INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 09/02/2008
Revision No.: 3
Effective Date 05/01/2015

TITLE: Institutional Review Board Waiver of Authorization
        WA 1004 Documentation of Wavier of Authorization

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: Researchers will be notified in writing of the determination of the IRB regarding the request for waiver or alteration of authorization.

Reviews and Determinations of requests for waiver or alteration of authorization will be documented per SOP FO 305. Documentation will be kept on file for a minimum of 7 years by the Office of the IRB.

GENERAL PROVISIONS:
Documentation of an approval for a waiver or alteration of authorization must be completed as required by the federal regulations. Where minutes are recorded for reviews of requests for waiver or alterations of authorization, such minutes shall be recorded separately from minutes for determinations regarding research reviewed per regulations at 21 CFR 50 and 56 and 45 CFR 46.

The documentation required of Mercy Health IRB when granting approval of waiver, partial waiver or alteration of authorization for releasing of PHI must include:

A statement identifying the Mercy Health IRB approving the action, and the date of such approval;

A statement the Mercy Health IRB has determined that the waiver, partial waiver or alteration of authorization satisfies all of the criteria set forth in 45 C.F.R § 164.512

Notification of Determinations
Documentation of waiver or alteration of authorization shall conform with requirements at 45 CFR 164.512(i)(2)(i-v). Written notification will be provided to the principal investigator outlining the Mercy Health IRB's determination related to the request for waiver or alteration of authorization.

ATTACHMENTS:
WA 1004-A Documentation of Waiver of Authorization Approval

REFERENCES:
45 CFR 164.512(i)(2)(i-v).
45 CFR 164.514(d)(3)(iii)(D)
21 CFR 50 and 56
45 CFR 46
PROCEDURE: All Mercy Health Campuses

**Responsibility**
IRB Specialist/IRB Coordinator

**Action**
1. Notify IRB Chairperson of receipt of submissions request waiver or alteration of informed consent.
2. Provide IRB Chair with review packet including all materials needed to determine if waiver or alteration of informed consent is appropriate.
3. Issue correspondence as advised by the IRB Chairperson.
4. Place all review materials and documentation on file as required.

IRB Chairperson (or designee)

1. Review incoming submission requesting waiver or alteration of informed consent.
2. Complete appropriate checklists
3. Return all review materials and documentation of review and approval of waiver or alteration of authorization to the IRB Clinical Research Assistant for filing purposes.
4. Advise IRB Clinical Research Assistant regarding appropriate correspondence to be issued to the principal investigator.

**CONCURRENT CONSENTS:**

Institutional Official

[Signature]

Version Date 05/01/2015