STANDARD ADMINISTRATIVE PROCEDURE

16.99.99.M0.24 Uses and Disclosures of Protected Health Information for Research

Approved October 27, 2014
Next scheduled review: October 27, 2019

SAP Statement

This procedure applies to Texas A&M Health Science Center (TAMHSC) health care providers, its participating physicians and clinicians, employees and business units who provide management, administrative, financial, legal, and operational support to or on behalf of the health care provider and has been designated as a member of the TAMHSC Health Care Component. This procedure pertains to protected health information covered by the TAMHSC Health Care Component's Notice of Privacy Practices.

Official procedure

1. GENERAL

The I.R.B. will be responsible for ensuring that strict policies and procedures regarding access, use[i], and disclosure of protected health information for research purposes are followed.

Protected Health Information obtained by TAMHSC HIPAA Health Care Component may not be used internally or disclosed to any persons or organizations outside TAMHSC Health Care Component for research purposes without the prior approval of the Institutional Review Board (I.R.B.) acting on behalf of TAMHSC Health Care Component.

1.1 Certain requirements apply to the use and disclosure of protected health information in connection with research involving human subjects. As a rule, the I.R.B. may not authorize the use or disclosure of protected health information for research purposes except for the following.

1.1.1 For research on the protected health information of a decedent.

1.1.2 If TAMHSC Health Care Component has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003).

1.1.3 If the information is completely "de-identified".

1.1.4 If the information is partially de-identified into a "limited data set" and the recipient of the information signs a data use agreement to protect the privacy of such information.

1.1.5 If TAMHSC Health Care Component has obtained a valid authorization from the individual subject of the information.

1.1.6 The I.R.B. approves a waiver of the individual authorization requirement.

1.2 The I.R.B. must determine that one of the exceptions described below applies for permitting the use and disclosure of any protected health information for research purposes.

1.3 The I.R.B. should require either an individual authorization or must grant a waiver of authorization if none of the other exceptions apply.

1.4 All research activities must also comply with other applicable TAMHSC Health Care Component policies relating to research and with any additional requirements that apply to the specific types of information identified above as having special rules.

1.5 Finally, to the extent that TAMHSC Health Care Component provides treatment to subjects as part of a research study, they must follow other policies to the extent those policies apply to the provision of health care to individuals.

2. PROCEDURE

2.1 Research Defined. For purposes of this procedure, research includes any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of or contribution to generalizable knowledge.

2.1.1 Knowledge may be generalizable even if a research study only uses protected health information held within TAMHSC Health Care Component and the results are generalizable only to the population served by TAMHSC Health Care Component.

2.1.2 Research is therefore not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this procedure.

2.1.3 The development or contribution to generalizable knowledge must be the primary purpose of the investigation for this procedure to be applicable. In

some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal hospital outcome evaluation, for example, may produce information that TAMHSC Health Care Component administration intends to generalize.

2.1.4 If the purpose of a study changes and the results will be generalized, the investigator must document the change in status of the activity and obtain approval from the I.R.B.

2.1.5 Research authorization requires the subjects' permission to use and disclose PHI.

2.1.6 If an activity would be considered "research" under other applicable policies, it should be considered research for purposes of this procedure. However, research that is exempt under the Common Rule may not be exempt under HIPAA and the procedures set forth in this procedure must be followed with respect to such research.

2.2 General Prohibition and Exceptions. The I.R.B. may not authorize the use or disclosure of protected health information for research purposes unless at least one of the following exceptions applies.

2.2.1 Reviews Preparatory to Research. The I.R.B. may permit the use and disclosure of protected health information to develop a research protocol or for similar purposes preparatory to research (*e.g.*, to determine whether TAMHSC Health Care Component has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study).

2.2.2 The preparatory research provision of the HIPAA Privacy Rule 45CFR 164.512(i)(1)(i) et seq. permits covered entities to use or disclose PHI as an aid to study recruitment, although it does not permit the researcher to remove PHI from the covered entity's site.

2.2.3 The provision allows a researcher to identify prospective research participants for purposes of seeking authorization to use or disclose PHI for a research study.

2.2.4 A researcher who is not part of the covered entity may not use the preparatory research provision to contact prospective research subjects. Rather, the outside researcher could obtain contact information through a partial waiver of authorization by the I.R.B. Actual contact would have to be made by someone who works as part of the covered entity and reasonably has access to the protected health information. In order to permit the use or disclosure of protected health information under this exception, the I.R.B. must obtain representations from the researcher that:

2.2.4.1 The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;

2.2.4.2 No researcher will remove any protected health information from TAMHSC Health Care Component premises in the course of the review;

2.2.4.3 The protected health information for which use or access is sought is necessary for the research purposes; and

2.2.4.4 During the preparatory review, those granted access may only record information in a form that is "de-identified."

2.2.4.5 **Appendix A** describes the de-identified information.

2.2.4.6 **Appendix C** includes a researcher certification form that would be signed by researchers seeking a waiver of authorization to access protected health information.

2.3 Research on the Protected Health Information of a Decedent The I.R.B. may permit the use and disclosure of the protected health information of a decedent for research purposes. In order to permit such a use or disclosure, the I.R.B. must:

2.3.1 Obtain representations from the principal investigator that the use or disclosure is sought solely for research on the protected health information of a decedent (*e.g.*, researchers may not request a decedent's medical history to obtain health information about a decedent's living relative); and/or

2.3.2 Verify that the information for which use or disclosure is sought is necessary for the research purposes.

2.4 Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003.

2.4.1 The I.R.B. may approve the use or disclosure of protected health information for a specific research project provided that one of the three following requirements are met:

2.4.2 Express Legal Permission for Use and Disclosure of Protected Health Information. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of protected health information for purposes of the research project, the I.R.B. may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.

2.4.3 General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's informed consent to participate in a specific research project, the I.R.B. may permit the use or disclosure for purposes of that project even though the formed consent does not specifically authorize the use or disclosure of protected health information for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.

2.4.4 Waiver of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an I.R.B. waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, the I.R.B. may permit a use or disclosure of the individual's protected health information for purposes of that project. However, if the researcher obtains an individual subject's informed consent at any time after April 14, 2003, the researcher will also be required to obtain the individual's Research Authorization (as provided in this procedure) at that time.

2.5 Completely De-identified Information.

2.5.1 The I.R.B. may allow completely de-identified information to be used and disclosed for research purposes without restriction. Information may only be considered completely de-identified when either:

2.5.2 A qualified statistician documents his or her determination that the risk of identification is very small, or

2.5.3 The information meets the requirements described in Appendix A of this procedure. If the I.R.B. has any doubts as to whether protected health information has been completely de-identified within the meaning of this procedure, the information should be treated as though it were not completely de-identified and neither used nor disclosed for research purposes without meeting another exception.

2.6 Limited Data Set.

2.6.1 The I.R.B. may allow the use and disclosure for research purposes of a limited data set including a partially de-identified subset of the individual's protected health information, provided that the person using or receiving the information has signed a Data Use Agreement through which he or she agrees to protect the privacy of the information received.

2.6.2 **Appendix B** of this procedure provides more information about the identifiers that must be removed from an individual's protected health information in order to create a limited data set.

2.7 Subject Authorization for Research.

2.7.1 The I.R.B. may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization.

2.7.2 Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may be more limited than what TAMHSC Health Care Component's Notice of Privacy Practices describes.

2.7.3 The Research Authorization must be completed by the principal investigator for the research subject's review and signature.

2.7.4 It is the responsibility of the principal investigator to ensure that the Research Authorization covers the uses and disclosures necessary for the research study.

2.7.5 When obtaining a Research Authorization, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the Research Authorization form.

2.7.6 In presenting the Research Authorization form to prospective subjects, researchers should never suggest that failure to sign the form will limit access to any treatment that may be available outside the study.

2.8 Approval of Waiver.

2.8.1 The I.R.B. may allow the use and disclosure of protected health information for research purposes if the I.R.B. grants a partial or total waiver of the authorization requirement. If the I.R.B. grants only a partial waiver – that is, if it modifies or waives only some elements of the Research Authorization form – the I.R.B. must condition the use and/or disclosure of any protected health information for research purposes on compliance with any authorization requirements not waived and as modified.

2.8.2 For example, if the I.R.B. grants a partial waiver of authorization to allow a researcher to obtain protected health information to recruit potential research participants, the researcher would still have to obtain Research Authorizations from the subjects to use and disclose protected health information to conduct the research study.

2.9 Individual Access.

2.9.1 Individuals generally have a right to access all their protected health information maintained by TAMHSC Health Care Component or its business associates.

2.10 Any patient requesting access to protected health information obtained in the course of research (including protected health information that may be contained in research records) should be directed to submit his or her request to the manager of the specific site for processing in accordance with TAMHSC Health Care Component's procedure.

2.10.1 Patient Access to Protected Health Information, which provides detailed guidelines for responding to such requests. The manager of the specific site will determine, with assistance from the researcher and the Privacy Official, whether access to protected health information should be denied under any of the exceptions described in that procedure.

2.11 Documentation.

2.11.1 The I.R.B. must retain any writings or documentation required by this procedure for six years from the date of its creation or the date when it last was in effect, whichever is later.

3. VIOLATIONS

The Privacy Officer has general responsibility for implementation of this procedure. Employees who violate this procedure will be subject to disciplinary action up to and including termination of employment. Anyone who knows or has reason to believe that another person has violated this procedure should report the matter promptly to his or her supervisor or the Privacy Officer. All reported matters will be investigated, and, where appropriate, steps will be taken to remedy the situation. Where possible, every effort will be made to handle the reported matter confidentially. Any attempt to retaliate against a person for reporting a violation of this procedure will itself be considered a violation of this procedure that may result in disciplinary action up to and including termination of employment.

i HIPAA Code: §164.512(i)

Contact Office

TAMHSC Vice President of Finance and Administration

APPENDIX A

COMPLETE DE-IDENTIFICATION

Information is completely de-identified if none of the following 18 types of identifiers is contained in the information and if no one accessing the information has actual knowledge that the information could be used – alone or in combination with other information – to identify any individual who is the subject of the information. Note that this does not prohibit coding records so that they may later be re-identified, so long as the code does not contain information about the subject of the information (for example, the code may not be a derivative of the individual's Social Security Number) and is not used or disclosed for any other purpose, and so long as the relinking mechanism (e.g., the subject log or coding algorithm) is not disclosed to any persons or organizations outside the TAMHSC Health Care Component.

1.) Names
2.) All geographic subdivisions smaller than a State, including:
- street address
- city
- county
- precinct
- zip codes 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:
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.) Telephone numbers
4.) Fax numbers
5.) E-mail addresses
6.) Social Security numbers
7.) Medical record numbers
8.) Health plan beneficiary numbers
9.) Account numbers
10.) All elements of dates (except year) for dates related to an individual, including:
- birth date
- admission date
- discharge date
- date of death
- 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
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 numbers or characteristics

APPENDIX B

CREATION OF LIMITED DATA SET

The I.R.B. may approve the use and disclosure of a limited data set for research purposes if the person who would use or receive the information has signed a Data Use Agreement through which the person agrees to protect the privacy of the information received.

A limited data set may be created by removing from the individual's protected health information the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1.) Names;
2.) Postal address information, other than town or city, state, and zip code;
3.) Telephone numbers;
4.) Fax numbers;
5.) Electronic mail addresses;
6.) Social security numbers;
7.) Medical record numbers;
8.) Health plan beneficiary numbers;
9.) Account numbers;
10.) Certificate/license numbers;
11.) Vehicle identifiers and serial numbers, including license plate numbers;
12.) Device identifiers and serial numbers;
13.) Web Universal Resource Locators (URLs);
14.) Internet Protocol (IP) address numbers;
15.) Biometric identifiers, including finger and voice prints; and
16.) Full face photographic images and any comparable images.

Note: Limited data sets may also be used and disclosed for the TAMHSC Health Care Component recipient's health care operations and for public health purposes, but requirements for the use and disclosure of a limited dataset for these non-research purposes are set forth in the data use agreement. Any questions concerning use and disclosure of a limited data set for research or non-research purposes should be directed to TAMHSC Health Care Component's Privacy Official or his or her designee.

APPENDIX C

APPLICATION FOR I.R.B. WAIVER OR ALTERATION AUTHORIZATION

Project title: _____

Principal Investigator: _____

1.) Describe the protected health information you plan to review and the purpose for your review. Protected health information may not be reused or disclosed to any other person or entity, except as required by law.
2.) Describe or list sources of names of patients whose PHI will be included in this review (e.g. search of electronic records or lab database, review of physician's cases, review of departmental log or census).
3.) If this review is to identify prospective research subjects, describe the plans for contacting prospective subjects. For reviews preparatory to research, protected health information may not be removed from the covered entity's site.
4.) Describe the plans to protect subject identifiers from improper use and disclosure.
5.) Describe plans to destroy the participant identifiers at the earliest opportunity consistent with the research unless retention is required for reasons of health, research, or law. Please explain when/if the participant identifiers will be stored or retained. If there is a health or research justification for retaining the identifiers, please explain.
6.) Explain why the research could not practicably be conducted without the waiver.
7.) Explain why the research could not be practicably conducted without access to and use of the PHI.

My research team and I will comply with the use and disclosure restrictions described above.

_____ _____

(Signatures) (Date)

APPENDIX D

I.R.B. WAIVER PROCESS

I.R.B.'s may grant waivers of the research authorization requirement described in this policy. The purpose of this Appendix is to assist researchers in submitting waiver requests to an I.R.B. by providing a brief description of the role of the I.R.B. and explaining what the I.R.B. is required by federal law to consider when evaluating such requests. TAMHSC Health Care Component affiliated I.R.B. will follow similar procedures. For more information, researchers should consult the operations manual of the I.R.B. from which a waiver is sought.

Composition of I.R.B.'s. To approve a waiver request under HIPAA, an I.R.B. must be established in accordance with the Common Rule 45CFR 46.107.

Criteria I.R.B. Must Consider. To grant a waiver of Research Authorization, an I.R.B. must find the following:

A.) The use or disclosure of patient health information involves no more than minimal risk to the individuals involved;

B.) There is an adequate plan to protect the "identifiers" from improper use and disclosure (Appendix A);

C.) There is an adequate plan to destroy the "identifiers" at the earliest opportunity, unless there is a health (*i.e.*, individual care) or research justification for retaining the identifiers or their retention is required by law;

D.) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except

(1) as required by law,
(2) for authorized oversight of the research project, or
(3) for other research for which the use or disclosure of protected health information is otherwise permissible under federal policy;

E.) The research could not practicably be conducted without the waiver; and

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

Review Procedures. If an investigator applies to an I.R.B. to grant a waiver of research as described above, the I.R.B. will follow the procedures as set forth in the Common Rule for full board review 45CFR 46.108 or expedited review 45CFR 46.110 as applicable