Section 23. **Health Insurance Portability and Accountability Act (HIPAA)**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the creation of a Privacy Rule for identifiable health information. While the primary impact of the Privacy Rule is on the routine provision of and billing for health care, the Privacy Rule also affects the conduct and oversight of research.

The Privacy Rule defines individually identifiable health information transmitted or maintained by a covered entity in any form (electronic, written, or oral) as Protected Health Information (PHI) and establishes the conditions under which investigators may access and use this information in the conduct of research.

Except as otherwise permitted, the Privacy Rule requires that a research subject "authorize" the use or disclosure of his/her PHI to be used in research. This authorization is distinct from the subject's consent to participate in research, which is required under the Common Rule and FDA regulations.

Under the Privacy Rule, a HIPAA Authorization may be combined with the consent document for research. When the consent document is combined with an Authorization, and require IRB review of the combined document.

At the medical school, for exempt projects and other research that does not require IRB review, the IRB chair or designee may act on requests for waivers and alterations of the HIPAA Authorization requirement for research purposes.

23.1 Definitions

These definitions are adapted from *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, published by DHHS.

- **Access**: Access is the mechanism of obtaining or using information electronically, on paper, or other medium for the purpose of performing an official function.

- **Accounting of Disclosures**: Information that describes a covered entity's disclosures of PHI other than for treatment, payment, and health care operations; disclosures made with Authorization; and certain other limited disclosures. For those categories of disclosures that need to be in the accounting, the accounting must include disclosures that have occurred during the 6 years (or a shorter time period at the request of the individual) prior to the date of the request for an accounting. However, PHI disclosures made before the compliance date for a covered entity are not part of the accounting requirement.

- **Authorization**: An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise

permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.

- **Covered entity**: A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which DHHS has adopted a standard.

- **Data Use Agreement**: An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

- **Designated Record Set**: A group of records maintained by or for a covered entity that includes: (1) medical and billing records about individuals maintained by or for a covered health care provider; (2) enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (3) used, in whole or in part, by or for the covered entity to make decisions about individuals. A record is any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.

- **Disclosure**: The release, transfer, access to, or divulging of information in any other manner *outside* the entity holding the information.

- **Health Information**: Health Information means any information, whether oral or recorded in any form or medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

- **Individually Identifiable Health Information**: Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

- **Limited Data Set**: Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

- **Minimum Necessary**: The standard that uses the least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request. Unless an exception applies, this standard applies to a covered entity when using or disclosing PHI or when requesting PHI from another covered entity. A covered entity that is using or disclosing PHI for research without Authorization must make reasonable efforts to limit PHI to the minimum necessary. A covered entity may rely, if reasonable under the circumstances, on documentation of IRB or Privacy Board approval or other appropriate representations and documentation under section 164.512(i) as establishing that the request for protected health information for the research meets the minimum necessary requirements.

- **Privacy Board**: A board that is established to review and approve requests for waivers or alterations of Authorization in connection with a use or disclosure of PHI as an alternative to obtaining such waivers or alterations from an IRB. A Privacy Board consists of members with varying backgrounds and appropriate professional competencies as necessary to review the effect of the protocol/research plan on an individual's privacy rights and related interests. The board must include at least one member who is not affiliated with the covered entity, is not affiliated with any entity conducting or sponsoring the research, and is not related to any person who is affiliated with any such entities. A Privacy Board cannot have any member participating in a review of any project in which the member has a conflict of interest or commitment.

- **Protected Health Information**: PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

- **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.

- **Use**: With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity or health care component (for hybrid entities) that maintains such information.

- **Waiver or Alteration of Authorization**: The documentation that the covered entity obtains from an investigator or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

- **Workforce**: Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity is under the direct control of the covered entity, whether or not they are paid by the covered entity.

23.2 The Role of the IRB under the Privacy Rule

Under the Privacy Rule, IRBs gained authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. Although DHHS and FDA Protection of Human Subjects Regulations include protections to help ensure the privacy of subjects and the confidentiality of information, the Privacy Rule supplements these protections by requiring covered entities to implement specific measures to safeguard the privacy of PHI. If certain conditions are met, an IRB may grant a waiver or an alteration of the Authorization requirement for research uses or disclosures of PHI.

The medical school has designated the medical school IRB to fulfill the functions of a Privacy Board for human subject research.

The Privacy Rule does not change the composition of an IRB. The Privacy Rule permits a covered entity to accept documentation of waiver or alteration approval from any qualified IRB or Privacy Board -- not only the IRB overseeing the organization's research.

When acting upon a request to waive or alter the Authorization requirement, an IRB must follow the procedural requirements of the DHHS Protection of Human Subjects regulations and, if applicable, FDA regulations, including using either the normal review procedures (review by the convened IRB) or the expedited review procedures.

When a request for a waiver or an alteration of the Authorization requirement is considered by the convened IRB, a majority of the IRB members must be present at the meeting, including at least one member whose primary concerns are in nonscientific areas. In order for an approval of a waiver or an alteration of the Privacy Rule's Authorization requirement to be effective, it must be approved by a majority of the IRB members present at the convened meeting. If a member of the IRB has a conflict of interest or commitment with respect to the PHI use and disclosure for which a waiver or an alteration approval is being sought, that member may not participate in the IRB review. DHHS and FDA have established categories of research that may be reviewed by an IRB through an expedited review procedure. Expedited review of a request for a waiver or an alteration of the Authorization requirement is permitted where the research activity is on the DHHS or FDA list of approved categories and involves no more than minimal risks. In addition, and permit an IRB to use an expedited review procedure to review minor changes in previously approved research. A modification to a previously approved protocol/research plan, which only involves the addition of an Authorization for the use or disclosure of PHI to the IRB-approved informed consent, may be reviewed by the IRB through an expedited review procedure, because this type of

modification may be considered to be no more than a minor change to research. If expedited review procedures are appropriate for acting on the request, the review may be carried out by the IRB chair or by one or more experienced reviewers designated by the Chair from among the IRB members. A member with a conflict of interest or commitment may not participate in an expedited review. If an IRB uses expedited review procedures, it must adopt methods for keeping all of its members advised of requests for waivers or alterations of the Authorization requirement as well as those requests that have been granted under an expedited review procedure. IRB documentation of approval of a waiver or alteration of the authorization requirement includes:

- The identity of the approving IRB.
- The date on which the waiver or alteration was approved.
- A statement that the IRB has determined that all the specified criteria for a waiver or an alteration were met.
- A brief description of the PHI for which use or access has been determined by the IRB to be necessary in connection with the specific research activity.
- A statement that the waiver or alteration was reviewed and approved under either normal or expedited review procedures.
- The required signature of the IRB chair or designee.

The medical school does not release PHI to investigators without individual authorization or proper documentation of an IRB or Privacy Board approval of a waiver or alteration of the requirement. In order to ensure that appropriate approvals are in place and that uses of patient information for research are in accordance with medical school standards, the medical school does not accept waivers or alterations approved by an external Privacy Board or IRB without review and approval of the requested disclosure by the medical school HRPP.

23.3 Authorization

Except as otherwise permitted, the Privacy Rule requires that a research subject "authorize" the use or disclosure of his/her PHI to be used in research. This authorization is distinct from the subject's consent to participate in research, which is required under the Common Rule and FDA regulations. Just as a valid consent under Common Rule and FDA regulations must meet certain requirements, a valid authorization must contain certain statements and core elements [(c)]. At the medical school, authorization is typically a stand-alone document. Template HIPAA authorization forms are available from the HRPP.

Once executed, a signed copy must be provided to the individual providing authorization. Signed authorizations must be retained by the covered entity for six (6) years from the date of creation or the date it was last in effect, whichever is later.

A research subject has the right to revoke their authorization at any time. Investigators are not required to retrieve information that was disclosed under the authorization

before learning of the revocation. Additionally, investigators may continue to use and disclosure PHI that was already obtained for the research under an authorization to the extent necessary to protect the integrity of the research.
When an authorization permits disclosure of PHI to a person or organization that is not a covered entity (such as a sponsor or funding source), the Privacy Rule does not continue to protect the PHI disclosed to such entity. However, other federal and state laws and agreements between the covered entity and recipient such as a Business Associate Agreement (BAA) or Confidentiality Agreement may establish continuing protections for the disclosed information. Under the DHHS Protection of Human Subjects regulations or the FDA Protection of Human Subjects regulations, an IRB may impose further restrictions on the use or disclosure of research information to protect subjects.

Authorization core elements include:

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

The Authorization must include the following required statements.

- A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

23.4 Waiver or Alteration of the Authorization Requirement

Obtaining signed authorization to access and use of PHI for research is not always feasible. The Privacy Rule contains criteria for waiver or alterations of authorization. If a

covered entity has used or disclosed PHI for research pursuant to a waiver or alteration of authorization, documentation of the approval of the waiver or authorization must be retained for six (6) years from the date of its creation or the date it was last in effect, whichever is later.
For research uses and disclosures of PHI, an IRB or Privacy Board may approve a waiver or an alteration of the authorization requirement in whole or in part. A complete waiver occurs when the IRB or Privacy Board determines that no authorization will be required for a covered entity to use and disclose PHI for a particular research project. A partial waiver of authorization occurs when the IRB or Privacy Board determines that a covered entity does not need authorization for all PHI uses and disclosures for research purposes, such as accessing PHI for research recruitment purposes. An IRB or Privacy Board may also approve a request that removes some PHI, but not all, or alters the requirements for an authorization (an alteration).

In order for an IRB or Privacy Board to waive or alter authorization, the Privacy Rule ((i)(2)(ii)) requires the IRB or Privacy Board to determine the following:

- 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:
    - An adequate plan to protect health information identifiers from improper use and disclosure.
    - An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a healthcare or research justification for retaining them or a legal requirement to do so).
    - Adequate written assurances that the PHI will not be reused or disclosed to (or shared with) 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 the PHI would be permitted under the Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

The Privacy Rule allows institutions to rely on a waiver or an alteration of Authorization obtained from a single Privacy Board to be used to obtain or release PHI in connection with a multi-site project. However, DHHS also recognizes that “covered entities may elect to require duplicate Privacy Board reviews before disclosing [PHI] to requesting researchers” (67 Federal Register 53232, August 14, 2002). At the medical school, PHI may not be disclosed for the purposes of research pursuant to a waiver provided by an external Privacy Board without the approval of the HRPP or IRB.

23.5 Activities Preparatory to Research

Under the preparatory to research provision of the Privacy Rule, a covered entity may permit a investigator who works for that covered entity to use PHI for purposes preparatory to research such as assessing the feasibility of conducting a research project,

developing a grant application, or identifying potential subjects. A covered entity may also permit, as a disclosure of PHI, a researcher who is not a workforce member of that covered entity to review PHI (within that covered entity) for purposes preparatory to research.

The covered entity must obtain from a investigator representations that (1) the use or disclosure is requested solely to review PHI as necessary to prepare a protocol/research plan or for similar purposes preparatory to research, (2) the PHI will not be removed from the covered entity in the course of review, and (3) the PHI for which use or access is requested is necessary for the research.

At the medical school, this is accomplished by the investigator submitting either a *Preparatory to Research* form, for projects in development, or a request for waiver of consent and authorization for screening purposes to the HRPP.

23.6 Research Using Decedent's Information

For research using decedent's information, HRPP/IRB staff obtains all of the following from the investigator:

- Representation that the use or disclosure sought is solely for research on the protected health information of decedents.
- Documentation, at the request of the covered entity, of the death of such individuals.
- Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

23.7 Future Uses: Databases and Repositories

The Privacy Rule recognizes the creation of a research database or a specimen repository to be a research activity if the data/specimens to be stored contain PHI. There are two separate activities that the covered entity must consider: (1) the use or disclosure of PHI for creating a research database or repository; and (2) the subsequent use or disclosure of PHI in the database for a particular protocol/research plan.

Individual authorization for the storage of PHI for future research must be sought unless the IRB has determined that the criteria for a waiver of the authorization requirement are satisfied. See Section 23.4 for a discussion of waivers of authorization.

For medical school investigators, consent for research and authorization for use and/or disclosure of PHI may be combined in one document. As with any research activity, the combined consent/authorization for future research must describe the future research uses in sufficient detail to allow the potential subject to make an informed decision. The investigator and IRB should be cognizant of uses of information/specimens that the target community may consider particularly sensitive, such as genetics, mental health, studies of origin, and use of tissues that may have cultural significance.

The authorization for future research can be a stand-alone document or may be incorporated into another consent/authorization if the information/specimens will originate from another research activity, such as a clinical trial, unless the research involves the use or disclosure of psychotherapy notes. Authorizations for the use or disclosure of psychotherapy notes can only be combined with another authorization for a use or disclosure of psychotherapy notes.

If the authorization for future research is combined with consent/authorization for another research activity (eg, a clinical trial), the consent/authorization must clearly differentiate between the research activities and allow the individual to opt-in to the future research. The use of opt-outs for future research are not permitted under the Privacy Rule because an opt-out process does not provide individuals with a clear ability to authorize the use of their PHI for future research, and may be viewed as coercive.

23.8 Corollary and Sub-studies

As with any other research, subject participation in corollary or sub-studies not essential to the primary aims of the research should be on a voluntary basis. This is particularly important when the primary research offers a potential benefit, such as treatment, that might compel the potential subject to agree to something that they otherwise would not.

HIPAA reinforces this ethical principle by explicitly stating that authorization for "unconditioned" activities, for which there is no associated treatment, benefit, or other effect on the individual subject associated with participation, cannot be required. The published preamble to HIPAA Omnibus clarifies the basis for this position, and the requirement that authorization for unconditioned activities involve a clear opt-in mechanism, stating:

> "This limitation on certain compound authorizations was intended to help ensure that individuals understand that they may decline the activity described in the unconditioned authorization yet still receive treatment or other benefits or services by agreeing to the conditioned authorization."
>
> and
>
> "…an opt out option does not provide individuals with a clear ability to authorize the optional research activity, and may be viewed as coercive by individuals."

As with authorization for future research, it is acceptable to combine in a single document the authorization for a conditioned activity, such as a clinical trial, with authorization for an unconditioned activity such as a corollary or sub-study that does not directly benefit or effect the individual participant, provided that:

- The authorization clearly differentiates between the conditioned and unconditioned research activities.

- The authorization clearly allows the individual the option to opt in to the unconditioned research activities.
- Sufficient information is provided for the individual to be able to make an informed choice about both the conditioned and unconditioned activities.

Separate authorization must be obtained for each research activity that involves the use and disclosure of psychotherapy notes. For example, authorization for the use and disclosure of psychotherapy notes for a clinical trial cannot be combined with an authorization for the use and disclosure of those psychotherapy notes for a corollary research activity.

23.9 De-identification of PHI under the Privacy Rule

Covered entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. The "Safe Harbor" method permits a covered entity to de-identify data by removing all 18 data elements that could be used to identify the individual or the individual's relatives, employers, or household members. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify individuals. Under this method, the identifiers that must be removed are the following:

- Names.
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
    - The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
    - The initial three digits of a ZIP Code containing 20,000 or fewer people are changed to "000."
- All elements of dates except the year for dates:
    - Directly related to an individual, including birth date, admission date, discharge date, and date of death.
    - All ages over 89 years and all elements of dates (including year) indicative of such ages; such ages and elements may be aggregated into a single category of age 90 years and older.
- Telephone numbers.
- Facsimile numbers.
- Electronic mail addresses.
- Social security numbers.
- Medical record numbers.
- Health plan beneficiary numbers.
- Account numbers.
- Certificate/license numbers.
- Vehicle identifiers and serial numbers, including license plate numbers.
- Device identifiers and serial numbers.

- Web universal resource locators (URLs).
- Internet Protocol (IP) address numbers.
- Biometric identifiers, including fingerprints and voiceprints.
- Full-face photographic images and any comparable images.
- Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Alternatively, a qualified statistician may certify that the risk is very small that health information could be used, alone or in combination with other available information, to identify individuals. The qualified statistician must document the methods and results of the analysis that justify such a determination. This analysis must be retained by the covered entity for six (6) years from the date of its creation or when it was last acted on, whichever is later.

The Privacy Rule permits a covered entity to assign to, and retain with, the de-identified health information, a code or other means of record re-identification if that code is not derived from or related to the information about the individual and is not otherwise capable of being translated to identify the individual. The covered entity may not use or disclose the code or other means of record identification for any other purpose and may not disclose its method of re-identifying the information.

Data that is considered de-identified under HIPAA may still be considered human subject data under the Common Rule, particularly when working with a small data set or a data set that contains sufficient detail that investigators can readily ascertain the identity of individual subjects using the data set alone or combining it with other data sources. Additionally, while coded information may be de-identified under HIPAA, if the investigator holds or has the ability to access both the code and the data, the information is considered identifiable private information under the Common Rule.

23.10 Limited Data Sets and Data Use Agreements

Limited data sets are data sets stripped of certain direct identifiers. Limited data sets may be used or disclosed only for public health, research, or health care operations purposes. Because limited data sets may contain identifiable information, they are still PHI and as such are not considered de-identified under the Privacy Rule. Unlike de-identified data, PHI in limited data sets may include: addresses other than street name or street address or post office boxes; all elements of dates (such as admission and discharge dates); and unique codes or identifiers not listed as direct identifiers. The following direct identifiers must be removed for PHI to qualify as a limited data set:

- Names.
- Postal address information, other than town or city, state, and ZIP code.
- Telephone numbers.
- Fax numbers.
- Email addresses.
- Social Security numbers.

- Medical record numbers.
- Health plan beneficiary numbers.
- Account numbers.
- Certificate and license numbers.
- Vehicle identifiers and license plate numbers.
- Device identifiers and serial numbers.
- Web universal resource locators (URLs).
- Internet protocol (IP) addresses.
- Biometric identifiers.
- Full-face photographs and any comparable images.

Before disclosing a limited data set, a covered entity must enter into a data use agreement (DUA) with the recipient, even when the recipient is a member of its workforce. The DUA establishes the parameters around the proposed uses and disclosures of the data, who is permitted to have access to the data, and stipulates that no other use will be made of the data, no attempt will be made to identify or contact individuals whose data are included in the limited data set, that appropriate safeguards are in place to protect the data from unauthorized use, and that the recipient will report any uses or disclosures of the PHI that they become aware of that not in keeping with the terms of the DUA. DUAs for the purposes of research are available through HRPP. DUAs should be submitted to the IRB along with the other project materials so that the medical school has a record of the agreement.

23.11 Research Subject Access to PHI

With few exceptions, the Privacy Rule guarantees individuals access to their medical records and other types of health information. One exception is during a clinical trial, when the subject's right of access can be suspended while the research is in progress. The subject must have been notified of and agreed to the temporary denial of access when providing consent and authorization. Any such notice must also inform the individual that the right to access will be restored upon conclusion of the clinical trial. Language accommodating this exclusion is included in the applicable medical school research authorization templates.

23.12 Accounting of Disclosures

The Privacy Rule generally grants individuals the right to a written "Accounting of Disclosures" of their PHI made by a covered entity without the individual's authorization in the six (6) years prior to their request for an accounting. A covered entity must therefore keep records of such PHI disclosures for six (6) years.

It is important to understand the difference between a *use* and a *disclosure* of PHI. In general, the *use* of PHI means communicating that information within the covered entity. A *disclosure* of PHI means communicating that information to a person or entity outside the covered entity. The Privacy Rule restricts both uses and disclosures of PHI, but it requires an accounting only for certain PHI disclosures.

Generally, an Accounting of Disclosures is required for:

- Routinely Permitted Disclosures (eg, under public health authority, to regulatory agencies, to persons with FDA-related responsibilities) with limited exceptions (eg, law enforcement, national security).
- Disclosures made pursuant to:
    - Waiver of Authorization.
    - Research on decedents' information.
    - Reviews Preparatory to Research.

An accounting is not needed when the PHI disclosure is made:

- For treatment, payment, or health care operations.
- Under an Authorization for the disclosure.
- To an individual about himself or herself.
- As part of a limited data set under a data use agreement.

The Privacy Rule allows three methods for accounting for research-related disclosures that are made without the individual's Authorization or other than a limited data set: (1) a standard approach; (2) a multiple-disclosures approach; and (3) an alternative for disclosures involving 50 or more individuals. Whichever approach is selected, the accounting is made in writing and provided to the requesting individual. Accounting reports to individuals may include results from more than one accounting method.

See medical school policy HIM27, *Accounting of Disclosure of Protected Health Information Policy*, for a detailed discussion on accounting of disclosures.