MIDWESTERN UNIVERSITY
OFFICE OF RESEARCH AND SPONSORED PROGRAMS
Institutional Review Board (IRB) – Glendale Campus

SOP #724: USE OF PROTECTED HEALTH INFORMATION IN RETROSPECTIVE CHART REVIEW STUDIES WITHOUT THE SUBJECT'S WRITTEN AUTHORIZATION

MWU researchers seeking IRB approval may use patient chart information when written authorization from the research subject cannot practically be obtained for purposes of conducting retrospective chart review studies ("RCRS") provided, however, that certain conditions are met. In addition to the appropriate circumstances, researchers must perform retrospective chart review studies in a manner that satisfies the HIPAA Privacy Rule and the Common Rule for protection of human subjects.

Purpose: The purpose of this guideline is to describe two potential approaches to implement applicable provisions of the HIPAA Privacy Rule in cases of RCRS when written authorization from the research subject cannot practically be obtained.

Scope: This guideline applies to the researcher and all individuals involved in collecting, reviewing, and/or analyzing data concerning the RCRS in clinics of the Glendale campus.

Responsibilities: The RCRS primary investigator ("PI") is responsible for ensuring compliance with this guideline.

1. De-Identified Data

De-identified data is not PHI and thus not subject to the HIPAA Privacy Rule requirements. De-identification does not eliminate the need for IRB review and approval. Researchers are advised to consult with the IRB regarding all RCRS prior to submission of Form A.

Data are de-identified if either (a) the data do not include any of the 18 HIPAA Identifiers, or (b) an experienced expert determines that the risk that certain information could be used to identify an individual is "very small" and documents and justifies the determination. PHI may be de-identified in one of two ways:

Safe Harbor Method: Remove all 18 HIPAA Identifiers. The remaining information cannot be used alone or in combination to identify the individual who is the subject of the information.

Statistical Method: Instead of removing all 18 identifiers, an expert with appropriate knowledge of and experience in rendering data unidentifiable may apply accepted statistical methods (e.g., k-anonymity) to establish that a data set is de-identified. The expert must provide the researcher and the IRB with documentation of their methods and results proving how he or she came to the determination that the data has been de-identified.

In order to safeguard the privacy of MWU employees, families, and students, either the Safe Harbor or the Statistical Method of de-identification must be performed by an *Honest Broker* when the RCRS involves records from any MWU clinic. An Honest Broker is an individual who has access to the desired data by virtue of his or her clinic responsibilities; has advanced training in

HIPAA privacy rules; and who is not, in any manner, part of the RCRS research team. The IRB may request the qualifications and certifications of the Honest Broker as part of the PI's application.

2. Use of Coded Data or Use of a Limited Data Set

The HIPAA Privacy Rule permits a covered entity (*i.e.,* a clinic or hospital) to provide a researcher with either (a) *coded data* that has been de-identified or (b) with *limited data sets*. A covered entity may use the service of an Honest Broker to generate coded data or a limited data set.

Coded data are data that are separated from personal identifiers through use of a code. As long as a link or code key exists, data are considered indirectly identifiable and not anonymous, anonymized, or de-identified. The covered entity maintains a code key or link to the identifiable data. Using the code key, a researcher can request the covered entity provide additional medical information corresponding to a given research subject. The re-identification code may not be derived from or related to information about the individual or otherwise be capable of being translated to identify the individual. Additionally, the covered entity may not use or disclose the code key for any other purpose or disclose the mechanism for re-identification. The code key or link must remain only with the covered entity, and cannot be shared with any member of the research team.

A limited data set is a set of data in which most of the PHI has been removed. The HIPAA Privacy Rule requires that specific HIPAA Identifiers *be removed* even in a limited data set. Before providing the limited data set to the researcher, the covered entity and the researcher must commit to a data use agreement. The data use agreement must (a) identify who will receive the limited data set, (b) establish how the data may be used and disclosed by the researcher, and (c) provide assurances that the data will be protected.

3. Additional Requirements

These guidelines are merely intended to be general instructions and are subject to change or deviation when appropriate, with or without notice. Additional terms and conditions may apply when an MWU researcher desires to use patient chart information when written authorization from the research subject cannot practically be obtained for purposes of conducting retrospective chart review studies. To the extent federal or state laws, regulations, or rules apply to the circumstances addressed by these guidelines, those laws regulations, or rules shall supersede these guidelines and control. Similarly, MWU policies may apply and, when applicable, those policies shall supersede these guidelines and control. The requirements of the Common Rule, which are designed to provide additional protection for human subjects must always be considered, balanced, and applied in connection with these guidelines.

Please note, RCRS applications must be accompanied by Form D. Contact the IRB if you have questions.