HIPAA (Health Insurance Portability and Accountability Act) Requirements for Waiver of Authorization to Use Protected Health Information in Research.

1.0 INTRODUCTION

The requirements to approve use of identifiable private health information (PHI) for research without subject consent will change with the implementation of HIPAA on April 14, 2003. Research that is already approved will not be affected; only new applications.

The Privacy Rule permits the use of PHI in medical research without obtaining the subjects’ individually signed authorizations under several conditions. The conditions include: (1) review of PHI preparatory to research; (2) research involving subjects who are decedents; (3) research involving the use of limited data sets; and (4) research in which a waiver or alteration of authorization is granted by the IRB.

The requirement to obtain IRB approval prior to doing any research activity remains the same. However, additional specific justifications and documentation will be required to comply with the HIPAA regulations for research activity which requests waiver or alteration of obtaining subject consent to access PHI. The main types of research affected are those that involve the use of human tissues, medical record reviews, and use of verbal consent (i.e. an information sheet instead of a signed consent.) These types of research are generally approved under Exempt or Expedited IRB procedures.

2.0 REVIEWS OF PHI PREPARATORY TO RESEARCH [45 CFR § 164.514(i)(1)(ii)]

2.1 Investigators may review PHI without obtaining the authorization of each patient/subject in the preparation for a research study, e.g., to assist in the formulation of a study hypothesis or determine if there is an adequate qualified population to conduct a research study. In order to use PHI under this provision of the regulations, the researcher must provide assurances to the covered entity (owner/custodian of the medical record) holding the PHI that:

(1) the use or disclosure of PHI is sought solely for the purpose of preparing a research protocol or for similar purposes preparatory to research;

(2) no PHI is to be removed from the covered entity by the researcher in the course of review; and

(3) the PHI for which use or access is sought is necessary for research purposes.

2.2 To comply with this exemption, the researcher must not transfer PHI electronically to the researcher’s office. Specifically, the researcher may not email, transfer to a disc or CD any PHI. In addition, review preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference. (The covered entity determines how this may be done)

2.3 HOW TO PROCEED: Researchers wishing to conduct reviews of PHI Preparatory to Research should contact the covered entity that manages the PHI, to obtain instructions.
3.0 RESEARCH INVOLVING SUBJECTS WHO ARE DECEDE NTS (deceased) [45 CFR § 164.512(i)(1)(iii)]

3.1 Investigators may proceed without authorization of decedents’ next of kin when using PHI that is derived entirely from decedents. Qualification under this provision of the Privacy Rule requires that the researcher provide to the covered entity

(1) assurance 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) assurance that use of the PHI is necessary for the research purposes.

3.2 HOW TO PROCEED: Researchers wishing to conduct research using decedents’ PHI should contact the covered entity that manages the PHI, to obtain instructions.

4.0 HUMAN SPECIMEN USE AND RECORD REVIEW RESEARCH SUBMITTED FOR EXEMPT IRB REVIEW (DATA OR SPECIMENS EXIST PRIOR TO RESEARCH)

4.1 HIPAA [45 CFR § 164.514(b)] defines a data set which is considered to be “de-identified” and does not require a waiver of the requirement to obtain an authorization. There are only two ways for a data set to qualify as “de-identified.”

4.2 One way is for a person, who possesses appropriate knowledge and experience in using accepted statistical and scientific principles and methods for rendering information not individually identifiable, to make a determination that the risk is very small that the information could be used by the recipient, alone or in combination with other information, to identify individual subjects. When this method is used for determining that PHI has been de-identified, the individual making this determination must document the methods and results of the analysis that justify his/her determination that the health information is properly de-identified.

4.3 The second way is to use a “safe harbor” data set that is considered de-identified. A safe harbor data set excludes all of the 18 identifiers listed below:

1. Names of an individual or any relative or contact person;
2. 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 the geographical unit represented by the three initial digits contain more that 20,000 people;
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 indicative of age over 89, 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) 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.

4.4 HOW TO PROCEED: Use of a de-identified data set can be submitted for IRB review under procedures for non-research/non-human research.

5.0 LIMITED DATA SETS

5.1 The HIPAA rule at 45 CFR § 164.514(e) states that a “limited data set” requires the removal of fewer identifiers than a de-identified data set. The identifiers to be removed are the following:

1. Photographs;
2. Names of an individual or relatives or any contact person;
3. Medical record numbers;
4. Street or postal address other than city, state and zip code.
5. Telephone and fax numbers;
6. Email address;
7. Social security number;
8. Certificate/license numbers;
9. Vehicle identifiers and serial numbers;
10. URLs and IP addresses;
11. Biometric identifiers, including finger and voice prints;
12. Any other identifiers by which an individual could be easily identified.

5.2 Identifiers which can be kept are the following:

1. Admission, discharge, and service dates;
2. Date of death;
3. Age (including 90 or over);
4. Five digit zip code or any other geographic subdivision such as state, county, city, precinct, and their equivalent geocodes; and
5. Date of birth.

5.3 The recipient of a limited data set must sign a data-use agreement provided by the covered entity that will disclose the PHI [per 45 CFR § 164.514(e)(2)].
5.4 HOW TO PROCEED: A protocol using a limited data set, including the data-use agreement, may be submitted for IRB review for exempt research. Information about data use agreements should be obtained from the covered entity holding the PHI (the institution whose records you want to use).

6.0 IRB WAIVER OF AUTHORIZATION FOR RESEARCH USE OF PHI

6.1 The Privacy Rule [45 CFR § 164.512(i)(1)(i)] permits investigators to use PHI in research under an alteration or waiver of the authorization requirements when they obtain approval from an IRB or “privacy board.” Investigators are required to secure the waiver or alteration of only one IRB or privacy board, even if they will seek PHI from more than one covered entity maintaining such information. In addition, the committee utilized by the investigator is not required to be the IRB or privacy board of the covered entity. However, covered entities providing PHI are permitted to request that their own IRB or privacy board approve requests for waiver or alteration of authorization prior to allowing use or disclosure of PHI to investigators. Because the UTHSCSA IRB will be used as the mechanism for reviewing requests from investigators done at facilities covered by our IRB, the privacy board mechanism will not be discussed here further.

6.2 The criteria for determining whether a study qualifies for a waiver or alteration of authorization, are specified in the Privacy Rule. The investigator must provide information about the research study that enables the IRB to determine that the following conditions are satisfied:

(1) there must be no more than minimal risk to the privacy of individual subjects based on the presence of the following elements: (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) 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 identifiers or such retention is otherwise required by law; and (c) an adequate written assurance that the PHI will not be reused 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 of disclosure is permitted without authorization;

(2) it must not be practicable to conduct the research without the waiver or alteration of the authorization requirement;

(3) it must not be practicable to conduct the research without access to and use of the PHI for which the waiver or alteration of the authorization requirement is sought; and

(4) the rights or welfare of subjects will not be adversely affected.

6.3 After the IRB has approved the waiver or alteration of authorization, the investigator must provide the covered entity maintaining the PHI with documentation of that approval using the IRB approval letter.

6.4 HOW TO PROCEED: Waiver of authorization may be sought for three specific research uses of PHI: (i) to identify potential research subjects through review of their PHI; (ii) to contact potential subjects in order to determine their interest in research participation; and (iii) to receive or collect PHI during the conduct of research studies.
6.4.i Identification of Potential Subjects

Although investigators can use PHI in activities that are preparatory to research without obtaining authorizations and without a waiver, such use must not involve either removing records from the facilities or copying PHI from these records. If an investigator needs to copy or remove information from medical records in order to identify potential subjects, then he/she must secure a waiver of authorization to examine these medical records unless he/she is a staff member of the institution and a direct care provider for the individuals whose records will be reviewed. [Note: Check with the covered entity that holds the records you want to review to obtain their policy about when a waiver is required, since some covered entities will be more stringent that others.]

IRB Form J must be used to request a waiver of authorization for identifying potential subjects. Complete the form and submit it along with your research proposal for IRB review. If applicable provide data collection sheet, screening log etc.

6.4.ii Recruitment of Potential Subjects

Once potential research subjects have been identified, they must be contacted in accordance with the provisions of the regulations. Personnel from the institution holding the records may use PHI to make the initial contact, without prior authorization from potential subjects, to determine their interest in participating in a research study. Direct care providers may communicate with their current or past patients about research opportunities with prior authorization of these patients. However, an investigator may not use the PHI maintained by another provider or facility in order to make the initial contact with individuals about participation in a research study, unless those individuals have given prior authorization for such a contact or the IRB has provided a waiver of authorization to the investigator.

IRB Form J must be used to request a waiver of authorization for recruitment of potential subjects. Complete the form and submit it along with your research proposal for IRB review.

6.4.iii Use of Protected Health Information in the Conduct of Research Studies

Investigators may obtain a waiver or alteration of prior authorization by subjects if the research use of their PHI meets the conditions described above for approval by the IRB. This option will normally be relevant only to studies in which waiver or alteration of informed consent for research participation is also being sought. The most common use of the waiver option will relate to retrospective studies of PHI associated with existing medical records and specimens. The most common use of an alteration to an authorization will relate to studies which have circumstances that would cause some of the required elements to be omitted or altered.

IRB Form J must be used to request a waiver of prior authorization for research use of PHI. Complete the form and submit it along with your research proposal for IRB review.

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