

OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES

HIPAA MANUAL FOR RESEARCH

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Summary of the HIPAA Privacy Rule

Effective April 14, 2003 health care consumers have new rights to control the use and disclosure of their health information. Under the Health Insurance Portability and Accountability Act (HIPAA), health care providers must grant their clinic patients the following rights:

- Right to receive a written notice about the entity's privacy practices
- Right to inspect and have copied one's own medical record
- Right to amend the record, where appropriate
- Right to request confidential communications regarding health information
- Right to request that uses and disclosures be restricted
- Right to obtain an accounting of all disclosures not authorized by the patient and not for treatment, payment or healthcare operations
- Right to complain about privacy violations to the entity and to the Department of Health and Human Services

Along with these patient rights come new responsibilities for the health care professional. Providers must obtain written acknowledgment of the receipt of the Notice of Privacy Practices. Health information may be used only for treatment, payment or operational activities unless individual authorization is granted or the use is specifically allowed by law. Apart from treatment activities, providers must use only the "minimum necessary" information to accomplish the intended purpose. Clinics and hospitals must implement new levels of office security and define appropriate levels of access to patient information for each job title. Business contracts will be affected, since organizations need to ensure that businesses who handle their patient information comply with the law. Finally, the regulations require that each member of the workforce receive special training about privacy protections.

Basic Premises

The HIPAA Privacy Rule governs the use and disclosure of "protected health information." Protected health information (PHI) is information that is created or received by a health care provider, a health plan or health care clearinghouse that relates to the past, present or future physical or mental health of an individual. Information about the payment for health care also may be PHI. To qualify as PHI, the information must identify the person directly or be sufficiently specific that the person could be identified. The Privacy Rule governs all PHI in all forms, whether electronic, paper, medical media, or conversation.

Regulations in the HIPAA Privacy Rule are founded on the principle that patients should be aware of all the uses and disclosures of their protected health information. Patients are informed about an entity's use of their information in three ways:

- Through receipt of the entity's Notice of Privacy Practices
- By written authorization prior to certain uses and disclosures, when specified by the law
- By exercising their right to receive an accounting of disclosures of their information

Another guiding principle of the Privacy Rule is that of “minimum necessary.” Health care entities must use only the minimum necessary information to accomplish the intended purpose of the use or disclosure. Exceptions to the minimum necessary standard include uses and disclosures related to treatment, disclosures to the individual patient, and certain disclosures required by law.

Using Patient Data for Research

The HIPAA Privacy Rule outlines the conditions under which health care data may lawfully be used or disclosed for research purposes. Any research use of PHI must meet one of two conditions:

1. Permission is granted by the patient through a written authorization form

OR

2. One of the following criteria is met:
 - a) the information is completely de-identified and no longer governed by HIPAA
 - b) a waiver of the individual authorization requirement is obtained from an institutional review board (IRB) or privacy board
 - c) the information is compiled into a “limited data set” and a data use agreement is executed
 - d) the activity qualifies as “preparatory to research”
 - e) the researcher is accessing information solely on decedents

The pages that follow outline detailed requirements for each of the categories listed above.

Written Authorization

Written authorization from the patient is the default requirement for use of protected health information in research. Prospective research, such as a clinical trial, generally requires prior authorization. The authorization differs from informed consent in that the authorization obtains specific permission to use and disclose protected health information for the research project. Elements of a privacy authorization should be incorporated into the informed consent document, and must contain the following elements:

- A specific description of the protected health information to be used or disclosed
- The names or classes of individuals authorized to make the use or disclosure
- The names or classes of individuals authorized to receive the use or disclosure
- Description of each purpose of the requested use or disclosure. Specific purposes must be listed; no “blanket” authorization is permitted.
- An expiration date or event for the authorization (*may be stated as the end of the need of the information for research purposes*)
- A statement that the individual has a right to revoke the authorization
- A reference to the covered entity’s right to condition service on the authorization, or the consequences of refusal to sign.
- A statement that the information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and no longer protected by the Privacy Rule.

The authorization must be written in plain language, and the subject must receive a copy of their **signed** authorization.

Authorizations must be study-specific. For projects that have sub-studies, a privacy authorization also must be obtained for the sub-study.

Research subjects may revoke their privacy authorization at any time during the research. If permission is revoked, the Privacy Rule allows continued use and disclosure of the information that was obtained prior to the revocation, to preserve the integrity of the study. For example, the researcher may use the information to account for study withdrawals, to report adverse events to FDA or to comply with study audits.

Instructions

1. All new subjects enrolled into previously–approved studies, on or after April 14, 2003, must receive a valid privacy authorization along with the study consent form. Refer to the authorization template found at Appendix “A”.
2. Subjects who are re-consented on or after April 14, 2003, also must receive a privacy authorization form.
3. Data from subjects who were enrolled prior to April 14, 2003 is “grandfathered in.” No privacy authorization is required, unless those subjects are re-consented after the compliance date.
4. Authorization forms for ongoing studies will be reviewed by the OSU-CHS Research Office. Draft authorization forms, along with the current consent form and protocol

summary, must be submitted to the OSU-CHS Research Office by **April 4, 2003** in order to assure review by the implementation deadline.

5. Starting in April 2003, consent forms for new studies should contain the required privacy authorization elements. These elements should be incorporated into the Confidentiality and Withdrawal sections of the consent document, in accordance with the new Consent Template. When the study is approved by the OSU-CHS IRB, the IRB report of action also will note approval for HIPAA compliance.
6. When research will require the use or disclosure of psychotherapy notes, a privacy authorization form separate from the informed consent form must be used.
7. If an individual revokes the privacy authorization form, the investigator must notify the IRB. The IRB will determine whether continued inclusion of PHI obtained prior to the revocation is necessary to preserve the integrity of the research. A form for Revocation of Authorization is found at Appendix H.

De-identification

Certain research projects can be accomplished through the use of de-identified data. For example, a de-identified data set might include age, gender, marital status, ethnicity, and relevant medical data or an unidentified tissue sample. De-identified data is not subject to HIPAA regulations.

To qualify as being de-identified under the Privacy Rule, the following data elements about the individual and the individual's relatives, employers, or household members must be **removed**:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;

(C) All elements of dates (except year) for dates directly related to an individual including:

- birth date

- admission date

- discharge date

- date of death; and

- all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code.

If the investigator receives only de-identified data or samples, then the Privacy Rule does not apply. However, if the investigator him/herself views records that contain identifiable information and from those records extracts a de-identified data set, then the project must undergo human subjects review and must qualify for a waiver of privacy authorization

(addressed below). If the project does not qualify for a waiver of privacy authorization, an honest broker must be used to create the de-identified data set.

Honest Broker De-identification of Protected Health Information for Retrospective Reviews and Subject Recruitment

An “honest broker” is an individual or system that is utilized by the health care provider (HIPAA covered entity), or a business associate thereof, to de-identify the PHI that they own/hold so that it can be provided to the investigator. De-identification means that the PHI has been stripped of HIPAA-defined patient identifiers such that an investigator (or others) can not directly or indirectly identify the corresponding patients-subjects. The de-identified information provided to an investigator by an honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries, however the information linking this code to the patient’s identity is retained by the honest broker and subsequent inquiries are conducted through the honest broker. Of course, the honest broker cannot be one of the research investigators.

This honest broker approach satisfactorily addresses the issues associated with the conduct of retrospective research involving existing medical record information. This approach can also be used to identify eligible patients for subsequent recruitment into clinical trials. For example, based on defined search criteria, the honest broker would provide a listing of potentially eligible subjects (identified by code number only), and their corresponding health information, to the clinical trial investigators. The investigators would then determine which of these patients appear to meet eligibility criteria and convey the respective code number back to the honest broker. The honest broker would subsequently provide the names of the identified patients to the patients’ personal physicians who would make contact with the patients to: 1) introduce the research study; 2) determine their interest in study participation; and 3) obtain their approval to be contacted by the investigators. Note that direct contact of the patients by the honest broker would constitute “cold-calling,” which is prohibited by OSU-CHS.

Instructions

1. To request a de-identified data set, contact the OSU-CHS Research Office to determine which honest brokers have been certified to create the de-identified data set. If none has been certified as of the date of the request, the investigator must sponsor the desired honest broker to de-identify the desired PHI. To do so, refer to the OSU-CHS Policy entitled “Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker”. This policy is found at Appendix “B”. The Application to be certified as an Honest Broker is found at Appendix “C”.
2. If an Honest Broker is selected that is certified by the OSU-CHS Research office but that is not otherwise affiliated with or part of OSU-CHS, verify that the OSU-CHS Research Office has a Business Associate Agreement on file with that Honest Broker. The Business Associate Agreement for Honest Broker is found at Appendix “D”.

3. Submit an Application to Hones Broker to Create De-Identified Data or Limited Data Set to the certified Honest Broker, identifying the data base from which the de-identified data should be drawn. The Application is attached hereto as Appendix “E”.
4. These standards also apply to any databases with clinical information that are maintained apart from the hospital or clinic setting but that are under the custody or control of OSU-CHS.

The Role of Honest Brokers in Research Activities at OSU-CHS

In connection with HIPAA, an OSU-CHS policy, entitled *Use and Disclosure of Protected Health Information for Research Purposes Pursuant to the HIPAA Privacy Rules* has been created. This policy affects all investigators that in any way use an OSU-CHS entity (i.e., hospital or clinic) in conducting their research. The OSU-CHS policy specifies, among other things, that for retrospective research involving the collection and analysis of health information, investigators must either obtain prospectively the written informed consent/authorization of the patients for the use of their identifiable information or must use an honest broker (including appropriate processes and systems) to de-identify the health information. The OSU-CHS policy does consider IRB-granted waivers of federal policy-required informed consent and HIPAA-required authorization but only in extraordinary circumstances. A request for an IRB waiver requires pre-approval of the OSU-CHS Privacy Officer. Furthermore, if a waiver is granted, the investigator is required to provide a detailed accounting of the record review to the entity's medical record director or privacy officer.

In order to ensure appropriate institutional oversight, the honest broker process must be developed at a department or school level, rather than each investigator having his/her own honest broker system, and must be prospectively approved by the OSU-CHS Privacy Officer and the IRB that serves the OSU-CHS entity that has the records of interest to the investigator. Alternatively, departments, schools or individual investigators may opt to use a third party honest broker such as that provided by the OSU-CHS Office of Clinical Research. OSU-CHS, itself, will typically not incur the expense associated with an honest broker system. OSU-CHS, specifically the OSU-CHS Privacy Officer, will be responsible for approving all honest brokers that request access to OSU-CHS held PHI for the purpose of de-identification or creating a limited data set and for executing business associate agreements with them.

The IRBs of record for the various OSU-CHS entities are expected to assist OSU-CHS in the HIPAA research compliance effort. Assistance is expected with educating investigators and holding them accountable with respect to the requirements of HIPAA set forth in the OSU-CHS HIPAA policies, forms and procedures.

Waiver of Individual Authorization

Some research projects do not involve written consent from the subject. The OSU-CHS IRB may approve a waiver of written consent if the risk is minimal, informed consent is not practicable, and a waiver of consent does not adversely affect the rights of the subject. For those studies, the investigator also may apply for a waiver of the privacy authorization. The IRB will approve a waiver of the privacy authorization if the research meets the following criteria:

- (A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements;
 - i. An adequate plan to protect the identifiers from improper use and disclosure;
 - ii. An adequate plan to destroy the identifier at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - iii. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;

- (B) The research could not practicably be conducted without the alteration or waiver;
and

- (C) The research could not practicably be conducted without access to and use of the protected health information.

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

HIPAA regulations require that when a medical record is accessed through a waiver of authorization, the researcher's access must be included in the patient's accounting of disclosures (see Accounting for Disclosures, below).

Studies that are "Exempt" under OSU-CHS IRB standards also may require a HIPAA waiver of privacy authorization, if the researcher must access the entire medical record to perform the data collection. However, if an Honest Broker or the holder of the medical record performs the data extraction and delivers only de-identified data to the researcher, no HIPAA waiver is required.

Instructions

1. A standard OSU-CHS Research Protocol process is required.
2. Additionally, the application for approval should include an Application for Waiver of HIPAA Privacy Authorization. This Application is found at Appendix "F".
3. Upon approval, the investigator should present the Research Waiver Approval to an Honest Broker or the holder of the medical records.

4. If the records accessed are held by an OSU-CHS clinic or hospital, that entity's Medical Records Department or the clinic manager will fulfill HIPAA requirements for tracking these disclosures so that an appropriate accounting may be provided to patients when requested.
5. Retrospective chart reviews generally will require a waiver of privacy authorization since the researcher has access to the full, identifiable medical record.
6. Projects that obtain PHI directly from the subject, but do not involve a written informed consent document, generally will require a waiver of privacy authorization. Examples would include a telephone survey. The waiver is required even if PHI from a medical record is not being disclosed, because the university is "using" PHI without written permission from the subject.

Limited Data Set

Certain research projects involve the use of data or tissue samples that do not meet the HIPAA standards for de-identification. The Privacy Rule allows the use of a “limited data set” for research purposes. A limited data set is one in which direct identifiers have been removed, but certain potential identifiers remain. For example, a limited data set might include the subject’s zip code, date of birth, hospitalization dates, and relevant medical information. Use of a limited data set is contingent upon the negotiation of a data use agreement. A copy of the approved Data Use Agreement is found at Appendix “G”.

A limited data set is protected health information that **excludes** the following direct identifiers of the individual and of relatives, employers, or household members of the individual:

- Names;
- Street address/Postal address information, other than town or city, State, and zip code;*
- Telephone and fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers, health plan beneficiary numbers or other account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers;
- Web universal resource locators (URLs) or Internet protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

*[*Unlike de-identified data, the limited data set may include five-digit zip code or any other geographic subdivisions, such as State, county, city, precinct and their equivalent geocodes. These geographic designations are permitted in order to support a range of research and public health activities, such as the analysis of local variations in disease burdens or statistics on the provision of health care services.]*

While the Privacy Rule dictates the identifiers that *must* be removed in a limited data set, the minimum necessary standard of the regulation remains in effect for any other health information. Researchers are responsible for requesting only the information that is necessary to accomplish the research purpose. For example, if age expressed in years, months, or days will suffice, date of birth should not be requested.

A limited data set is considered to be protected health information under the Privacy Rule. Prior to using the limited data set, the researcher must provide a data use agreement. The agreement must contain the following elements:

- The permitted uses and disclosures by the recipient
- The approved users and recipients of the data
- Agreement by the recipient not to re-identify the data or contact the individuals
- Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the data use agreement

- Agreement that the researcher will report to the covered entity any uses or disclosures of the limited data set which were not specifically allowed
- Agreement to require that any agents and subcontractors adhere to the same safeguards

Because certain potential identifiers are allowed, research employing a limited data set is subject to human subjects regulations. The project must be approved by the OSU-CHS IRB prior to initiation.

Disclosures in the form of a Limited Data Set are *exempt* from the HIPAA requirements for accounting of disclosures.

Instructions

1. Submit the application for approval of a research protocol, accompanied by an Application for Honest Broker to Create a Limited Data Set to the IRB.
2. Concurrently, submit the proposed Data Use Agreement, along with the protocol summary, to the OSU-CHS Research Office.
3. Send the IRB approval and the approved Data Use Agreement to the Honest Broker to create the research data or samples.
4. If an OSU-CHS affiliated hospital or clinic Medical Records Department acts as the Honest Broker to create a limited data set for a researcher, the Director of Medical Records or the Clinic Manager is responsible for assuring that information has IRB approval and an approved Data Use Agreement. If an outside Honest Broker will be used to create the Limited Data Set, the policies governing Honest Broker must also be met.

Reviews that are Preparatory to Research

The Privacy Rule allows a researcher to access protected health information if he/she attests that:

- The information is being sought solely to prepare a research protocol or for similar purposes preparatory to research.
- No protected health information will be removed from the medical record offices.
- The information being sought is necessary for research purposes.

This provision may be useful for examining medical records in order to formulate hypotheses, assess feasibility of a project, or determine the availability of data or a patient base. Researchers may **review** identifiable data in order to make these determinations; however, HIPAA requires that any information recorded during that review must meet de-identification standards. The preparatory review may not be used for recruitment purposes. For example, researchers may not record names and contact information during the review.

HIPAA regulations require that when a medical record is accessed for activities preparatory to research, the researcher's access must be included in the patient's accounting of disclosures (see Accounting for Disclosures, below).

Instructions

1. Researchers requesting medical records for protocol development should complete and sign the Application for Review Preparatory to Research. A copy of this Application is found at Appendix "I".

The OSU-CHS Medical Records Department will log each chart that is accessed in order to fulfill the HIPAA requirement for tracking these disclosures to the researcher.

Research on Decedents

Research on decedents is not subject to federal human subject regulations; however, it is subject to the HIPAA Privacy Rule. In order to access medical records on decedents, the researcher must provide the holder of the medical record with assurances that:

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

The holder of the medical record has a right to require documentation of the death of the individuals. A copy of the Request for Access to Decedent Information is found at Appendix “J”.

HIPAA regulations require that when a medical record is accessed for research on decedents, the researcher’s access must be included in the patient’s accounting of disclosures (see Accounting for Disclosures, below).

Instructions

1. Researchers should obtain a Request for Access to Decedent Information from the OSU-CHS IRB Office.
2. The holder of the medical record is responsible for providing the information and recording the researcher’s access in the patient’s accounting of disclosures.

Research Recruitment under HIPAA

The requirements of the Privacy Rule impact the way in which potential subjects are identified and recruited for studies. According to the rule, health care providers involved in the treatment of an individual are allowed to talk with their patient about enrolling in a research study. This discussion would not require a privacy authorization. However, if the health care provider shares the patient's information with a researcher who is not involved in the patient's care, some form of privacy permission must be in place, either through written authorization from the patient or an IRB waiver of authorization for the recruitment activity. The written permission or the waiver allows the researcher to view the patient's protected health information in order to make a determination about study eligibility. A copy of the OSU-CHS form to obtain a patient's permission to share information for purposes of research is found at Appendix "K".

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

Allowable Recruitment Practices

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

Research Repositories

The Privacy Rule specifies three ways in which protected health information can be compiled for a research repository:

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

Prospective collection of data or tissue samples for a research repository generally requires informed consent and a privacy authorization. Researchers should note that if approval is granted for the general purpose of constructing and maintaining the repository, then subsequent studies of the material also will require IRB review. Depending on the nature of the subsequent study, the IRB will determine whether consent/privacy authorization is required or if the consent/privacy authorization requirement is waived.

Individually-held Clinical Databases

For various reasons, clinical faculty may choose to maintain a database of their patients. These clinical databases may include, Disease Registries for research on a particular disease. Maintenance of this information is permissible, provided that the information is secured, either through the university network or certification of the computer, and provided that access is limited to personnel who need the information to perform their clinical job duties. Before a patient's medical information is included in a Disease Registry, the patient will be asked to sign a consent form to be included in the Disease Registry. The Research Registry Informed Consent Document is found at Appendix "L". A Sample Research Registry Protocol is found at Appendix "M".

Human subjects regulations and the HIPAA Privacy Rule mandate that **any** access of these clinical databases for a research purpose must first be approved by the IRB. The IRB will determine whether informed consent or a waiver of consent is appropriate. If consent is required, a privacy authorization also must be obtained. If consent is waived, then the researcher may apply for a waiver of the privacy authorization.

Additional HIPAA Effects on Research

“Minimum Necessary” Provision and Role-Based Access

When conducting research apart from an individual privacy authorization, HIPAA requires that researchers request and maintain only the minimum necessary protected health information to accomplish the research purpose. The holder of the medical record may reasonably rely on the researcher’s representation that the information being requested is indeed the minimum necessary.

The HIPAA principle of role-based access complements the standard of minimum necessary. Under the role-based access provision, health care providers must identify categories of the workforce who need access to PHI in order to carry out job duties. Providers then must limit the access by those individuals to the minimum level of PHI appropriate for job functions. OSU-CHS researchers are responsible for designating personnel who need access to study files that contain identifiable data. Access should be commensurate with the role on the research project.

Transition Requirements for Ongoing Research

Under HIPAA’s transition provisions, researchers are allowed to use study-specific protected health information that is obtained either before or after April 14, 2003, provided that the subject’s written informed consent or an IRB waiver of consent occurred prior to that date. For ongoing studies employing written consent, new subjects enrolled after April 14, 2003 must sign a HIPAA privacy authorization in addition to the informed consent document prior to study participation. Additionally, all subjects who are re-consented starting April 14th also must sign a privacy authorization.

*[NOTE: Studies that are conducted under an IRB exemption are **not** “grandfathered in” under HIPAA. Any exempt study that is still collecting data after April 14, 2003 must undergo a HIPAA review to determine whether privacy requirements apply. Investigators with open exempt studies will be individually contacted so that they can notify IRB of their plans for data collection.]*

Accounting for Research Disclosures

Under the Privacy Rule, patients have the right to receive an accounting of certain disclosures of their protected health information. The accounting process was established so that patients could learn about how their information was disclosed in cases where written permission was not required. Disclosures from a patient’s medical record that are made under a waiver of authorization, for activities preparatory to research, or for studies on decedents must be included in the accounting process. Researchers are responsible for assisting the holder of the medical

record in fulfilling their accounting duties. Accounting forms approved by the OSU-CHS Research Office are found at Appendix “N”.

Research Subjects’ Access to Research Records

Under the HIPAA Privacy Rule, patients have a right to access their information that is maintained in a “designated record set.” The designated record set is the collection of medical and billing information that is used, in whole or in part, to make clinical decisions about a patient. The Office of Civil Rights has given guidance that research records would not necessarily be considered as a designated record set. **However, researchers are obligated to ensure that all information in the research record that is clinically relevant is duplicated in the patient’s medical chart. If the Authorization to Use or Disclose PHI for Research Purposes signed by the patient/subject limits access to the research records, access may be withheld until the research study is complete.**

Record Retention

Researchers are responsible for appropriate record retention to meet HIPAA and other compliance requirements. The Privacy Rule requires that all documentation concerning patient privacy must be maintained for six years from the date it was last in effect. Clinical trial data should be retained at minimum for six years, and longer if required by the sponsor and/or FDA.