TITLE: Institutional Review Board Review of Research
RR 412 Review of Data Preparatory to Research

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The term “preparatory to research” refers to a provision of the HIPAA Privacy Rule. This provision allows a covered entity as defined by the HIPAA Privacy Rule (e.g., Mercy Health) to use or disclose personal health information (PHI) to a researcher for the purpose of developing a research protocol or for similar purposes preparatory to research (Preparatory to Research Review) without the patient’s authorization or a waiver or an alteration of authorization by an Institutional Review Board (IRB). However, at Mercy Health all human subjects research, including screening of records and recruitment of subjects, must be approved by the IRB. Because the IRB reviews and approves all screening of records and recruitment of subjects, HIPAA’s concept of “reviews preparatory to research” is incorporated into the IRB review process. The IRB may permit the use and disclosure of PHI to develop a research protocol or for similar purposes preparatory to research (e.g. to determine whether Mercy Health has a sufficient number of prospective research participants that would meet the eligibility criteria for enrollment in a research study). This exception does not permit the continued use or disclosure of the protected health information once the Principal Investigator has determined to go forward with the study.

GENERAL PROVISIONS: Under the HIPAA Privacy Rule, Mercy Health Regional IRB must obtain from the researcher written representations that the use or disclosure is requested. The following representations must be made:

i. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research,

ii. the PHI will not be removed from the covered entity by the researcher in the course of the review, and

iii. the PHI for which use or access is requested is necessary for the research purposes.

Mercy Health Regional IRB prohibits the use of data accessed preparatory to research to recruit subjects or to link to other data. Mercy Health’s policy is that use of the “review preparatory to research” option under HIPAA (a) is limited to preparation of a research protocol or assessment of feasibility of performing a specific research protocol; (b) does not permit recording or copying any PHI; and (c) may not be used to prescreen patients as part of the recruitment process. Data Preparatory to Research review may be used only to determine the existence of potential research subjects and not to identify them or to permit a more comprehensive review of the medical record. Once there is intent to recruit subjects pursuant to a formulated protocol, then the research activity is sufficiently well prepared and requires IRB approval.

There may be additional requirements for confidentiality under Michigan and other federal laws for certain sensitive PHI such as psychotherapy notes and other mental health or developmental disability treatment information, AIDS/HIV information, genetic information, or alcohol or drug abuse treatment and prevention information. If the preparatory to research proposal requires review of records containing any of these types of sensitive PHI, additional guidance from the Mercy Health Privacy Officer and legal department should be sought.
In order to conduct a Preparatory to Research Review, a submission to the IRB (who has been designated by the Privacy Board Officer for these types of reviews) requesting a formal approval of "A Request for Review of Data Preparatory to Research" must be completed. If an individual needs to collect information to design a research study or to assess the feasibility of conducting a study and will also need to record HIPAA identifiers, they must also request and justify waiver of informed consent. HHS regulations at 45 CFR 46.102(d) define "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

HHS regulations at 45 CFR 46.102(f) define "human subject" as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information...Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

All human subjects research requires an informed consent unless a waiver or alteration of consent is requested and granted by the IRB.

In order to grant a waiver of consent, the submitter's request must clearly describe:

1. Justification why using these procedures would be considered minimal risk to the potential subjects.
2. Justification why a waiver of consent would not adversely affect the rights and welfare of the potential subjects.
3. Justification why the research could not practicably be carried out without the waiver.
4. Whenever appropriate, a procedure for providing potential subjects with additional pertinent information after participation.

The HIPAA Privacy Rule does not require documentation of Institutional Review Board (IRB) or Privacy Board approval of an alteration or waiver of individual HIPAA authorization before a covered entity may use or disclose protected health information for the use in activities preparatory to research 45 CFR 164.512(i)(1)(ii)

REFERENCE:
45 CFR 164.502
45 CFR 164.512
21 CFR 50.20
38 CFR 16.116
45 CFR 46.116
MCL 333.20201( c)
https://privacyruleandresearch.nih.gov/faq.asp#21

ATTACHMENTS:
RR 412-A Request for Review Data Preparatory to Research Form
RR 412-B Form for Review of Request to Review Data Preparatory to Research

PROCEDURE:

Responsibility
IRB Specialist/IRB Coordinator

Action
1. Notify IRB Chairperson or designated reviewer by email that a request for review of data preparatory to research has been received and is ready to be reviewed.
2. After review is complete, add item to the agenda for the next IRB meeting.
3. Provide the agenda and associated materials to IRB members prior to the next IRB meeting.
4. Issue correspondence as advised by the IRB Chairperson or designated reviewer.
Institutional Policy & Procedure

IRB Chairperson (or designee)

1. Perform primary review, using the appropriate worksheets.
3. Upon completion of the review, provide review documentation to IRB Specialist/IRB Coordinator with request for issuance of appropriate correspondence and inclusion on next meeting agenda.

IRB Committee Members

1. Review the monthly IRB meeting agenda for notifications of expedited review of requests for review of data preparatory to research.

Investigator

1. Submit Request for Review of Data Preparatory to Research form if comprehensive review of patients' protected health information is to occur in preparation of the conduct of research.

CONCURRENT CONSENTS:

Institutional Official