TITLE: Institutional Review Board General Administration
      GA 101 Policies and Procedures Maintenance

ORIGINATOR: Institutional Official
APPROVAL: Institutional Official

POLICY STATEMENT: Following regulations and guidance of OHRP, FDA, and the International Conference on Harmonisation (ICH), the development of institutional policies ensures that the rights and welfare of the human participants of research will be overseen and protected in a uniform manner. Written procedures must be in place to ensure the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

Standard operating policies and procedures (SOPs) provide the framework for the ethical review and scientifically sound conduct of human research.

1. Review, Revision, Approval of Policies & Procedures

   Changes to regulations, federal guidelines, or research practice as well as the policies and procedures of Mercy Health and Trinity Health may require a new IRB SOP or a revision to a previously issued IRB SOP. Policies and procedures will be reviewed by the Office of the IRB staff and leadership at intervals established by Mercy Health. Approval of new or revised SOPs is required by Mercy Health. Documentation of review and approval is required by signature of the responsible and authorized individuals.

2. SOP Dissemination and Training

   When new or revised SOPs are approved, they will be disseminated to the appropriate individuals & departments as detailed in form GA 101. Training will be provided as appropriate to all members of the IRB, Office of the IRB staff, Investigators and key study personnel on any new or revised policy and/or procedure. Evidence of training must be documented and filed with the Office of the IRB. Evidence of training must be documented and on file in the Office of the IRB.

3. Forms

   Forms are used to 1) ensure that policies are integrated into the daily operations of the IRB and the IRB review process within the Mercy Health system, and 2) enable IRB staff to manage review, tracking, and notification functions consistently. Forms are either controlled or non-controlled.

   Controlled forms are regulatory documents that become part of the permanent record of IRB review and determination. Therefore, they must be reviewed and approved as described in section 1.

   Non-controlled forms are management tools that are not subject to the standards of control cited in section 1.

   Worksheets: Worksheets are tools that may be used to confirm regulatory criteria have been met.

   Checklists: Checklists are tools that must be used and must be kept on file with the IRB study documentation

REFERENCE:
21 CFR 56.108, 56.109, 56.113
45 CFR 46.108
PROCEDURE: All Mercy Health Campuses

**Responsibility**  
IRB Coordinator

**Action**
1. Discuss changes with OIRB staff.
2. Plan education of OIRB staff, investigators and key study personnel based on impact and need for each change to be implemented (with IRB Chairperson).
3. Archive previous policies and forms.
4. Review the current policies annually and make necessary changes.
5. Keep record of documentation of IRB SOP training for Office of the IRB Staff.

IRB Specialist

1. Update the IRBManager system as changes are approved by the Institutional Official
2. Update PolicyTech system with most current policy version.
3. Notify TIS (Technology Information Services) to make changes in electronic system that posts policies to intranet and internet.
4. Assist in the archival of previous policies and forms.

President

1. Sign revised IRB policies as appropriate.

Institutional Official

1. Sign revised IRB policies as appropriate.

IRB Chairperson

1. May update forms as needed.
2. Sign revised IRB policies as appropriate.

**ATTACHMENTS**

<table>
<thead>
<tr>
<th>GA 101-A</th>
<th>GA 101-B</th>
<th>GA 101-C</th>
<th>GA 101-D</th>
<th>GA 101-E</th>
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</thead>
<tbody>
<tr>
<td>Hold for Future Use</td>
<td>Hold for Future Use</td>
<td>SOP Revision Log</td>
<td>SOP Template</td>
<td>Hold for Future Use</td>
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</tbody>
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**CONCURRENT CONSENTS:**

Institutional Official

[Signature]

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