POLICY STATEMENT: Informed consent is one of the fundamental principles of ethical conduct in the use of human subjects and is mandated by Federal Regulations at 45 CFR 46.116 [add FDA]. Generally, a potential research participant (or his or her legally authorized representative) must be given a complete explanation of the IRB-approved protocol, including a description of its risks, benefits and alternatives, and be given the voluntary and uncoerced choice to participate in research. Additionally, an individual’s agreement to participate usually must be documented on an IRB-approved consent form. Occasionally, however, there are reasons to waive written consent or to alter the requirements of consent. There are special regulatory allowances which permit an IRB to approve, under limited circumstances, a waiver of consent, an alternative form of consent, or a waiver of the requirement to document consent. The HIPAA Privacy Rule has its own list of criteria that must be met in order to waive a participants written authorization to use and disclose individually identifiable health information for research. This policy addresses the process for request for review of waivers of authorization related to the HIPAA privacy regulation. The process for review of requests for waiver or alteration of informed consent are addressed separately from this policy and can be found in IRB SOP IC 701.

When reviewing requests to waive a participants written HIPAA authorization, the IRB will follow the requirements of 45 CFR 160, 164.

Researchers that intend to use or disclose identifiable health information without first obtaining authorization or consent from the participants of the research, are required to meet certain criteria before study related disclosure and use of PHI can be initiated.

This policy delineates the minimal requirements that requests for Waiver of Authorization must meet in order to be approved by the Mercy Health IRB.

GENERAL PROVISIONS:
The following three criteria must be satisfied for the IRB to approve a waiver of authorization under the Privacy Rule:

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:
   a. an adequate plan to protect the identifiers from improper use and disclosure;
   b. 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
   c. 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 by this subpart;
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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.

In cases where the documentation requirement is waived, the Mercy Health IRB may require the investigator provide research participants with a written statement regarding the research.

Investigator Responsibilities
1. When requesting a waiver of authorization, justification must be provided as to why the study meets the requirements for the waiver.
   a. The justification requirement applies even in cases where the Investigator uses deception in research.
2. When a waiver or authorization in place allowing participant anonymity, for example no signature line, the PI must maintain strict practices to protect privacy. This includes avoiding markings and identifications on consent forms and information sheets.
3. The research team must provide additional pertinent information to the participant as the IRB has determined, this could include informing participants that research has been conducted under a waiver, without consent.
4. Accounting for Research Disclosures
   a. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity.
   b. When a waiver of authorization is in place, accounting for disclosures is required.

Mercy Health IRB Responsibilities
1. Review the submitted study information to determine the applicability of the HIPAA privacy rule
2. Review the waiver of authorization request taking into account:
   a. The level of risk of the study;
   b. The extent to which privacy will be invaded;
   c. The sensitivity of the information to which the investigators will have access;
   d. The necessity of the data;
   e. Plans for further contact of the subjects;
   f. If the study involves procedures which normally require consent and
   g. The feasibility of obtaining consent from all subjects.
3. Approve or disapprove a waiver of authorization per the regulatory requirements.
4. For studies requesting to use deception:
   a. First, decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research. Research should not be permitted at all if the subjects are not being informed of things they would consider material to a decision to participate.
   b. Second, decide if subjects should be debriefed, either after participating in research unwittingly or after knowingly participating in research that involved some form of deception.
   c. In order to grant the waiver of authorization, document the following three things:
      a. the study presents no more than minimal risk;
      b. the waiver would not adversely affect the rights and welfare of subjects; and
      c. the waiver is essential to the ability to carry out the research.
5. IRB minutes shall record the expedited review process and any committee decision for approval of waivers or alterations of consent and waivers of authorization. All elements must be documented in the minutes.
6. Approvals of waivers of informed consent, documentation of informed consent, or requirements for debriefing will be documented in the review correspondence letter to the PI. Additionally, waivers of authorization will be detailed, including requirements to account for disclosures.
7. In certain circumstances, for example when the PI has an ongoing relationship with the participants, the IRB may require that the PI provide additional pertinent data to participants.

DEFINITIONS:
Waiver of Authorization- An approval granted under HIPAA regulations, in limited circumstances, of a waiver of the requirement for authorization from an individual to allow for the use or disclosure of private protected health information. A waiver of the need for authorization may be granted from the IRB to the researcher.

Protected health information (PHI)- Any information about health status, provision of health care, or payment for health care that can be linked to a specific individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history

REFERENCE:
45 CFR 46.116(d)
45 CFR 160
45 CFR 164
ATTACHMENTS:
WA 1003-A Criteria for Waiver of Authorization Flowchart
WA 1003-B Checklist for Review of Request for Waiver of Authorization
WA 1003-C Checklist for Waiver of Authorization Identifiers

PROCEDURE:

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| IRB Specialist/IRB Coordinator  | 1. Review incoming submissions requesting a waiver of authorization to ensure all required documentation has been completed and submitted as required.  
2. Notify IRB Chairperson that a request for waiver of authorization has been received.  
3. Notify IRB Committee of approvals of waivers of authorization within the monthly IRB meeting agenda and minutes.  
4. Issue correspondence as directed by the IRB Chairperson. |
| IRB Chairperson (or designee)   | 1. Perform primary review of request for waiver of authorization using appropriate worksheets. (May refer to full committee as deemed necessary)  
2. Ensure all required components for approval of a waiver of authorization have been reviewed and considered.  
3. Document determination, sign reviewer form(s). If designee performing review return completed forms to the IRB Chairperson.  
4. Inform IRB CRA/IRB Coordinator of the determination and request issuance of necessary correspondence. |
| IRB Committee                   | 1. Be aware of research activities that have been granted a waiver of authorization by reviewing the monthly IRB meeting agenda for reports of expedited reviews and other study activities.  
2. Review requests for waiver of authorization as requested by the IRB Chairperson. |
| Investigator                    | 1. Submit request for waiver of authorization with required materials and documentation.  
2. Ensure the written plan for adequate protection of the protected health information is followed.  
3. Follow all actions required by IRB for |

CONCURRENT CONSENTS:

Institutional Official

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