the recipient will only use or disclose the information in the Limited Data Set for specific, limited purposes [§164.514(e)(4)]. A Sample Data Use Agreement is provided in Appendix A.

De-Identified Information. Health information that does not identify an individual. Health information can be rendered de-identified either by (i) removal of 18 specified kinds of information about the individual and the individual's relatives, employers, or household members; or (ii) documentation from a professional knowledgeable in statistical and scientific methods that the risk of identification is very small [§164.514(b)]. De-identified information is not subject

to the HIPAA privacy requirements [§164.514(a)]. THR's De-Identification Policy is provided in Appendix B.

Designated Record Set. A group of records (including any item, collection, or grouping of information that contains Protected Health Information) that is used by or for a Covered Entity to make decisions about individuals. Designated record sets include (but are not limited to) medical records, billing records, health plan enrollment records, payment records, claims records, case management records, and medical management records [§164.501].

Disclosure. The release, transfer, provision of access to, or divulging in any manner of information outside the Entity holding the information [§164.501].

Individually Identifiable Health Information. Any information, including demographic information collected from an individual, that:

- Is created or received by a health care provider, health plan, employer, or health care clearinghouse.
  and
- Relates to (a) the past, present, or future physical or mental health or condition of an individual; (b) the provision of health care to an individual; or (c) the past, present or future payment for the provision of health care to the individual.
  and
- Identifies the individual or there is a reasonable basis to believe can be used to identify the individual [§160.103].

Institutional Review Board (IRB). A committee established to review and approve research involving human subjects in accordance with FDA (21 CFR Part 56) and DHHS Human Subject Protection regulations (45 CFR Part 46). When authorized by the Covered Entity, IRBs may grant waivers of the Privacy Rule's usual requirement for Authorization from the patient-subject for the Use or Disclosure of Protected Health Information in research. Covered Entity's may establish separate Privacy Boards for this purpose, or may delegate this authority to their IRBs [§164.512(i)(1)(i)].

Legally Authorized Representative. A personal representative who has the authority under applicable State law to sign an authorization on behalf of another individual. HIPAA requires that a description of the representative's authority to act for the individual must be provided with the authorization [§164.502(g), 164.508(c)(vi)]. THR policy (see Standard Definitions in Appendix B) recognizes the following legally authorized representatives:

> (1) A parent or legal guardian, if the patient is a Minor;
> (2) a legal guardian, if the patient has been found by a court to be incapable of managing the patient's personal affairs;

(3) an agent of the patient authorized under a Medical Power of Attorney for the purpose of making a health care decision when the patient is incompetent; (4) an attorney ad litem and/or guardian ad litem appointed for the patient by a court;
(5) A person authorized to consent to medical treatment on behalf of the patient under Chapter 313 of the Texas Consent to Medical Treatment Act
(6) a personal representative or heir of the patient, if the patient is deceased; (7) an attorney retained by the patient or by the patient's legally authorized representative;
(8) a person exercising a power granted to the person in the person's capacity as an attorney-in-fact or agent of the patient by a Statutory Durable Power of Attorney that is signed by the patient as principal. (See THR Policy on Health Information Uses and Disclosures for full definition).

Limited Data Set. Health information that excludes 16 specified kinds of information about the individual and the individual's relatives, employers, or household members. Limited data sets may be used or disclosed for purposes of research under a written Data Use Agreement that satisfies seven specified criteria [§164.514(e)].

Minimum Necessary Standard. A Covered Entity must make reasonable efforts to use, disclose, or request the least amount of information needed for the intended purpose [§164.502(b)]. THR's Minimum Necessary Use and Disclosure Policy is provided in Appendix B. Relative to research, the Minimum Necessary Standard applies to use or disclosure under (i) a Waiver of Authorization; (ii) Activities Preparatory to Research; (iii) Decedents Information; and (iv) "Limited Data Sets" (the latter also require a Data Use Agreement [§164.514(e)]). The Minimum Necessary Standard does **not** apply to (i) uses or disclosures made under an Authorization, including an Authorization for research [§164.502(b)]; and (ii) Protected Health Information that has been "de-identified" [§164.502(d)].

Minor. An individual who has not reached the age at which a person is legally competent or responsible. In the State of Texas, a minor is a person under 18 years of age who has not (i) been married or (ii) had minority status removed by a court.

Privacy Board. A committee established under HIPAA to grant waivers of the Privacy Rule's usual requirement for Authorization from the patient-subject for the Use or Disclosure of Protected Health Information in research. Covered Entity's may establish separate Privacy Boards for this purpose, or may give this authority to their IRBs [§164.512(i)(1)(i)].

Protected Health Information. Individually identifiable health information that is transmitted or maintained electronically or in any other form or medium, including

on paper or orally. Protected Health Information does **not include**: (1) education records covered by the Family Educational Rights and Privacy Act, (2) a hospital's Individually Identifiable Health Information regarding a patient who has been deceased for more than 50 years, (3) a physician's medical record for patients: who have been deceased for more than 50 years where the records are at least 75 years old and where the records are requested for historical research purposes only (Tex. Occupations Code. §159.002(d)), and (4) employment records held by a Covered Entity in its role as an employer [§164.501].

Psychotherapy Notes. Notes recorded in any medium by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the medical record. *Psychotherapy Notes* do not include medication prescription and monitoring; session start and stop times; modalities and frequencies of treatment furnished; results of clinical tests; and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, or progress [§164.501].

Re-Identification. Use of a code or other means designed to enable coded or otherwise de-identified information to be rendered identifiable. Protected Health Information that is re-identified is subject to the usual HIPAA privacy requirements [§164.502(d)(2)(i),(ii)].

Research. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [§164.501].

Subcontractor. A person to whom a Business Associate delegates a function, activity, or service, other than in the capacity of a Workforce member of the Business Associate.

Use. The sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an Entity that maintains such information [§164.501].

Chapter 4.
THR Research Privacy Mechanisms

Goal:	**Clarify THR Mechanisms for Managing the Use and Disclosure of "Protected Health Information" in Research**

General Rule:	**THR Research Privacy Protections are implemented at both the Corporate and Entity levels**

Regulatory References:	
Administrative Requirements:	**45 CFR 164.530**
HIPAA Applicability:	**45 CFR 164.104 & 164.500**

A. THR Officials

The following individuals are responsible for implementing HIPAA privacy requirements within THR.

THR Privacy Officer. The THR Chief Compliance Officer shall designate an individual to serve as the THR Corporate Privacy Officer. The THR Privacy Officer is ultimately responsible for all matters relating to development and implementation of HIPAA Privacy Rule requirements within THR and THR Entities subject to the direction of the THR Chief Compliance Officer. The THR Privacy Officer has the authority to make final decisions regarding applicability of the Privacy Rule, even where other THR individuals disagree. Designation of such an official is specifically required under the Privacy Rule at §164.530(a)(1)(i). Relative to research, the THR Privacy Officer is responsible for:

- Ensuring that up-to-date policies and procedures are established and maintained within THR and THR Entities.
- Identifying compliance problems within THR research programs.
- Educating the research community about Privacy Rule requirements.

Privacy Rule Complaint and Contact Official. The THR Privacy Officer serves as the THR Privacy Rule Complaint and Contact Official. This individual is responsible for (a) receiving all complaints relating to the use and disclosure of Protected Health Information of individuals, and (b) providing information about matters covered by the Institutional Notice of Privacy Practices.

Entity Privacy Officers. Each THR Entity designates an individual to serve as Entity Privacy Officer. With the THR Privacy Officer, the Entity Privacy Officer is responsible for matters relating to the development and implementation of HIPAA Privacy Rule requirements at the Entity level.

B. Privacy Boards and Committees

The following committees are responsible for implementing HIPAA privacy requirements within THR.

THR Privacy and Security Council. The THR Privacy and Security Council facilitates proper implementation of programs to ensure the privacy and security of Protected Health Information within THR and THR Entities. The Council's duties include:

- Analyzing, and advising THR and THR Entities concerning, regulatory requirements related to the privacy and security of Protected Health Information.
- Providing feedback to THR and THR Entities concerning Program effectiveness.
- Reviewing and approving system policies.
- Reviewing the results of periodic audits and risk assessments, and assisting in the development of remediation strategies.
- Receiving and reviewing periodic privacy compliance and monitoring reports.
- Assisting in the identification of resources required for implementation of Program initiatives.
- Advising on appropriate strategies to promote compliance with THR's privacy policies and procedures.

The THR Privacy and Security Council meets at least annually and includes the following members:
:

- The THR Corporate Privacy Officer (Chairperson)
- The THR Chief Compliance Officer
- The THR Entity Privacy Officers
- Other members as deemed appropriate by the THR Privacy Officer

Institutional Review Board(s). The THR IRB shall normally serve as that Privacy Board for THR Entities engaged in research. The IRB may utilize expedited or convened review procedures as described in Section "C" below.

Entity Privacy Boards. Although the THR IRB shall normally serve as the Privacy Board, for THR entities engaged in research, the THR Corporate Privacy Officer, with the agreement of the THR Chief Compliance Officer, may authorize a separate THR Privacy Board should extraordinary circumstances so warrant. The separate THR Privacy Board so established will have the same authority and responsibilities relative to Privacy Rule enforcement as the THR IRB that it replaces.

A Privacy Board under HIPAA must meet each of the following requirements [§164.512(i)(1)(i)(B)]:

- Include members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests; *and*
- Include at least one member who is not affiliated with the Covered Entity, not affiliated with any Entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; *and*
- Does not include any member participating in a review of any project in which the member has a conflict of interest.

The THR Privacy Board will meet in a convened meeting at any time that the Chairperson or a Board member deems such a meeting warranted. Otherwise, the Privacy Board may use the expedited review procedure set forth in 45 CFR 46.110. This procedure is as follows:

- One member (or more if desired) reviews a request for waiver or alteration of an authorization.
- The member makes the regulatory determinations for authorization of waiver or alteration of the authorization.
- If the member approves a requested waiver or alteration, this determination is recorded in the official records of the Privacy Board and communicated to Privacy Board Members.
- If the member does not approve a requested waiver or alteration, the request must be reviewed by the convened Privacy Board.

Documentation of Determinations. The IRB's (or Privacy Board's) discussion of Privacy Rule issues and its determinations regarding waivers of Authorization shall be specifically documented in relevant meeting minutes and protocol records. For protocols reviewed during a meeting, the waiver of Authorization will be documented as part of the protocol discussion in the meeting minutes. For expedited reviews, the Board receives a notification in their meeting materials that reports are available to them to review the expedited submissions reviewed and approved since the previously held Board meeting. Where appropriate, waiver of Authorizations for these expeditable reviews are documented as part of the protocol's eIRB record. During the meeting, the reports are referred to by the Chair and discussed by the Board to the extent necessary and these actions are

documented in the meeting minutes. Documentation of the approval of waivers of Authorization, whether by convened review or expedited review, shall include protocol-specific determinations for each relevant regulatory criterion.

C. Applicability within THR

Texas Health Resources (THR) and its Entities are together considered a "Single Affiliated Covered Entity" under HIPAA.

THR Employees and Agents. The HIPAA privacy regulations apply to:

- All human subject research conducted by any THR employee or agent.
- All human subject research conducted in any THR wholly owned or controlled Entity (THR Entity).
- Exempt studies containing Protected Health Information.

Thus, any investigator involved in a study that concerns human subjects and where THR is Engaged is bound by the HIPAA privacy requirements.

Engaged in research – THR is engaged in a research study when (1) an entity of THR has contracted with a sponsor to conduct a clinical trial; (2) THR employees or agents provide administrative support, research coordination or hospital services to investigators in the conduct of a clinical trial; or (3) an investigator recruits from the hospital grounds for the research study to include both study subject recruitment and or study advertisements.

As is the case for all human subject research, a THR agent is any individual who:

- Acts on behalf of THR or any THR Entity.
- Represents herself/himself as affiliated with THR or any THR Entity in (i) the planning, design, conduct (including data analysis), or support of research; (ii) the solicitation of funds or in-kind support for research; (iii) the recruitment of research subjects; (iv) obtaining the informed consent of research subjects; or (v) the publication or presentation of research results.

THR Business Associates. Under HIPAA, a THR Business Associate is person who, although not a member of the THR workforce, performs (or assists in performing) a function or activity on behalf of THR that involves the use or disclosure of individually identifiable health information.

Activities of Business Associate involving Protected Health Information may only take place under a contractual agreement that clearly establishes the permitted and required disclosures for both THR and the Business Associate in compliance with the Privacy Rule requirements. The THR Business Associates Policy is provided in Appendix B.

An individual who performs only research-related activities is rarely considered a Business Associate. The use or disclosure of Protected Health Information for research purposes does NOT require a Business Associate Contract/Agreement, even where the researcher has been hired by THR (or a THR Entity) to perform research activities on behalf of THR. Research sponsors, collaborators, and others performing research-related activities are not considered Business Associates unless the person or entity also performs a function regulated by the Administrative Simplification Rules [per §160.103], such as payment , claims billing, or health care operations.

Outside Sponsored Research. Research involving THR employees, agents, or entities and an outside sponsor may only be conducted under an official, written agreement between THR and the sponsor. This includes industry sponsors, government sponsors, and private or foundation sponsors.

Such outside research sponsors are rarely considered Business Associates unless the person or entity also performs a function regulated by the Administrative Simplification Rules [per §160.103], such as payment, claims billing, or health care operations. When in doubt, investigators should contact the Entity Privacy Officer or the THR Privacy Officer for clarification.

Collaborative Research. When engaging in collaborative research involving institutions or investigators outside THR (or THR Entities), THR strongly encourages investigators to execute written agreements describing the roles, responsibilities, and prerogatives of each party. Where appropriate, such agreements should specify each party's responsibilities related to the privacy and security of Protected Health Information.

Research collaborators are rarely considered Business Associates unless the person or entity also performs a function regulated by the Administrative Simplification Rules [per §160.103], such as payment, claims billing, or health care operations. When in doubt, investigators should contact the Entity Privacy Officer or the THR Privacy Officer for clarification.

D. Required Education

THR is required under HIPAA to provide and document adequate and timely training of all members of its workforce on its policies and procedures for dealing with Protected Health Information [45 CFR 164.530(b)].

The THR Privacy Officer determines the nature and frequency of Privacy Protection Training for all members of the THR workforce.

Research Privacy training shall be completed by each individual involved in conducting a study.

E. Minimum Necessary Standard

THR is required under the Privacy Rule to see that uses and disclosures of Protected Health Information (and requests for Protected Health Information) are limited to the least amount of information needed to accomplish the intended purpose of the use, disclosure, or request [§164.502(b)].

The Minimum Necessary Standard does **not** apply to:

- Uses or disclosure made under an Authorization for Research Use and Disclosure.
  or
- Protected Health Information that has been de-identified.

These situations will be described in subsequent Chapters. THR's Minimum Necessary Use and Disclosure Policy is provided in Appendix B.

F. Sale of Protected Health Information

Sale of Protected Health Information means a disclosure of Protected Health Information by a Covered Entity or Business Associate where remuneration (financial or nonfinancial benefits) is received directly or indirectly from or on behalf of the recipient of the Protected Health Information in exchange for the Protected Health Information.

Protected Health Information may not be sold except with the Individual's Authorization or under an exception of the HIPAA Privacy Rule. One exception is for research purposes where the only remuneration received by the Covered Entity or Business Associate is a reasonable cost-based fee to cover the cost to prepare and transmit the Protected Health Information for research purposes.

Chapter 5.
Authorization for Use and Disclosure of Protected Health Information in Research

Goal:	**Safeguard Uses and Disclosures of "Protected Health Information in the Conduct of Research**

General Rule:	**Use or Disclosure of "Protected Health Information" for research purposes requires either:** • **A written authorization from the subject** ***or*** • **A satisfactory representation that the research involves:** ○ **De-Identified Information** ○ **Limited Data Sets** ○ **Reviews Preparatory to Research** ○ **Decedents' Information** ***or*** • **A formal waiver approved by the Privacy Board / IRB**

Regulatory References:	
The HIPAA Privacy Regulations:	**45 CFR Parts 160 & 164**
Authorization Requirement:	**45 CFR 164.508(a)**
Authorization Elements:	**45 CFR 164.508(c)**
Prior Consent for Research:	**45 CFR 164.532(c)**

A. General Requirements

Identifiable health information (Protected Health Information) may not be used or disclosed for research purposes unless:

- Written authorization has been obtained from the patient-subject.
  or

- The Covered Entity receives a satisfactory representation that the research involves only de-identified information, limited data sets, reviews preparatory research, or decedents' information.
  or
- A Privacy Board (or the IRB acting in place of a Privacy Board) approves and documents a formal Waiver of the Authorization requirement.

The Chapter describes the requirements relating to Authorization from the patient-subject for the research use or disclosure of Protected Health Information.

The next Chapter describes the Waiver of Authorization and the other conditions under which Protected Health Information may be used or disclosed for research without Authorization from the patient-subject.

B. Authorization Requirements

Except for the waiver and exceptions noted above (and discussed in the next Chapter), research investigators must obtain the patient-subject's written "authorization" for the use or disclosure of Protected Health Information [§164.508(a)].

Several of the Privacy Rule authorization elements are similar to the informed consent elements found in the federal human subject regulations, which require that the document be written in language understandable to the individual and that the individual sign the document.

However, the Privacy Rule authorization adds elements to those specified under the informed consent requirements of the federal human subject regulations.

Sample Authorization documents are provided in Appendix A.

Core Elements. A valid Privacy Rule Authorization must include at least the following core elements [§164.508(c)(1)].

1. A specific, meaningful description of the Protected Health Information that is to be used or disclosed.
2. The name or other specific identification of the persons or class of persons authorized to make the requested use or disclosure of the Protected Health Information.
3. The name or other specific identification of the persons or class of persons (investigators under a study approved by an Institutional Review Board) by whom the information may be used and/or to whom the information may be disclosed.

4. A description of each purpose of the requested use or disclosure. The statement "at the request of (a specified individual)" is a sufficient description where applicable.
5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study" or "none" or similar language is sufficient for research, including for the creation and maintenance of a research database or research repository.
6. The signature of the patient-subject and the date. If the authorization is signed by a personal representative of the patient-subject, a description of the representative's authority to act for the patient-subject must also be provided.
7. Future Research:
    - IRB approval will be required for Authorizations for future research purposes. An Authorization form, that authorizes the subject's specimen or PHI can be used for future research purposes, must include an adequate description so that it would be reasonable for an individual to expect that his or her information could be used or disclosed for future research.
    - <u>The Authorization must provide the subject a choice to opt in (agree) or opt out (decline) of future research activities described in the unconditioned Authorization.</u>

Additional Statements. In addition to the core elements above, a Privacy Rule Authorization must also include statements notifying the patient-subject of each of the following [§164.508(c)(2)].

1. The patient-subject's right to revoke the authorization in writing, any exceptions to the right to revoke the authorization, and a description of how to revoke the authorization. [Note: A reference to the Covered Entity's privacy notice may be substituted for the latter two items where appropriate.]
2. The potential that information disclosed under the authorization may subsequently be disclosed by the recipient without the protections of the Privacy Rule.
3. Notice of the Covered Entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and if applicable, the consequences of failure to provide Authorization for research-related treatment (see section below – Authorization as a Condition for Research-Related Treatment).

Legally Authorized Representative. If a research subject is a child (i.e., a minor under applicable State law), or is not competent to provide Authorization, the Authorization must be signed by a personal representative who has the authority under applicable State law to sign an authorization on behalf of another individual.

In the State of Texas, a minor is a person under 18 years of age who has not (i) been married or (ii) had minority status removed by a court.

The Privacy Rule requires that a description of the representative's authority to act for the individual must be provided with the authorization [§164.502(g), 164.508(c)(vi)].

THR policy (see Standard Definitions in Appendix B) recognizes the following legally authorized representatives:

> (1) A parent or legal guardian, if the patient is a Minor;
> (2) A legal guardian, if the patient has been found by a court to be incapable of managing the patient's personal affairs;
> (3) An agent of the patient authorized under a Medical Power of Attorney for the purpose of making a health care decision when the patient is incompetent;
> (4) an attorney ad litem and/or guardian ad litem appointed for the patient by a court;
> (5) A person authorized to consent to medical treatment on behalf of the patient under Chapter 313 of the Texas Consent to Medical Treatment Act;
> (6) A personal representative or heir of the patient, if the patient is deceased;
> (7) An attorney retained by the patient or by the patient's legally authorized representative;
> (8) A person exercising a power granted to the person in the person's capacity as an attorney-in-fact or agent of the patient by a Statutory Durable Power of Attorney that is signed by the patient as principal. (See THR Policy on Health Information Uses and Disclosures for full definition).

Authorization as a Condition for Research-Related Treatment. The provision of research-related treatment may be conditioned on the patient-subject's Authorization for the use or disclosure of Protected Health Information for such research [§164.508(b)(4)(i)]. The consequences of failure to provide the Authorization must be described in the Authorization.

Combining Research Authorization and Research Informed Consent. Under Texas law, an authorization to disclose health care information cannot be combined or contained in the document signed by the patient to consent to medical treatment.

Combining Multiple Research Authorizations. The IRB discourages the use of combined Authorizations. An Authorization for the use or disclosure of Protected Health Information for a research study may be combined with any other Authorization (except Psychotherapy Notes) for the same or another research study. This exception includes combining an Authorization for the use or disclosure of PHI for a research study with another Authorization for the same research study or with an Authorization for the creation or maintenance of a research database or repository.

In the combined Authorization, if one section is conditioned upon the subject's Authorization to release Protected Health Information in order to receive research-related treatment and the other section of the combined Authorization is not conditioned, the combined authorization must clearly identify the conditioned and unconditioned components and provide the subject an opportunity to opt in (agree) to the research activities described in the unconditioned Authorization.. For example:

> I agree to the use of my/my child's protected health information and/or fluid/tissue samples for future research involving *[Add a brief description of the future research – for example…genetic causes of your xxx disease/condition]*.
>
> ❑ Yes ❑ No Initials: _____ Date: _____

Separate Authorization for Psychotherapy Notes. The above notwithstanding, an authorization for the use and disclosure of Psychotherapy Notes may only be combined with another authorization for use or disclosure of Psychotherapy Notes [§164.508(b)(3)(ii)]. Authorization for use and disclosure of Psychotherapy Notes may not be combined with Informed Consent for research.

Psychotherapy Notes under HIPAA are notes recorded in any medium by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the medical record. Psychotherapy Notes do not include medication prescription and monitoring; session start and stop times; modalities and frequencies of treatment furnished; results of clinical tests; and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, or progress [§164.501].

Plain Language. HIPAA requires that a Privacy Rule Authorization be written in plain language [§164.508(c)(3)].

Copy to Subject. A copy of the signed Privacy Rule Authorization must be given to the patient-subject [§164.508(c)(4)].

Retention of Authorizations. Signed Privacy Rule Authorizations must be retained for six years [§164.530(j)(1)(ii)].

Minimum Necessary Standard Does Not Apply. Uses and disclosures of Protected Health Information that are made under an Authorization from the patient-subject are **not** limited by the Minimum Necessary Standard.

C. Revocation of Authorization

An individual may revoke an authorization for the use or disclosure of Protected Health Information in research at any time by notifying the investigator in writing. Once authorization is revoked, the investigator may not subsequently use or disclosure the individual's Protected Health Information [§164.508(b)(5)].

Investigators may continue to use information even where the subject has revoked authorization if the investigator has already "taken action in reliance thereon" [§164.508(b)(5)(i)]. This reliance exception is "intended to allow for certain continued uses of the information as appropriate to preserve the integrity of the research study, e.g., as necessary to account for the individual's withdrawal from the study" [67 FR 14776, 14794, March 27, 2000].

Under the HIPAA Privacy Rule, a subject must provide a written notification to the investigator in order to revoke authorization for the research use or disclosure of Protected Health Information. This written notice is separate from the subject's right to withdraw from research participation, which does not require written notification. Depending upon the nature of the research, a subject might elect to discontinue research-related procedures or interventions, but permit continued access by the researcher to past or future protected health information.

D. Research Consents Obtained Prior to April 14, 2003. As indicated in Chapter 2, Protected Health Information may continue to be created, received, used, or disclosed for research after April 14, 2003 (the Privacy Rule compliance deadline), if one of the following has been obtained prior to the April 14, 2003 deadline:

1. Express legal permission or authorization from the individual to use or disclose Protected Health Information for the research.
   or
2. The informed consent of the individual to participate in the research.
   or

3. Approval by the THR IRB of a waiver of informed consent requirements in accordance with the requirements of the Common Rule and DHHS regulations at 45 CFR 46.116(d).

Thus, Privacy Rule Authorization is not required from subjects who have provided informed consent for research prior to April 14, 2003. However, Privacy Rule Authorization must be obtained for any subject enrolled in the research on or after April 14, 2003 [§164.532(c)].

Chapter 6.
Research Use and Disclosure of Protected Health Information Without Authorization

Goal:	**Permit Certain Research Uses and Disclosures of "Protected Health Information" without Authorization of the Patient-Subject**

General Rule:	**Use or disclosure of "Protected Health Information" for research purposes requires either:** • **A written authorization from the subject** ***or*** • **A determination by the Covered Entity that the research involves:** ○ **De-Identified Information** ○ **Limited Data Sets** ○ **Reviews Preparatory to Research** ○ **Decedents' Information** ***or*** • **A formal waiver approved by the Privacy Board / IRB**

Regulatory References:	
De-Identified Information:	**45 CFR 164.502(d) & 164.514(a)-(c)**
Limited Data Sets:	**45 CFR 164.514(e)**
Preparation for Research:	**45 CFR 164.512(i)(1)(ii)**
Decedents' Information:	**45 CFR 164.512(i)(1)(iii)**
Waiver of Authorization:	**45 CFR 164.512(i)(1)(i)**
Minimum Necessary Standard:	**45 CFR 164.502(b) & 164.514(d)**

A. General Requirements

As indicated in the previous Chapter, identifiable health information (i.e., Protected Health Information) may not be used or disclosed for research purposes unless:

- Written authorization has been obtained from the patient-subject.
  or
- The Covered Entity receives a satisfactory representation that the research involves only de-identified information, limited data sets, reviews preparatory research, or decedents' information.
  or
- A Privacy Board (or an IRB acting in place of a Privacy Board) approves and documents a formal Waiver of the Authorization requirement.

The previous Chapter described the requirements relating to Authorization from the patient-subject for the research use or disclosure of Protected Health Information.

While the Privacy Rule allows representations from the research investigator to replace the Authorization requirement in situations described in Sections B, C, D and E below, THR entities will require a Waiver of Authorization by an IRB.

This Chapter describes the Waiver of Authorization and the other conditions under which Protected Health Information may be used or disclosed for research without Authorization from the patient-subject.

B. Research Using De-Identified Information

Protected Health Information may be used to create information that is not individually identifiable. Once it is de-identified, the information is no longer subject to the HIPAA privacy requirements. Of course, if de-identified information is re-identified, then the privacy requirements again apply [§164.502(b),(d)].

Requirements for De-Identified Information. Health information is not identifiable if it does not (i) identify an individual or (ii) contain information that can reasonably be used to identify an individual. Health information which has been de-identified is no longer considered to be Protected Health Information and would not be subject to the HIPAA Privacy Rule. [§164.514(a)].

A Covered Entity may use either of two methods to determine that health information is not identified: (i) reliance on the determination of an expert, or (ii) removal of specific identifiers listed in the regulations [§164.514(b)].

Expert Determinations. One method that a Covered Entity may use to determine that health information is not identifiable is to rely on the determination of an expert as follows:

- The expert must have appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable.

- The expert must determine and document that the risk is very small that the information could be used, either alone or in combination with other reasonably available information, to identify an individual.

Removal of Specific Identifiers. Assuming that the Covered Entity does not have actual knowledge that information could be used to identify an individual, the second method that may be used to determine that health information is not identifiable is to verify that all of the following specific identifiers of the individual (or of relatives, employers, or household members of the individual) have been removed:

1. Names.
2. All geographic subdivisions smaller than a State, including street address, county, precinct, zip codes, and their equivalent geocodes, **except for the first three digits of a zip code, if** (i) current Census Bureau data indicate that the geographic unit corresponding to the three digits contains more than 20,000 people, or (ii) the three digits are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual; all ages over 89; and all elements of dates (including year) for ages over 89, except that all such ages and elements may be aggregated into a single category for age 90 or older.
4. Telephone numbers.
5. Fax numbers.
6. Electronic mail 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. Web Universal Resource Locators (URLs).
15. Internet Protocol (IP) address numbers.
16. Biometric identifiers, including finger and voice prints.
17. Full face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code except as noted below.

Minimum Necessary Standard Does Not Apply. The Minimum Necessary Standard does not apply to the use or disclosure of De-Identified Information [§164.502(b)].

Documentation for Use of De-Identified Information in Research. As the Covered Entity under HIPAA, it is THR's responsibility to determine that Protected Health Information has been de-identified in accordance with the Privacy Rule. Consequently, THR requires a written representation from the

investigator prior to the use or disclosure of de-identified information for research. A form for this purpose is provided in Appendix A.

Re-Identification Codes. A Covered Entity may assign a code or other means of record identification to allow de-identified information to be re-identified by the Covered Entity. However, the Covered Entity **may not disclose** the code or record identifier for re-identification, and the code or record locator **may not be**:

- Derived from or related to the individual.
- Capable of being translated to identify the individual.
- Used or disclosed for any purpose other than re-identification by the Covered Entity.

The Privacy Rule protections, including the Minimum Necessary Standard, apply to any Protected Health Information that has been re-identified [§164.514(d)].

IRB Approval Requirement for Research Involving De-Identified Information with Re-Identification Codes. De-Identified Information that includes Re-Identification Codes (i.e., codes or other means to allow De-Identified Information to be re-identified) is considered **"identifiable"** by DHHS and is **not exempt** under the Common Rule and the DHHS human subject protection regulations at 45 CFR 46.101(b)(4). **Consequently, research involving De-Identified Information that includes Re-Identification Codes must receive prospective review and approval by the THR IRB.**

C. Research Using Limited Data Sets

A Covered Entity may use or disclose a "Limited Data Set" of Protected Health Information for research purposes if it obtains a "Data Use Agreement" which stipulates that the recipient will use or disclose the information only for the limited purposes described in the agreement [45 CFR 164.514(e)].

A Limited Data Set may only be used for purposes of:

- Research.
- Public health.
- Health care operations.

Requirements for a Limited Data Set. A Limited Data Set consists of Protected Health Information that excludes all of the following direct identifiers of the individual (or of relatives, employers, or household members of the individual):

1. Names.
2. Postal address (but the town, city, State and zip code are acceptable).
3. Telephone numbers.
4. Fax numbers.

5. Electronic mail addresses.
6. Social Security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers.
11. Vehicle identifiers and serial numbers, including license plate numbers.
12. Device identifiers and serial numbers.
13. Web Universal Resource Locators (URLs).
14. Internet Protocol (IP) address numbers.
15. Biometric identifiers, including finger and voice prints.
16. Full face photographic images and any comparable images.

Uses of a Limited Data Set for Research. A research investigator may take Protected Health Information to which the researcher has legitimate access and change the information so as to eliminate the identifiers noted above, and thus create a Limited Data Set. The investigator can then share the Limited Data Set with colleagues at other institutions under the terms of a Data Use Agreement (see below). In order for the research investigator to access Protected Health Information, the research investigator would obtain a waiver of Authorization preparatory to research or for remainder of research study by the Privacy Board/IRB. The waiver would be completed via the eIRB submission system.

Likewise, a Covered Entity can take Protected Health Information and create a Limited Data Set for use by research investigators in its own workforce who would ordinarily not have legitimate access to it in identifiable form.

Data Use Agreement. A Data Use Agreement is a written agreement entered into by the Covered Entity and the person or institution that will receive the Limited Data Set. The agreement must state that the recipient will only use or disclose the information in the Limited Data Set for specific, limited purposes.

The Data Use Agreement must:

1. Establish the permitted uses and disclosures of the information by the recipient (for example, that the use or disclosure will be for research involving diabetes).
2. Indicate that the recipient may not use or further disclose the information in any way that would violate Privacy Rule requirements, the conditions stated in the Agreement, or applicable law.
3. Identify who is permitted to use or receive the information.
4. Require the recipient to use appropriate safeguards to prevent unauthorized uses or disclosures of the information.
5. Require the recipient to report to the covered Entity any unauthorized use or disclosure of the information.

6. Require the recipient to ensure that all agents or subcontractors of the recipient have agreed to the same restrictions and conditions on use or disclosure of the information.
7. Require the recipient not to identify the information or contact the individuals with whom the information is associated.

A sample Data Use Agreement for research use of a Limited Data Set is provided in Appendix A.

As a Covered Entity, THR is required to take appropriate action if the Set recipient commits a material breach of the Data Use Agreement.

Minimum Necessary Standard Applies. The Minimum Necessary Standard applies to the use or disclosure of Limited Data Set Information [§164.514(e)], and a Data Use Agreement is also required (see above).

Documentation for Use of a Limited Data Set in Research. As the Covered Entity under HIPAA, it is THR's responsibility to determine that Limited Data Sets are used and disclosed under a Data Use Agreement that meets the HIPAA Privacy Rule requirements. Consequently, THR requires the investigator to provide THR with a copy of the applicable Data Use Agreement prior to the use or disclosure of a Limited Data Set in research. A form for this purpose is provided in Appendix A.

IRB Approval Requirement for Research Involving Limited Data Sets with Re-Identification Codes. A Limited Data Set that includes Re-Identification Codes (i.e., codes or other means to allow Limited Data Set information to be Re-Identified) is considered **"identifiable"** by DHHS and is **not exempt** under the Common Rule and the DHHS human subject protection regulations at 45 CFR 46.101(b)(4). **Consequently, research involving Limited Data Set information that includes Re-Identification Codes must receive prospective review and approval by the THR IRB.**

D. Reviews Preparatory to Research

The Privacy Rule does not require an Authorization from the patient-subject for reviews of Protected Health Information preparatory to research (e.g., to prepare a protocol or estimate the number of available subjects) [§164.512(i)(1)(ii)].

In lieu of Authorization, the Privacy Rule permits a Covered Entity to obtain the following three representations from the research investigator or the research investigator must receive a waiver of the Authorization requirement from the Privacy Board/IRB via the eIRB submission system.

All three of the following representations must be obtained from the investigator in order to dispense with the Authorization requirement.

1. That the use or disclosure of Protected Health Information is sought solely to review Protected Health Information as necessary to prepare a research protocol or for similar purposes preparatory to research.
   and
2. That the Protected Health Information will not be removed from the Covered Entity during the course of the researcher's review.
   and
3. That review or use of the Protected Health Information is necessary for the purposes of the research.

Permitted Activities Preparatory to Research. The provision for Reviews Preparatory to Research permits investigators to access THR-held Protected Health Information to prepare research protocols or estimate the number of available subjects. However, the Protected Health Information may not be removed from the THR facility, even for a brief or limited period of time. Any Review Preparatory to Research must be performed entirely within the THR facility in which the Protected Health Information normally resides. Removal of THR-held Protected Health Information from the THR facility requires either (i) prior Authorization from the patient-subject, or (ii) formal approval of an appropriate Waiver of Authorization by the THR IRB.

Recruitment of Research Subjects Not Permitted. Although possibly permitted under the Privacy Rule, THR policy does not recognize subject recruitment as a Review Preparatory to Research. The use or disclosure of THR-held Protected Health Information for subject recruitment requires either (i) prior Authorization from the patient-subject, or (ii) formal approval of an appropriate Waiver of Authorization by the THR IRB. In addition, THR policy requires that research investigators notify the relevant clinical care physician before contacting the physician's patients for recruitment into research.

Minimum Necessary Standard Applies. As suggested by Item (3) above, any use or disclose of Protected Heath Information for a Review Preparatory to Research must be limited to the least amount of information needed for the intended purpose [§164.502(b)].

Documentation of Reviews Preparatory to Research. As the Covered Entity under HIPAA, it is THR's responsibility to obtain representations from investigators relating to reviews preparatory to research or the investigator must obtain a waiver of the Authorization requirement from the Privacy Board/IRB via the eIRB submission system. A representation form is provided in Appendix A.
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IRB Approval Requirement for Reviews Preparatory to Research. If a Review Preparatory to Research involves **recording** private information such that subjects can be identified (either directly or through identifiers linked to the subjects), the activity is **not exempt** under the Common Rule and the DHHS

human subject protection regulations at 45 CFR 46.101(b)(4). **Consequently, Activities Preparatory to Research that involve recording identifiable private information must receive prospective review and approval by the THR IRB.**

Note: Identification of research activities that are exempt from the human subject regulations requires a level of expertise and is not left to individual investigators.

All exemptions claimed for research conducted at THR or by employees or agents of THR must be verified by the Chairperson of the THR IRB, or an individual designated by the Chairperson.

E. Research Involving Decedents Information

Although the Privacy Rule generally provides safeguards for the Protected Health Information of decedents, it does not require an Authorization (from the patient-subject prior to death or a representative of the patient-subject after death) for research involving decedents' information [§164.512(i)(1)(iii)].

In lieu of Authorization, the Privacy Rule permits a Covered Entity to obtain the following three representations from the research investigator. All three of the following representations must be obtained from the investigator in order to dispense with the Authorization requirement.

1. That the use or disclosure is sought solely to perform research using the Protected Health Information of decedents (and not of family members). *and*
2. That documentation of the death of the individual(s) has been obtained. *and*
3. That review or use of the Protected Health Information is necessary for the purposes of the research.

Alternatively, in lieu of Authorization, the research investigator would need to obtain a waiver of the Authorization requirement from the Privacy Board/IRB via the eIRB electronic submission system.

Under federal law, a hospital's Individually Identifiable Health Information regarding a patient who has been deceased for more than 50 years is no longer considered to be Protected Health Information.

To satisfy both federal and Texas state law, a physician's medical record for patients who have been deceased for more than 50 years where the records are at least 75 years old and where the records are requested for historical research purposes are no longer considered to be privileged or Protected Health Information. (HIPAA Privacy Rule and Tex. Occupations Code. §159.002(d)).

Minimum Necessary Standard Applies. As suggested by Item (3) above, any use or disclose of Decedents' Protected Heath Information for research must be limited to the least amount of information needed for the intended purpose [§164.502(b)].

Documentation for Research Involving Decedents' Information. As the Covered Entity under HIPAA, it is THR's responsibility to obtain representations from investigators relating to research involving decedents' information. A form is provided for this purpose in Appendix A. Alternatively, the research investigator must receive a waiver of the Authorization requirement from the Privacy Board/IRB via the eIRB submission system.

F. Waiver of Authorization Requirement for Research

Under the Privacy Rule, an Institutional Review Board (IRB) or Privacy Board may waive or alter the Authorization requirement for use or disclosure of Protected Health Information in research [§164.512(i)(1)(i)(A).(B)].

Examples of research in which a Waiver of Authorization might be considered appropriate include:

- Research that involves the medical records of a large number of subjects where it would not be practicable to obtain Authorization.
- Epidemiology research that requires information about all cases within a diagnostic or disease category.
- Research in which it is impossible to separate the Protected Health Information of living individuals from the Protected Health Information of deceased individuals.
- Research involving Protected Health Information contained in data banks or registries that are created and maintained for non-research purposes (e.g., research utilizing Protected Health Information in a State-mandated Cancer Registry, or research utilizing Protected Health Information contained in an organizational or departmental Quality Assurance Data Base).
- Research involving Protected Health Information that was obtained under an Authorization for different research activities.

Criteria for Waiver of Authorization. In order to approve requests for alteration or waiver of the Privacy Rule Authorization requirement, the IRB or Privacy Board must determine that the alteration or waiver satisfies each of the following criteria [§64.512(i)(2)(ii)].

1. The use or disclosure of Protected Health Information involves no more that minimal risk to the privacy of individuals based on at least the following:

A. An adequate plan to protect the identifiers from improper use and disclosure;
and
B. An adequate plan to destroy the identifiers at the earliest possible opportunity unless there is a research or a health justification for retaining them (or retention is required by law);
and
C. Adequate written assurances that the Protected Health Information will not be reused or disclosed to another person or Entity (except as required by law, for authorized oversight of the research, etc.).

and

2. The research could not practicably be conducted without the alteration or waiver.
and
3. The research could not practicably be conducted without access to and use of the Protected Health Information.

Documentation of Alteration or Waiver of Authorization. The documentation indicating IRB approval of the alteration or waiver of authorization must be provided to the covered entity to comply with protected health information disclosure requirements. Documentation of the determination by the IRB or Privacy Board must include:

1. Identification of the THR IRB or Privacy Board.
2. The date of approval of the alteration or waiver of Authorization.
3. A brief description of the Protected Health Information to be use or accessed.
4. A statement that the alteration or waiver was reviewed and approved using (a) normal (full, convened) review procedures, or (b) expedited review procedures.
5. A statement that the THR IRB or Privacy Board has determined that the alteration to or waiver of individual authorization satisfies each of the criteria listed above.
6. The signature of the THR IRB or Privacy Board Chairperson, or other member of the IRB or Privacy Board, as designated by the Chairperson.

Chapter 7.
Disclosure of Protected Health Information For Legal and Regulatory Purposes

Goal:	**Permit disclosures of "Protected Health Information" Where Required under Statute or Regulation**

General Rule:	**The Privacy Rule generally permits Use and Disclosure of Protected Health Information as required under applicable statute or regulation**

Regulatory References:	
As Required by Law:	**45 CFR 164.512**
FDA-Regulated Activities:	**45 CFR 164.512(b)(iii)**
Health Oversight Activities:	**45 CFR 164.512(d)**
Whistleblowers & Crime Victims:	**45 CFR 164.502(j)**

The Privacy Rule generally permits the Use or Disclosure of Protected Health Information where required under applicable statute or regulation, so long as the use or disclosure complies with and is limited to the requirements of the law or regulation [§164.512(a)].

A. As Required by Law

The following Uses and Disclosures of Protected Health Information are among those permitted where required by law or regulation:

- For public health activities as conducted or directed by a Public Health or Other Government Authority [§164.512(a)-(c)], including
    - Prevention or control of disease, injury or disability.
    - Reporting of disease, injury, birth, death, or other vital event.
    - Public health surveillance, investigations; or interventions.
    - Reporting of child abuse or neglect, other abuse or neglect, or domestic violence (as defined and required by applicable State law or regulation).
- To avert a serious threat to individual or public health or safety [§164.512(j)].
- To coroners and medical examiners or for cadaveric organ, eye, or tissue donation [§164.512(g),(h)].

- For judicial and administrative proceedings in response to (i) an order of a court or administrative tribunal; or (ii) a subpoena, discovery request, other lawful process [§164.512(e)].
- For law enforcement purposes [§164.512(f)]; specialized government functions [§164.512(k)]; and workers compensation [§164.512(l)].
- By workforce members who are whistleblowers or victims of a criminal act [§164.502(j)].

B. Disclosures to Sponsors As Required Under FDA Regulations

The Privacy Rule permits the disclosure of Protected Health Information to persons who have responsibilities relating to the quality, safety, or effectiveness FDA-regulated products or activities [§164.512(b)(iii)]. Such persons clearly include the Sponsors of clinical investigations (and their agents, auditors, or monitors) for activities such as:

- Collecting or reporting adverse events, product defects or problems, or biological product deviations.
- Tracking FDA-regulated products.
- Enabling product recalls, repairs, replacements, or “lookbacks” (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems).
- Conducting post-marketing surveillance.

Disclosure of Protected Health Information for such purposes must be limited to the information needed under the relevant FDA requirements.

C. Disclosures for Health Oversight Activities

The Privacy Rule also permits disclosures to government health oversight agencies for activities authorized under law, including audits, administrative investigations, inspections, or other activities necessary for oversight [§164.512(d)]. This provision would include Disclosures of Protected Health Information to FDA and OHRP, which would again be limited to the information needed for the intended purpose.

In addition, the Secretary of Health and Human Services (HHS) has the authority to access any information needed to ascertain compliance with the Privacy Rule.

D. Reporting of Adverse Events and Unanticipated Problems

Given the provisions discussed above, the Privacy Rule has no affect on the existing institutional and regulatory requirements concerning the reporting of adverse events and unanticipated problems involving risks to subjects or others.

THR research investigators continue to be responsible for reporting these research-related occurrences to the IRB, the sponsor, the FDA, other government entities, and other entities legitimately entitled to this information.

E. Confidentiality Requirements for Research Informed Consent

Although the Privacy Rule permits disclosure of information required under law or regulation without Authorization of the patient-subject, FDA [21 CFR 50.25(a)(5)] and DHHS [45 CFR 46.116(a)(5)] human subject protection regulations require that subjects be informed about the extent to which confidentiality will be maintained in the research.

In general informed consent for research participation should make clear to the prospective subject that identifiable private information may be shared with the Study Sponsor, FDA, OHRP, and where applicable, the government funding agency.

Chapter 8.
Registries, Repositories, and Data Banks

Goal:	**Clarify Basic Privacy Rule Requirements for Registries, Repositories, and Data Banks**

General Rule:	**The Privacy Rule requirements for Registries, Repositories, and Data Banks depend upon how Protected Health Information is Collected, Used, and Disclosed**

Regulatory References:	
Authorization Required:	**45 CFR 164.508(a)**
Authorization Not Required:	**45 CFR 164.512(i)**
De-Identified Information:	**45 CFR 164.514(a)-(c)**
Limited Data Sets:	**45 CFR 164.514(e)**

Registries, Repositories, and Data Banks all involve the collection and storage of information and/or biological specimens for some future purpose. Some are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes, but may be accessed for research. The Privacy Rule requirements will vary depending upon the nature of the Registry, Repository, or Data Bank.

A. Research Registries, Research Repositories, and Research Data Banks

Privacy Rule requirements for Research Registries, Research Repositories, and Research Data Banks depend upon how Protected Health Information in the Registry, Repository, or Data Bank is collected, used, and disclosed.

Identifiable Information. For research purposes, the most useful Registries, Repositories, and Data Banks are those containing identifiable health information, i.e., Protected Health Information. Collecting or storing identifiable health information or identifiable biological specimens for research purposes generally requires specific Authorization from the patient-subject [§164.508(a)]. A sample Authorization form for this purpose is provided in Appendix A.

De-Identified Information. HIPAA privacy protections are not required for Research Registries, Repositories, and Data Banks that collect and store only De-Identified Information [§164.514(a)-(c)]. However, any THR investigator who maintains or utilizes a Registry, Repository, or Data Bank made up of De-

Identified Information must provide a written representation to THR regarding this activity (See Chapter 6). A form for this purpose is provided in Appendix A.

Limited Data Sets. Research Registries, Repositories, and Data Banks that collect and store only Limited Data Sets must obtain a Data Use Agreement from any investigator to whom the information is disclosed [§164.514(e)]. Any THR investigator who maintains or utilizes a Registry, Repository, or Data Bank made up of Limited Data Set Information must provide a Data Use Agreement to THR regarding this activity (See Chapter 6). A form for this purpose is provided in Appendix A.

Decedents Information. Any THR investigator who maintains or utilizes a Registry, Repository, or Data Bank made up of **Decedents' Information** must provide a written representation to THR regarding this activity or the investigator must receive a waiver of the Authorization requirement by the Privacy Board/IRB via the eIRB submission system [§164.512(i), See Chapter 6]. A representation form is provided in Appendix A.

Activities Preparatory to Research. Any THR investigator who utilizes a Registry, Repository, or Data Bank for an Activity Preparatory to Research must provide a written representation to THR regarding this activity or the investigator must receive a waiver of the Authorization requirement by the Privacy Board/IRB via the eIRB submission system [§164.512(i), See Chapter 6]. A representation form is provided in Appendix A.

De-Identified Biological Specimens. The HIPAA Privacy Rule does not apply to repositories that contain only unidentifiable biological specimens.

B. Non-Research Registries, Repositories, and Data Banks

Many Registries, Repositories, and Data Banks are created for non-research purposes. For example, certain Disease Registries may be mandated by State law or regulation for public health purposes. Other Registries, Repositories, and Data Banks may be created at the institutional level for quality assurance purposes. Privacy Rule requirements for the creation and maintenance of such Registries, Repositories, and Data Banks will vary depending upon their purpose and utilization.

Regardless of their intended purpose, such resources often hold information of value for research. Investigators who access information from non-research Registries, Repositories, and Data Banks for research purposes must adhere to the applicable IRB and Privacy Rule requirements.

Research Authorization Not Obtained. Privacy Rule Authorization for Research Use and Disclosure is not likely to have been obtained from the individuals whose Protected Health Information is contained in non-research

Registries, Repositories, and Data Banks. When prior Authorization for Research Use and Disclosure has not been obtained, access to the information will require either [§164.512(i)]:

1. A Waiver of Authorization approved by the relevant Privacy Board/IRB *or*
2. A written representation from the investigator that the research use involves only De-Identified Information, Limited Data Set Information, Decedents' Information, or Activities Preparatory to Research.

These conditions are described in Chapter 6. Forms for the required representations are provided in Appendix A.

C. IRB Oversight

When the **purpose** of the Registry, Repository, or Data Bank **includes** research (at least in part), its collection and storage activities are considered research and require oversight from an appropriate IRB. Examples of activities requiring prospective IRB review and approval include:

- Collection and/or storage of human tissue samples for use in research (as opposed to diagnostic purposes).
- Development and/or maintenance of a database for recruitment of prospective research subjects.
- Development and/or maintenance of an outcomes database for use in research (as opposed to quality assurance or quality improvement).

Whenever individually identifiable information or tissues from a Registry, Repository, or Data Bank are used in research (regardless of the purpose for which the Registry, Repository, or Data Bank was created), the **research use** requires IRB oversight.

The nature of IRB oversight depends upon the conditions surrounding the collection, storage, and use of the information or specimens. For example, if surgical discard tissues are collected anonymously, with no identifiable private information, then the research may be exempt from the human subject protection regulations, or (depending upon the circumstances) may not even constitute human subject research at all. On the other hand, collection, storage, or use of biological specimens and/or identifiable private information for research purposes may require full, convened review by the IRB.

THR investigators should consult with the THR IRB to determine the IRB review and oversight requirements for establishing a Registry, Repository, or Data Bank or for using information or specimens from a Registry, Repository, or Data Bank.

Chapter 9.
Individual Access to Protected Health Information

Goal:	**Provide Individuals with Access to "Protected Health Information" about Themselves**

General Rule:	**The Privacy Rule generally provides individuals with:** • **The right to access Protected Health Information about themselves** • **The right to obtain an accounting of Disclosures of their Protected Health Information**

Regulatory References:	
Designated Record Set:	**45 CFR 164.501**
Right of Access:	**45 CFR 164.524**
Suspension During Research:	**45 CFR 164.524(a)(2)(iii)**
Other Exceptions:	**45 CFR 164.524(a)**
Disclosures to Parents:	**45 CFR 164.502(g)**
Process for Access:	**45 CFR 164.524(b)**
Accounting of Disclosures:	**45 CFR 164.528**

A. Right of Access

In general, the Privacy Rule grants individuals the right to access, inspect, and obtain a copy of individually identifiable health information (i.e., Protected Health Information) about themselves that is maintained by a Covered Entity in what the Rule terms a "Designated Record Set" [§164.524(a)(1)].

Designated Record Set. A Designated Record Set is a group of records (including any item, collection, or grouping of information) that contains Protected Health Information and is used by or for a Covered Entity to make decisions about individuals. Designated record sets include (but are not limited to) medical records, billing records, health plan enrollment records, payment records, claims records, case management records, and medical management records [§164.501].

Under THR policy, Designated Record Sets are limited to those officially identified by THR or THR Entities. It has been determined that there are no additional research-specific designated record sets beyond those managed by THR entities.

In spite of individuals' general right to access, inspect, and obtain a copy of individually identifiable health information about themselves, the Privacy Rule delineates several exceptions to the right of access, several of which are relevant to the research context. These exceptions are discussed below.

B. Temporary Suspension of Individual Access During Research

A patient-subject's individual right of access to Protected Health Information may be suspended temporarily, if the information was obtained or created in the course of research that includes treatment [§164.524(a)(2)(iii)]. Requirements for the temporary suspension include all of the following:

1. The information must have been obtained or created in the research;
2. The research must include treatment;
3. The suspension of individual access may continue as long as the research is in progress;
4. The suspension of access must be included, and agreed to, in the informed consent for participation in the research; *and*
5. The patient-subject must be informed that the right of access will be reinstated upon the completion of the research.

Individual access to research-related Protected Health Information may be denied during research without providing the individual any opportunity for review of the decision to deny access.

Examples of research in which subjects' right of access to identifiable health information might be temporarily suspended include:

- Blinded treatment studies in which individual access to health information could jeopardize blinding.
- Treatment studies in which the release of individual health information could jeopardize the scientific integrity of the study or its findings.
- Treatment studies in which the premature release of individual health information could influence the outcomes or behaviors of the individual subject or of other subjects.

C. Other Exceptions to the Right of Access

In addition to the temporary suspension of the right of access during research, the Privacy Rule delineates several permanent exceptions to the right of access to one's own Protected Health Information [§164.524(a)(2)].

Individuals may be denied access to the following information about themselves without any opportunity for review of the decision to deny access.

1. Psychotherapy notes.
2. Protected Health Information maintained by a Covered Entity that is subject to the Clinical Laboratory Improvements Amendments (CLIA).
3. Protected Health Information maintained by a Covered Entity that is exempt from the CLIA Amendments as follows:
    - Any facility or component of a facility that only performs testing for forensic purposes.
    - Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients.
    - Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. (However, all other testing conducted by a NIDA-certified laboratory is subject to CLIA.)
4. Information compiled for a civil, criminal, or administration action or proceeding.
5. Protected Health Information that is contained in records for which access may be denied under the Federal Privacy Act.
6. Protected Health Information for which access would compromise a legitimately confidential source.

Individuals may be denied access to the following information about themselves [§164.524(a)(3)], but only where there is opportunity for review of the decision to deny access by a licensed healthcare professional designated by the Covered Entity [§164.524(a)(4)].

1. Where the requested access is likely to endanger the life or physical safety of the individual or another person, as determined by a licensed health care professional.
2. Where the requested access is likely to cause substantial harm to another person, as determined by a licensed health care professional.
3. Where access requested by an individual's personal representative is likely to cause substantial harm to another person, as determined by a licensed health care professional.

The professional who reviews the denial may not have participated in the original decision to deny.

D. Research Involving Children/Minors: Disclosures to Parents

The Privacy Rule right of access applies to both adults and children (i.e., minors under applicable State law). As the child's/minor's legally authorized personal representative, the child's/minor's parent will usually have provided the Authorization for Use and Disclosure of the child's/minor's Protected Health Information in the research, as well as informed consent for the child's/minor's participation in the research. In such cases, the parent (as the child's/minor's personal representative under the Privacy Rule) must be provided access to the child's/minor's Protected Health Information [§164.502(g)].

However, the Privacy Rule does not create new rights for parents. In general, Protected Health Information must be provided to parents, and may be denied to parents, to the extent dictated by, or consistent with, relevant State law.

If the parent has agreed to the minor obtaining confidential treatment, the minor has control over the related Protected Health Information.

Authorizations involving minors in research should generally make clear the circumstances for disclosing or denying Protected Health Information to the parents.

E. Disclosures to Legally Authorized Representatives of Subjects with Decisional Impairments

The legally authorized representative of a subject with decisional impairments will usually have provided the Authorization of Use and Disclosure of the subject's Protected Health Information in the research, as well as informed consent for the subject's participation in the research. In such cases, the legally authorized representative must be provided access to the subject's Protected Health Information.

F. Process When Access is Requested

As required by the Privacy Rule [§164.524(b)], THR implements the following processes when individuals request access to Protection Health Information about themselves. THR personnel should contact their Entity Privacy Officer or the THR Privacy Officer before responding to such requests.

- The request should be made in writing.
- A written response to the request should be provided to the requester within 15 days, unless the information is not accessible to THR.
- Information that is maintained in more than one record set or in more than one location need only be provided once.
- Access must be provided in the form or format requested, or in readable hard copy, or as mutually agreed.
- THR may charge a reasonable fee that includes only the costs of copying (including labor and supplies); postage; preparing an explanation or

summary of the Protected Health Information if the individual agrees to accept the information in a summary format.

- If access is denied, the requester must be provided with a written denial containing (i) the basis for the denial; (ii) a statement of review rights where applicable; and (iii) a description of how the individual may complain to THR and the Secretary of HHS, including the name, title, and telephone number of the THR Privacy Officer.

G. Accounting of Disclosures

The Privacy Rule generally grants individuals the right to a written "Accounting of Disclosures" of their Protected Health Information made in the six years prior to their request for an accounting [§164.528(a)].

In generally, an Accounting of Disclosures must be provided within 60 days of receipt of the request.

Required Accountings. Accountings are required for:

- Permitted Disclosures (e.g., under public health authority, to regulatory agencies, to persons with FDA-related responsibilities) with limited exceptions (e.g., law enforcement, national security, etc.)
- Disclosures pursuant to an authorization to use psychotherapy notes in research
- Disclosures made pursuant to a waiver of authorization; research on decedent's; and reviews preparatory to research.

Required Elements of Accountings. The accounting must include each of the following elements:

1. All Disclosures of the individual's Protected Health Information made by the Covered Entity, including disclosures to or by the Covered Entity's business associates.
   and
2. The date of each Disclosure.
   and
3. The name, and address if known, of the person or Entity receiving the information.
   and
4. A brief description of the Protected Health Information disclosed.
   and
5. A brief statement of the purpose of and basis for the disclosure, or a copy of the written request for the Disclosure.

Simplified Accounting for Multiple Disclosures. Where multiple Disclosures of Protected Health Information have been made to the same person or Entity for a single purpose, a full accounting of the first Disclosure is required as described

in the section above. Accounting for subsequent Disclosures may be accomplished by providing the following:

1. The frequency, periodicity, or number of Disclosures made.
2. The date of the last Disclosure.

Simplified Accounting for Waiver of Authorization, Activities Preparatory to Research, and Research Involving Decedents' Information. Where the requested accounting involves a Waiver of Authorization, Activities Preparatory to Research, or Research Involving Decedents' Information (see Chapter 6), a simplified accounting may be provided if the Disclosure involved 50 or more records.

The simplified accounting must include the following:

1. The name of the study or protocol.
2. A description of the purpose of the study and the criteria for selecting records.
3. A brief description of the type of Protected Health Information that was disclosed.
4. The date or timeframe of the disclosure, including the date of the last disclosure.
5. The name, address, and telephone number of the research investigator and the Entity to which the information was disclosed.
6. If requested, assistance in contacting the researchers to whom the information may have been disclosed.

H. Exceptions to the Accountings Requirement for Research

The Privacy Rule contains important exceptions to the Accounting of Disclosures requirement relative to research. These exceptions are described below.

Accounting Not Required for Disclosure Under an Authorization. An Accounting of Disclosures is NOT required where Protected Health Information has been disclosed under an Authorization, including an Authorization for research (see Chapter 6).

Accounting Not Required for Disclosure of De-Identified Information. An Accounting of Disclosures is NOT required where Protected Health Information has been De-Identified (see Chapter 6).

Accounting Not Required for Disclosure Within a Limited Data Set. An Accounting of Disclosures is NOT required where Protected Health Information has been disclosed within a Limited Data Set (see Chapter 6).

I. Procedures for Tracking Disclosures

Disclosure Tracking Database. The Privacy Officer at each THR Entity is responsible for developing and maintaining a Database for tracking disclosures of Protected Health Information. Operational procedures for updating the database are determined at the Entity level and may be either centralized or decentralized.

The Privacy Officer at each THR entity is also responsible for designating an individual to process requests for an Accounting of Disclosures. Responsibilities of this individual include checking the Disclosure Tracking Database and other key databases (e.g., Tumor Registry, Trauma Registry, Birth Certificate Database) in order to formulate a timely and accurate response to the requestor.

IRB Responsibilities. The THR IRB is responsible for tracking research protocols for which disclosures have been sanctioned pursuant to Reviews Preparatory to Research, Research Involving Decedents' Information, or a Waiver of Authorization for Research.

Chapter 10.
Quality Assurance Activities vs Human Subject Research

Goal:	**Discriminate Quality Assurance Activities from Human Subject Research and Clarify Privacy Rule Requirements**

General Rule:	**Quality Assurance activities constitute human subject research** when **they are designed or intended, at least in part, to develop or contribute to generalizable knowledge.** **In such cases, both the human subject protection requirements and the Privacy Rule research requirements apply.**

Regulatory References:	
Definition of Human Subject Research	**45 CFR 64.102(d)(f)**

Quality Assurance activities attempt to measure the effectiveness of programs or services.

Quality Assurance activities constitute human subject research when they are designed or intended, at least in part, to develop or contribute to generalizable knowledge. Under these circumstances:

- Human subject protection requirements apply, including requirements for prospective IRB review and informed consent.
- Privacy Rule research requirements apply, including requirements for Authorization for Research Use and Disclosure of Protected Health Information.

On the other hand, Quality Assurance activities that are designed solely for internal program evaluation purposes, with no external application or generalization, usually do not constitute human subject research. Under these circumstances:

- Human subject protection requirements do not apply. IRB review and research informed consent are not required.
- Privacy Rule research requirements do not apply. Authorization for Research Use and Disclosure of Protected Health Information is not required.

- Ordinary Privacy Rule requirements unrelated to research DO APPLY.

For example, suppose a medical department at a THR Entity conducts a review of patient records and then contacts patients to identify cases where recommended follow-up did not occur. If the sole intent is to improve the rate of follow-up at the THR facility, the activity is not human subject research. Human subject protection requirements for IRB and informed consent and Privacy Rule requirements **related to research** do not apply. Ordinary Privacy Rule requirements unrelated to research do apply.

However, if the intent of the activity, at least in part, includes extending the findings to patients at facilities outside THR, or disseminating the findings in such a way that applicability outside THR is stated or implied, then the activity does constitute human subject research**.** If the material (data) to be analyzed and presented outside of the local setting includes identifiable private information – information linked to one or more persons (for example, patients whose data were included in the QI initiative) – then the research would involve a human subject (45 CFR 46.102(f)) and a THR IRB protocol must be submitted and approved before analysis and presentation. If the material (data) were anonymized and de-identified before analysis and presentation, the IRB Office could declare the activity not to be subject to IRB review because the project would not involve a human subject (45 CFR 46.102(f)) and not be subject to the research provisions of the Privacy Rule (HIPAA), (45 CFR 164.500(a)) or FDA regulations (21 CFR 56.102(c)).

In cases where the intent of the activity changes after it has begun (e.g., findings from an activity intended solely for internal THR purposes lead to a desire to generalize and disseminate the results for application outside THR), the activity becomes research at the moment the intent to generalize the findings is formed, and the IRB should be contacted immediately. In such cases, the IRB will determine the conditions under which the investigator may pursue the relevant research objectives.

Where any disagreement arises about whether a Quality Assurance activity constitutes human subject research, the IRB, not the individual investigator, will determine the applicability of human subject protection requirements and Privacy Rule requirements.

Appendices

A. THR Privacy Rule eIRB Forms/eIRB Smartforms

1. Sample Authorization for Research Use and Disclosure of PHI
2. Sample Authorization for Research Use and Disclosure of Psychotherapy Notes
3. Sample Authorization for Collection, Storage, Use, and Disclosure of PHI for Research Registries, Repositories, or Data Banks
4. Application for Waiver or Alteration of Authorization for Research
5. Investigator Representation for Reviews Preparatory to Research
6. Investigator Representation for Research Involving Decedent Information
7. Limited Data Set User Agreement
8. Verification of De-Identified PHI Use or Disclosure
9. Investigator Checklist for Privacy Rule Compliance

Click Here to access items 1, 2, 3, 5, 6, 7 and 8
Click Here to access item 9
Click Here to access item 4 (form within initial submission application)

B. Related THR Privacy Rule Policies – See Policy Page on the THR Intranet

Privacy Policy Standard Definitions
Breach Notification
Business Associates
De-Identification of Health Information
Minimum Necessary Use and Disclosure of Health Information

C. HIPAA Privacy Regulations: 45 CFR Part 160 and Part 164

Click here to access the regulations