**Department:** **UAMS Institutional Review Board**
**Policy Number:** **13.3**
**Section:** **Confidentiality**
**Effective Date:** **April 15, 2003**
**Revision Date:** **June 10, 2004**

**SUBJECT: HIPAA Privacy Rule**

**Use and Disclosure of Information**

The HIPAA Privacy Rule identifies five distinct methods of using and disclosing information for research purposes. The researcher should be familiar with the five methods and should choose the method most suited to his or her study.

**Use and Disclosure with Authorization of the Subject**

The most direct method of using and disclosing data is to ask the permission of the subject of that data. The permission is termed "authorization" in the Privacy Rule. A researcher may use or disclose PHI for research purposes after obtaining a HIPAA Authorization from the individual who is the subject of the information. Such authorization is distinct from an informed consent for participation in a research study.

The Privacy Rule defines a valid authorization as having six "core elements" and four "required statements." These are detailed below. In addition to these items, the authorization must be written in plain language and a signed copy must be given to the individual. If a representative for the research subject signs the authorization, the representative's authority must also be noted. An authorization form does not have to be approved by the IRB to be valid for purposes of the Privacy Rule. However, because it will generally be part of the informed consent process, the IRB requires the authorization as part of its review of the informed consent process proposed by the researcher.

1. Core Elements of an Authorization
    a. Description of the PHI to be used and disclosed "in a specific and meaningful fashion" – To meet this definition, the description should be understandable to the individual; not a mere recitation of data elements understandable only to the research team. The description should be specific and the request should be limited to that information necessary to the research protocol. Examples of specific and meaningful descriptions include "Lab tests" "clinic visit data" "X-ray readings." Do not use medical jargon or test codes ("Chem7").

    b. Name or specific identification of the person or class of persons authorized to make the disclosure – This refers to the "covered entity" that holds the information.

    c. Name or specific identification of the person or class of persons authorized to receive the information – It is advisable to identify the principal investigator as receiving this information. An authorization also should refer to the "research team" that will work with the PI in conducting the research.

    d. Description of each purpose of the requested use or disclosure – The authorization should include a clear, concise and understandable description of the purpose of the research. This description may be drawn from the explanation of the research contained in the informed consent form.

    e. Expiration date or event – This is the date that the authorization to use or disclose the information will expire. For research purposes, this may be the end of the study. It is

acceptable, for studies that will include development of a database, for the authorization to indicate "no expiration date." If a study has a specific end date or event that will occur at the end, this should be used. However, the authorization must include this information in some form.

2. Required Statements in an Authorization Form
    a. A statement that the individual has a right to revoke the authorization in writing and EITHER
        i. The exceptions to this right and description of how the individual may revoke OR
        ii. A reference to the covered entity's notice of privacy practices, if the exception information is contained there.
    b. Ability or inability to condition treatment, etc., on signing the authorization – Because research may be dependent on the use and disclosure of PHI, participation in the study may be conditioned on the subject signing the authorization.
    c. The potential for information to redisclosed and no longer protected under HIPAA.
    d. A statement specifying any restrictions of the subject's access to medical information generated as a result of the research study.

**Waiver of Authorization**

To use or disclose a patient's identifiable health information for research based on a waiver, a researcher must have documentation of a waiver from the IRB. To obtain the waiver, the researcher must provide adequate justification to the IRB to allow the IRB to make its determination. It is recommended that the researcher write a memorandum to the IRB detailing his or her request and justification.

If the elements for a waiver of authorization are provided, the IRB may grant a waiver of authorization for new studies submitted after April 14, 2003 or for an ongoing existing study that does not meet the transition provisions (i.e., is not "grandfathered" under the Privacy Rule). In either case, the board may use either normal review procedures (38 CFR 16.108(b)) or expedited review procedures (38 CFR 16.110) as defined in the Common Rule. In any circumstance, the criteria for granting the waiver remain the same.

**Elements Required for Waiver of Authorization (45 CFR 164.512(i)(2))**

1) A brief description of the PHI to be used;
2) An adequate plan to protect the identifiers from improper use or disclosure;
3) An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or retention is required by law;
4) Representation that the PHI will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI would be permitted;
5) Certification that the research could not practicably be conducted without the waiver; and
6) Certification that the research could not practicably be conducted without access to and use of the PHI.

The IRB approval for the waiver of authorization should include **ALL** of the following:

1. Identification of the IRB

2. Date of IRB approval of waiver of authorization
3. Statement that alteration or waiver of authorization satisfies the following criteria:
    a. The use or disclosure of the requested 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 identifiers 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 requested 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 the requested information would be permitted by the Privacy Rule;
    b. The research could not practicably be conducted without the waiver or alteration; and
    c. The research could not practicably be conducted without access to and use of the requested information.
4. A brief description of the PHI for which the IRB has determined use or disclosure to be necessary
5. Identification of the review procedure used to approve the waiver of authorization (either normal review procedures (38 CFR 16.108(b) or expedited review procedures (38 CFR 16.110)).
6. Signature of chair of the IRB or member designated by the chair to approve the waiver of authorization.

**De-Identification (Safe Harbor)**

The HIPAA Privacy Rule applies only to identifiable information. If information received from an outside source is de-identified, it no longer is subject to the Privacy Rule. CAUTION: De-identification for HIPAA purposes may not be the same as “anonymizing” data as commonly understood by researchers. The investigator will be required to provide the IRB with a letter from the source providing the de-identified data set assuring the IRB that the information supplied to the investigator will be appropriately de-identified.

To meet the standard for de-identified data under the Privacy Rule, **a data set cannot include** any of the following 18 elements:

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if according to the current publicly available data from the Bureau of the census: a) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and b) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. 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.
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.

**Statistical Method of De-identification**

An alternative to the "safe harbor method" is the statistical method. This standard is met if a person with appropriate knowledge and experience applying generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable makes and documents a determination that there is only a small risk that the information could be used by others to identify a subject of the information. These techniques include removing all direct identifiers, reducing the number of variables on which a match might be made, and limiting the distribution of records through a "data use agreement"' or "restricted access agreement" in which the recipient agrees to limits on who can use or receive the data.

**Limited Data Set**

The limited data set option is less restrictive than complete de-identification but does not allow unfettered access to identifiable information but requires certain safeguards. A limited data set is one that has been stripped of the following elements:

1. Name
2. Street address (specifically, a postal address other than city, State and Zip code)
3. Telephone and fax numbers
4. E-mail address
5. Social security number
6. Certificate/license number
7. Vehicle identifiers and serial numbers
8. URLs and IP addresses
9. Full face photos and any other comparable images
10. Medical record numbers, health plan beneficiary numbers, and other account numbers
11. Device identifiers and serial numbers
12. Biometric identifiers, including finger and voice prints

The key differences between a de-identified data set and a limited data set would be the inclusion, in the latter, of dates and some geographic codes.

The use of a limited data set requires a data use agreement. This document is intended to provide assurance of the limited use or disclosure of the information in the limited data set. Under the Privacy Rule, a valid data use agreement must specify 1) the permitted uses and disclosures of information by the recipient, consistent with the purposes of the research, 2) the limits on who can use or receive the data, 3) that the recipient will not re-identify the data or contact the individuals, and 4) that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the Privacy Rule and data use agreement or as required by law.

If the investigator is receiving a limited data set agreement from an outside source, UAMS will be asked to sign a limited data set agreement with the outside source. The investigator should work with the UAMS HIPAA Research Privacy Officer in order to finalize this agreement. A copy of this agreement must be submitted to the IRB. Disclosure of the information in a limited data set does not require review by an IRB or Privacy Board. It will require working with the UAMS HIPAA Research Privacy Officer in order to develop an agreement governing the limited data set disclosure.

**Research on Decedents' Information**

Research on decedent's information is permitted if the covered entity obtains from the researcher, either orally or writing: 1) representation that the use or disclosure is sought solely for research on the PHI of decedents; 2) documentation, at the request of the covered entity, of the death of such individuals; and 3) representation that the PHI for which use or disclosure is sought is necessary for the research purposes. It is suggested that the researcher have written documentation in his/her files covering these issues.

**Transition Provision (Grandfather Provision)**

A transition provision was included in the Privacy Rule that allows for "grandfathering" certain research studies that were underway at the compliance date mandated for the Privacy Rule.

The Privacy Rule allows for use and disclosure of PHI created or received for research, either before or after April 14, 2003, if one of the following was obtained prior to that date:

- An authorization or other express legal permission from the individual to use or disclose his or her information for research,
- The legally effective informed consent of the individual to participate in the research, OR
- A valid waiver of informed consent from an IRB according to the Common Rule or an exception under the FDA's human subject protection regulation at 21 CFR 50.24

However, if a subject is asked for informed consent (or asked to re-consent) on or after April 14, 2003 an authorization must be obtained at that time.

**Summary of Transition Provisions:**

- Waiver of informed Consent obtained prior to April 14, 2003: No action necessary. The waiver is deemed "authorization" for Privacy Rule purposes.

- Informed Consent obtained prior to April 14, 2003: Information obtained pursuant to an informed consent signed prior to April 14, 2003, even if the information is not obtained until after April 14, 2003**,** is "grandfathered" under the Privacy Rule. HOWEVER, if the subject is "re-consented," that is, asked for a new informed consent ON OR AFTER April 14, 2003, a valid authorization must be obtained.

- Informed Consent obtained ON OR AFTER April 14, 2003: Must include a separate authorization form or authorization language within the informed consent form.