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 integrated 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 PROVISONS: Under the HIPAA Privacy Rule, Mercy Health 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 prohibits use of data used or 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. Such a 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 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 for these types of reviews) requesting a formal approval of "A Request for Review of Data
Institutional Policy & Procedure

Preparatory to Research must be completed. The Request for Review of Data Preparatory to Research will include a request and justification for waiver of informed consent.

In order to grant a waiver of consent, this 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 practically be carried out without the waiver.
4. Whenever appropriate, a procedure for providing potential subjects with additional pertinent information after participation.

REFERENCE:
45 CFR 164.502
45 CFR 164.512
21 CFR 50.20
38 CFR 16.116
45 CFR 46.116
MCL 333.20201(e)

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:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>Clinical Research Assistant/IRB Coordinator</td>
<td>1. Notify IRB Chairperson or designated reviewer by e-mail that a request for review of data preparatory to research has been received and is ready to be reviewed.</td>
</tr>
<tr>
<td></td>
<td>3. After review is complete, add item to the agenda.</td>
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<tr>
<td></td>
<td>4. Provide the agenda to the IRB members prior to the next IRB meeting.</td>
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<tr>
<td></td>
<td>5. Issue correspondence as advised by the IRB Chairperson</td>
</tr>
<tr>
<td>IRB Chairperson (or designee)</td>
<td>1. Perform primary review; using the appropriate worksheets.</td>
</tr>
<tr>
<td></td>
<td>2. Document result of review using Form for Review of Request to Review Data Preparatory to Research (RR 412-B)</td>
</tr>
<tr>
<td></td>
<td>3. Upon completion of the review, provide review documentation to IRB CRA with request for issuance of appropriate correspondence and inclusion on next meeting agenda.</td>
</tr>
<tr>
<td>IRB Committee Members</td>
<td>1. Review the monthly IRB meeting agenda for notifications of expedited review of requests for review of data preparatory to research.</td>
</tr>
</tbody>
</table>
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
REQUEST FOR REVIEW OF DATA PREPARATORY TO RESEARCH

RR 412-A

Instructions: While the Privacy Rule does not require documentation of IRB approval for Preparatory to Research Data Review Requests, the investigator must submit the request to Mercy Health IRB via the IRB Manager system and receive an acknowledgement of support before the Investigator can perform a comprehensive review of a patients record. The IRB must be aware of an investigators intention to access or use any protected health information (PHI) that is part of the Mercy Health system records for purposes preparatory to research, such as to aid in the determination that Mercy Health has a sufficient number of prospective research participants that would meet eligibility criteria for enrollment in a research study. Any comprehensive review of protected health information for research purposes preparatory to research must be reviewed and acknowledged by the IRB prior to access to the information.

1. Protocol Information

Study Title:
Principal Investigator

Today's Date:
Email:
Phone:

Study Coordinator Name
Study Coordinator Contact Information (Phone, email)

2. Acknowledgement of the Purpose of Use or Disclosure of PHI

- I acknowledge the use or disclosure sought is solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research
  - Identify the requested PHI and state why access to PHI is necessary.  
    (Example: Access to medical records is necessary to determine the size of the subject pool of persons with the following clearly identified conditions or diagnosis:

- I acknowledge no PHI will be removed from Mercy Health by the researcher in the course of the review.
- I acknowledge the PHI for which use or access is sought is necessary for the research purpose.
  - Explain why the information required cannot be obtained from another source:

3. Sensitive Information

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There are additional requirements for confidentiality under Michigan and federal law for the following sensitive PHI:
- Psychotherapy notes and other mental health or developmental disabilities treatment information
- AIDS/HIV information
- Genetic information; and
- Alcohol or drug abuse treatment and prevention information

If the preparatory to research project requires review of records containing any of these types of sensitive PHI, please describe any sensitive PHI to which you request access:

Please note that the Preparatory to Research exception may not be available to you to review sensitive PHI. Please contact the Mercy Health Office of the IRB at 616-685-6198 for assistance.

4. **Investigators Assurance**

By submitting this form, I assure that I agree to the following:
- Information disclosed to me for the purposes of research will be managed as required by the Mercy Health IRB.
- No PHI will be removed from Mercy Health in the course of the review.
- I am aware of the legal, regulatory and ethical requirements to protect human research participants, including without limitation, protection of their personal privacy and the privacy of all information identifying and/or relating to them, and agree to comply with all such human research participant protections.
- I will carry out the proposed data review and/or collection in compliance with the principles stated above.
- I will submit the proposed research protocol and materials to the Mercy Health IRB for review prior to initiation of any research activities.

**Comments:**

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**Investigator Signature**

**Date**

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Checklist for Review of Request for Review of Data Preparatory to Research

RR 412-B

Study Title:

Investigator:
Reviewer Name:
Date of Review:

The IRB Chair (or designee) has reviewed the preparatory to research filing and made the following determination:
☐ Accepted
☐ Denied
☐ Additional Information is required.

Comments:

______________________________  ________________________
Signature of IRB Chair           Date