Access to Electronic Health Record for Research

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PURPOSE:

The University of New Mexico Health Sciences Center ("UNMHSC") is obligated to protect the confidentiality of an individual's health information as required by law, professional ethics, and accreditation requirements. The Health Insurance Portability and Accountability Act ("HIPAA") of 1996, and its implementing regulations known as the "Privacy Rule" include provisions that protect the privacy of individually identifiable health information, and govern how health information is used and disclosed, including use and disclosure for research purposes. The purpose of this policy is to set forth the requirements to access PHI via the EHR for research purposes.

REVIEW OF RESEARCH INVOLVING ACCESS TO THE EHR /PHI:

The Human Research Review Committee (HRRC) is the IRB of record and designated privacy board for UNMHSC, and has oversight of any and all research involving UNMHSC, its agents (faculty, staff, students), or its components, including access to the EHR. Accordingly, all research protocols involving human participants must be submitted to the HRRC for review and approval before any data may be accessed.

OVERVIEW AND BASIC REQUIREMENTS

In order to access the EHR to utilize PHI in connection with research, researchers must (a) obtain written authorization from the individual who is participating as a research subject in accordance with HIPAA standards for authorization, usually as part of the informed consent process (b) obtain a waiver of the authorization requirement from the HRRC in accordance with federal regulations, (c) obtain approval for such use from the HRRC as preparatory to research, or d) notify the HRRC of such use as research on decedents' information.
PHI obtained in accordance with this policy may be used only by and disclosed only to the principal investigator and other members of the research team. The principal investigator ("PI") for any study involving the collection or analysis of data from the EHR must be compensated HSC faculty who are identified in the research protocol application.

More information on who may conduct research as a PI is available at:


SECURE USE OF PHI IN RESEARCH:

PIs are responsible for ensuring that data containing PHI is securely protected from unauthorized disclosures. Researchers must take precautions to securely maintain and dispose of PHI.

Data collected from the EHR, regardless of whether authorization was obtained from the participant, may not be released to any outside organization and must be used solely as indicated in the HRRC approved informed consent document.

Additionally, researchers are responsible for ensuring secure transfer of data containing PHI. When transmitting data electronically, researchers should ensure that 1) the data is securely encrypted and a Data Transfer Agreement has been expected between UNMHSC and the receiving organization; 2) that the receiver of the data is the individual for whom it is intended; and 3) the data remains secure until it is received by the intended receiver. Questions about the security of electronic data transfers may be directed to Barney Metzner, HSC HIPAA Security Officer, at 505.272.1696.

Any potential breach of confidentiality must be reported to the Privacy Officer and to the HRRC immediately upon discovery.

WAIVER OF HIPAA AUTHORIZATION:

If a research protocol proposes to obtain and use PHI in research without an authorization, the principal investigator must submit a request for a waiver of the authorization requirement to the HRRC.

An application for waiver will be approved only if the HRRC concludes that the criteria in the HIPAA rules have been satisfied. These include:

1. 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:
   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 protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted under the HIPAA Privacy Rule.

2. The research could not practicably be conducted without the waiver or alteration; and

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

EHR/PHI ACCESS PREPARATORY TO RESEARCH:

Because it may be necessary for a researcher to obtain access to and review PHI in order to prepare a research protocol, HIPAA rules allow such review upon compliance with specified criteria. This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study, or to identify potential participants for a study. An application for review of PHI preparatory to research must be submitted for review to the HRRC.

The IRB may only approve such applications if it is satisfied that all of the following requirements are satisfied:

1. The use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research;

2. No PHI will be removed in any manner, including by means of copying or notes, from the original source of the PHI; and

3. The PHI for which access is sought is necessary for the research purpose.

PHI OF DECEDEENTS:

PIs will notify the HRRC prior to engaging in research with the PHI of decedents. In order to gain access to the PHI maintained by a covered entity, principal investigators will need to demonstrate:

1. that the use or disclosure sought is solely for research on the PHI of decedents;

2. adequate documentation of the death of such individuals; and
3. that the PHI for which use or disclosure is sought is necessary for the purposes of the proposed research.

WITHDRAWAL OF AUTHORIZATION BY RESEARCH PARTICIPANT:

HIPAA rules allow a subject to revoke a prior authorization to use or disclose PHI for purposes of research. Participant requests for the revocation of authorization must be requested in writing to the PI. Researchers must honor this request, except to the extent the researcher has already relied on the authorization. Researchers may continue utilizing PHI that was obtained prior to the time the individual revoked his or her authorization, as necessary to maintain the integrity of the research study. In addition, use or disclosure of identifiable information previously obtained is permitted for purposes such as accounting for the participant's withdrawal, reporting adverse events, or complying with investigations.

RESEARCH COMMENCED PRIOR TO APRIL 14, 2003:

An authorization is not required under the HIPAA rule for participants who were enrolled in a research protocol before April 14, 2003 and who have signed a 45 CFR 46-compliant informed consent form. Even if participants enrolled before April 14th have follow-up visits after that date, authorization will not be required.

An authorization will be required for any participant enrolled in a study on or after April 14, 2003, even if the study was approved by the HRRC prior to that date. Therefore, if all participants were enrolled prior to April 14, 2003, there is no need for an authorization for those participants. However, authorization will be required for any new participants after April 14, 2003, either in the form of a separate authorization document or a modified informed consent form, which includes the required authorization language.

If researchers are conducting a medical records study under an HRRC-approved waiver of consent obtained prior to April 14, 2003, they should continue protecting the privacy of participants' information, but do not need to re-apply to the HRRC. Ongoing studies for which the HRRC approved a waiver of informed consent before April 14, 2003 are grandfathered under the HIPAA rule. Although a new waiver is not required, it is important to note that the individual rights provided by the Privacy Rule go into effect as of April 14, 2003.

FURTHER INFORMATION:

For questions, additional detail, please contact the Human Research Protections Office.