INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 09/02/2008
Revision No.: 4
Effective Date: 04/05/2016

TITLE: Institutional Review Board General Administration
        GA 105 Signatory Authority

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The IRB Chairperson is authorized to sign any and all documents in connection with the
review and approval of research projects involving the use of humans as participants, which have been reviewed and
approved pursuant to Mercy Health policies and procedures. This policy applies to all approval letters for the Mercy
Health Regional IRB.

1.1 Authorization for Signatory Authority
Authorization to sign documents not described in this policy may be made in writing to the IRB Chairperson.

1.2 Results of Reviews, Actions and Decisions
The results of reviews and actions taken by the IRB, either by the full IRB or by expedited review, that grant or
may appear to grant Investigators with initial or continuing approval of research, training or educational projects
involving human participants, may be signed by designated staff members.

1.3 Routine Internal Correspondence
Any action, letters, memos or e-mails between the IRB, and/or members of the faculty or staff of Mercy Health
that provides information concerning the review of research protocols by the IRB or staff which do not imply or
appear to imply approval of this activity, may be signed by designated staff members.

1.4 Correspondence with External Agencies
Any letters, memos or e-mails sent to agencies of the federal government, funding agencies (whether private or
public) or their agents will be signed by the Institutional Official or President.

1.5 Decisions Made by Chairperson
Any letters, memos or e-mail sent representing the decision or opinions of the Chairperson of the IRB or his/her
respective designees, as long as such correspondence does not imply review and approval of research projects,
may be signed by designated IRB staff.

REFERENCE:
45 CFR 46.103, 46.115

ATTACHMENT:
GA 105-A Definitions Related to Signatory Authority
**PROCEDURE: All Mercy Health Campuses**

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<th>Responsibility</th>
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| Institutional Official        | 1. Establish signature authority delegation based on nature of documents being signed.  
                                 | 2. Sign correspondence with external agencies.                          |
| Regional President            | 1. In the absence of the Institutional Official, the Regional President must sign correspondence with external agencies. |
| IRB Coordinator/IRB Specialist | 1. Sign routine internal correspondence or actions taken by an IRB Chairperson if authorized to do so by the Chairperson. |
| IRB Chairperson               | 1. Sign all documents related to the review and approval of research projects and correspondence with external agencies. |
| Vice Chairperson              | 1. May sign documents related to the review and approval of research projects in the absence of the Chairperson. |

**CONCURRENT CONSENTS:**

Institutional Official