CHAPTER 9

MEDICAL RESEARCH AND THE HIPAA PRIVACY RULE

I. BACKGROUND

Pursuant to the Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, the U.S. Department of Health & Human Services established rules governing the privacy of all individually identifiable patient health information (referred to as "protected health information" or "PHI") (45 CFR Parts 160, 162, and 164). These rules, known as the "Privacy Rule," govern the use and disclosure of PHI by certain health care providers and entities (covered entities), including Adventist HealthCare and its facilities. Adventist HealthCare's general policies on the use and disclosure of PHI are set forth in Adventist HealthCare's Corporate Policy Manual, Policy 4.5. In addition to these general policies, the use and disclosure of PHI for research purposes is subject to additional research-specific provisions of the Privacy Rule. These additional provisions and their implications are the subject of this Chapter of the IRB Handbook.

The Privacy Rule applies to any research involving PHI, including research involving medical treatment (such as clinical trials) and to research using data contained in patient records. In many cases, the Privacy Rule applies to research that also is covered by other regulations (such as the Common Rule or FDA regulations). However, in some cases, only one set of regulations may apply. Compliance with the Privacy Rule is mandatory and in addition to other requirements applicable to human subject research at Adventist HealthCare.

II. PROTECTED HEALTH INFORMATION

PHI includes any information created, received or maintained by Adventist HealthCare, including demographic data, relating to:

- the individual's past, present or future physical or mental health or condition of an individual,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual (or for which there is a reasonable basis to believe can be used to identify the individual). Individually identifiable health information includes many common identifiers (e.g., name, birth date, Social Security number, medical record number).

III. USING OR DISCLOSING PHI FOR RESEARCH PURPOSES

The Privacy Rule describes the ways in which Adventist HealthCare can use or disclose PHI for research purposes. In general, the Rule permits Adventist HealthCare to use and disclose PHI for research if specifically authorized to do so by the subject using a specific authorization form (an "Authorization"). In addition, in certain circumstances, the Rule permits Adventist HealthCare to use and disclose PHI without Authorization for certain, limited types of research activities. For example, PHI can be used or disclosed for research without an

Authorization if Adventist HealthCare has documentation that an IRB has waived the Authorization requirement per the applicable rules. The Rule also allows Adventist HealthCare to enter into a data use agreement for sharing a limited data set of information. Also, there are separate provisions regarding how PHI can be used or disclosed for activities considered preparatory to research and for research on decedents' information. These areas are discussed below.

A. Research With Individual Authorization

Adventist HealthCare may use and/or disclose PHI for research purposes when the research subject specifically authorizes the use or disclosure of his or her information using an Authorization that meets specific regulatory criteria. Specifically, the Authorization must be written in plain language and must contain six core elements and three required statements. There is a fourth statement, regarding access to a subject's own PHI, which may be required under certain circumstances (discussed below). Adventist HealthCare suggests that investigators use either Adventist HealthCare's stand-alone Authorization for the Use and Disclosure of Protected Health Information in Research form or the combined Consent to Take Part in a Research Study and Authorization to Use and Disclose Protected Health Information to obtain Authorization under the Privacy Rule. These sample forms, when properly completed, satisfy the Privacy Rule's regulatory requirements.

The Privacy Rule Authorization differs from the standard research informed consent document. Under the Privacy Rule, a patient's Authorization permits Adventist HealthCare (and specified others) to use and disclose PHI for specific research purposes. In contrast, an individual's informed consent, as required by federal human subjects regulations and Adventist HealthCare policies, spells out the nature of the research, the associated risks, benefits and alternatives, and provides the subject's consent to participate in the research study as a whole. However, both sets of requirements can be satisfied using a single form. Regardless of whether a stand-alone Authorization or a combined consent/Authorization form is used, the form must contain the core elements and required statements.

1. Core Elements

Each of the following elements must be contained in the Authorization:

- a specific and meaningful description of the information to be used or disclosed (i.e., What PHI will be used/disclosed?);
- the name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure (i.e., Who can disclose the PHI?);
- the name(s) or other specific identification of the person(s) or class of persons to whom the covered entity may make the requested disclosure (including the identity of research sponsors such as pharmaceutical companies) (i.e., To whom can PHI be disclosed?);
- a description of each purpose of the requested use or disclosure (this must be study specific; it cannot include future unspecified research);

- an expiration date or an expiration event upon which the authorization ends (which can state that the Authorization expires upon the termination of the research study or simply state that the Authorization does not expire, but which cannot be left out of the Authorization altogether); and
- the signature of the individual and date (if the Authorization is signed by a personal representative, it must include a description of his or her authority to act for the individual).

2. Required Statements

The Authorization must also contain the following three required statements (note that a fourth required statement, set forth below, also may be required):

- the individual has the right to revoke the Authorization in writing (this is likely to be conditional – see below*);
- whether participation in the research is conditioned on the individual's signing of the Authorization;
- there is a potential that information disclosed pursuant to the Authorization may be subject to redisclosure by the recipient and thus may no longer be protected by federal privacy regulations.

*** Explanation Regarding Revocation of an Authorization**: Under the Privacy Rule, an Authorization must be revocable by the subject at any time. However, this right of revocation is limited to the extent that the covered entity has acted in reliance on the original authorization. For research uses and disclosures, this reliance exception (45 CFR 164.508(b)(5)(i)) permits the continued use and disclosure of PHI already obtained pursuant to a valid authorization to the extent necessary to preserve the integrity of the research study. For example, the reliance exception would permit the continued use and disclosure of PHI to account for a subject's withdrawal from the research study, as necessary to incorporate the information as part of a marketing application submitted to the FDA, to conduct investigations of scientific misconduct, or to report adverse events. However, the reliance exception would not permit a covered entity to continue disclosing additional PHI to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.

3. Additional Required Statement – If the Subject's Access to PHI will be Suspended During the Study

Under the Privacy Rule, an individual may access and, under some circumstances, amend certain parts of his or her PHI. However, if such PHI is created or obtained in the course of research that includes treatment, the individual's access may be suspended for the duration of the research provided (1) the individual agrees to such a suspension of access when he or she consents to participate in the research, and (2) the covered entity reinstates the individual's right of access upon completion of the research. Sample language to this effect has been incorporated into the Adventist HealthCare Authorization for the Use and Disclosure of Protected Health Information in Research form.

B. Research Without Individual Authorization

A covered entity may use and/or disclose PHI for research purposes without the research subject's Authorization under the following limited circumstances (each of which is described further below):

- pursuant to a waiver (or modification) by an IRB or Privacy Board;
- to prepare a research protocol;
- if the subject is deceased;
- if the information has been de-identified; or
- if the information is part of a limited data set and the researcher has signed a data use agreement.

1. Waiver or Modification of Authorization Requirement by the IRB

Adventist HealthCare may use or disclose PHI without the Authorization of the research subject if the Adventist HealthCare IRB approves a waiver (in whole or in part) of the Authorization requirement. Under the Privacy Rule, the following requirements must be met in order for such a waiver to be approved:

a. the use or disclosure of the PHI involves no more than a minimal risk to the subject's privacy based on, at least, the following:

   - plans to protect identifiers from improper use and disclosure;
   - plans to destroy the identifiers at the earliest opportunity (unless retention is justified); and
   - adequate written assurances that the PHI will not be reused or re-disclosed except as required by law, for authorized oversight of the research study, or for other research uses or disclosures expressly permitted under the Privacy Rule;

b. the IRB must be satisfied that the research could not practicably be conducted without the waiver; and

c. the IRB must be satisfied that the research could not practicably be conducted without access to and use of the PHI.

Additionally, the IRB must document its approval of a waiver or alteration, which must include, at a minimum:

a. the date on which the alteration or waiver was issued;

b. a statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures and satisfies the Privacy Rule's waiver criteria;

c. 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; and

d. the signature of the IRB Chair (or designee).

2. Using PHI to Prepare for Research

Adventist HealthCare may permit researchers to review PHI in medical records or elsewhere during reviews considered preparatory to research. These reviews allow a researcher to determine, for example, if there are a sufficient number or type of potential subjects to conduct the research. Importantly, there are several conditions to this type of use. To permit a researcher to conduct a review preparatory to research, Adventist HealthCare must receive representations from the researcher that:

a. the use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes;

b. no PHI will be removed from the covered entity during the review; and

c. the PHI that the researcher seeks to use or access is necessary for the research purposes.

The researcher may not use the PHI for actual research purposes until and unless one of the other conditions governing the use or disclosure of PHI is satisfied (for example, there has been written Authorization by the subject or an IRB has waived the Authorization requirement).

Identifying and Recruiting Research Participants. Under the preparatory to research provision, Adventist HealthCare may disclose PHI to researchers (or use PHI to fulfill a researcher's request) to aid in study recruitment. Under this provision, Adventist HealthCare may allow a researcher to identify potential study if provided with the representations described above. No PHI may leave Adventist HealthCare under the preparatory to research provision.

If a researcher is an Adventist HealthCare employee or workforce member, the researcher may use PHI to contact potential study participants for the purposes of discussing a research study and seeking Authorization. If a researcher is not an Adventist HealthCare employee or workforce member, he or she may not use Adventist HealthCare PHI to contact potential study participants unless he or she obtains a partial waiver of the Authorization requirement from the IRB. A partial waiver would permit Adventist HealthCare to disclose that PHI necessary for the researcher to contact the individual. (See Section III.B.1 of this Chapter for more information on waivers.)

3. Use of a Deceased Subject's PHI

The Privacy Rule permits Adventist HealthCare to use or disclose the PHI of a deceased person if it is necessary for research purposes. The researcher must represent to Adventist HealthCare that the decedent's PHI is being sought and will be used solely for research, and the PHI is necessary for the research purposes. Adventist HealthCare may request that the researcher provide documentation that the individual is deceased. Authorization from a decedent's family or estate is not required.

4. Use of "De-identified" Health Information

Under the Privacy Rule, information that is de-identified is not considered PHI, and thus its use or disclosure is not restricted by the Privacy Rule. De-identified health information neither identifies nor provides a reasonable basis to identify an individual. Pursuant to the Privacy Rule, Adventist HealthCare may determine that health information is de-identified if all of the following specific identifiers are removed from the data:

- name;
- geographic subdivisions smaller than state;
- any dates (except year) directly related to patient, and any ages (including corresponding birth years) over 89;
- telephone numbers;
- fax numbers;
- e-mail addresses;
- Social Security numbers;
- medical record numbers;
- health plan beneficiary numbers;
- account numbers;
- certificate/license numbers;
- vehicle identifiers and serial numbers;
- device identifiers and serial numbers;
- web URLs;
- internet protocol (IP) address numbers;
- biometric identifiers, including finger and voice prints;
- full face photographic images and any comparable image; and
- any other unique identifying number, characteristic, or code except as permitted under the Privacy Rule to re-identify data.

The Privacy Rule provides an alternate method for de-identifying PHI, known as the statistical de-identification method. This type of de-identification permits Adventist HealthCare to de-identify information in such a way that a qualified statistician determines that the de-identification methods used will render the data as not individually identifiable and that the risk of re-identification by the anticipated recipient of the data is very small. The statistician must document the methods and results of the analysis that justify his or her determination.

5. Use of a Limited Data Set with a Data Use Agreement

Under the Privacy Rule, a limited data set may be used by an Adventist HealthCare employee or workforce member for research purposes without an Authorization from the subject and without a waiver from an IRB. However, the research still may be subject to the federal

regulations and Adventist HealthCare IRB policies governing human subject research, so Adventist HealthCare IRB review and approval may still be required.

A limited data set is PHI that excludes all the direct identifiers listed above in the de-identified information section, except that the following identifiers may be included:

- Geographic information identifying town, city, state, and/or zip code; and
- any dates directly related to patient (e.g., birth date, admission date, discharge date).

A limited data set may be disclosed outside of an Adventist HealthCare facility or to a researcher who is not an Adventist HealthCare employee or workforce member only if the facility's Privacy Officer enters into a data use agreement with the recipient of the data. The Privacy Rule sets forth the requirements of a data use agreement.

IV. ACCOUNTING FOR RESEARCH DISCLOSURES

Under the Privacy Rule, individuals have a right to an accounting of the disclosures of their PHI made by Adventist HealthCare or Adventist HealthCare's business associates (45 CFR 164.528). Adventist HealthCare's Privacy Officer or the Privacy Officer for a particular facility can provide additional information regarding the Privacy Rule's accounting provisions.

Relevant to research, two types of disclosures are exempt from the Privacy Rule's accounting requirement: (1) research disclosures made pursuant to an individual's Authorization; and (2) disclosures of the limited data set to researchers with a data use agreement. All other research disclosures must be tracked by Adventist HealthCare and accounted for upon a patient's request.

The Privacy Rule allow for three methods of accounting for research-related disclosures: (1) a standard approach; (2) a multiple disclosures approach; and (3) and alternative for disclosures involving 50 or more individuals.

A. STANDARD ACCOUNTING

Standard accounting includes the following for each disclosure:

- The date the disclosure was made.
- The name and address of the person or entity receiving the PHI.
- A brief description of the PHI disclosed.
- A brief statement of the reason for the disclosure.

B. MULTIPLE DUSCLOSURES ACCOUNTING

Multiple disclosures accounting is permissible if the covered entity has made multiple disclosures of PHI to the same person or entity for a single purpose. The following must be included for each disclosure:

- The date the initial disclosure was made.

- The name and address of the person or entity receiving the PHI.
- A brief description of the PHI disclosed.
- A brief statement of the reason for the disclosure.
- The frequency or number of disclosures made.
- The date of the last disclosure.

C. ALTERNATIVE ACCOUNTING

If a covered entity has made disclosures regarding 50 or more individuals for a particular research project, the accounting may be limited to the following information:

- The name of the protocol or research activity.
- A description of the research protocol or activity, purpose of the research, and criteria for selecting particular records.
- A brief description of the type of PHI disclosed.
- The date or period of time during which the disclosures may have occurred.
- The name and address of the entity that sponsored the research and of the researcher who received the PHI.
- A statement that the individual's PHI may or may not have been disclosed for a particular protocol or research activity.

V. RECRUITING FOR RESEARCH STUDIES

Under the Privacy Rule, Adventist HealthCare is permitted to disclose PHI to the individual who is the subject of the information, regardless of the purpose of the disclosure. Therefore, the Privacy Rule does not limit discussions between health care providers and their own patients, even if the discussions include the option of enrolling in a clinical trial. That is, a researcher or research team member who is an employee or a member of Adventist HealthCare's workforce may use PHI to contact prospective research subjects, while a researcher who is not an employee or a member of Adventist HealthCare's workforce must obtain a partial waiver of the authorization requirements.