TITLE: Institutional Review Board Waiver of Authorization
WA 1001 Statement of Authority – Privacy Board

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: In the environment of research, it is essential to ensure the confidentiality of data and privacy of the individuals who have agreed to be the participants of research. Since certain types of research require use and disclosure of PHI and since the nature of the research may preclude the obtaining of a HIPAA Authorization from the research subject to use or disclose such information, it may be necessary to proceed with such research without a written Authorization.

Mercy Health Board of Trustees delegates the authority and responsibility of the Privacy Board to review and approve requests for an alteration of authorization or a Waiver of Authorization with regard to the HIPAA privacy rule for research purposes to Mercy Health Regional IRB in accordance with federal standards at 45 CFR 164.512(i)(1)(i)(A) (See attachment WA 1001-A).

GENERAL PROVISIONS:
The Mercy Health Regional IRB/Privacy Board will determine whether a research study meets the HIPAA privacy rule criteria for use of PHI, e.g., deidentification, limited data set with data use agreement, representation for use of decedent’s PHI, use of PHI as preparatory to research (by the covered entity), valid authorization, approval of an alteration of authorization, or approval of a waiver of authorization. Only the Mercy Health Regional IRB can approve an alteration of authorization or waiver of authorization for a research study.

REFERENCE:
45 CFR 160, 164

ATTACHMENTS:
WA 1001-A 45 CFR 46 The Privacy Rule

PROCEDURE:

Responsibility  
Privacy Officer  

Action

1. Make every reasonable effort to be available to the Office of the IRB staff for questions related to the interpretation of the HIPAA privacy rule.

IRB Chairperson or designee  

1. Ensure requests for waivers of authorization are reviewed fully and appropriately.
2. Request issuance of IRB approval letters of waivers of authorization or alterations to authorization as needed.
1. Ensure requests for waivers of authorization are reviewed and documented fully and appropriately.
2. Issue IRB approval letters, as requested.

CONCURRENT CONSENTS:

Institutional Official

[Signature]