TITLE:  Institutional Review Board General Administration  
GA 102 Training and Education

ORIGINATOR:  Institutional Official

APPROVAL:  Institutional Official

POLICY STATEMENT: Training of IRB staff and IRB members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner throughout the Mercy Health research community. IRB members, IRB staff and others charged with responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics and policies applicable to human participants research.

All IRB members and IRB staff will be apprised of Mercy Health organizational structure with emphasis on the independent nature of the relationship between the IRB and Mercy Health. The actions of the IRB Committee and the IRB administrative staff relating to their responsibilities to protect human participants of research will not be measured or evaluated in terms of institutional or financial goals.

1. Training
   A. IRB staff and members of the IRB who are overseeing research on human participants, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an entity under the jurisdiction of the Trustees of Mercy Health will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.
   B. Office of the IRB establishes the educational and training requirements for IRB members and IRB staff who review biomedical and social & behavioral research involving human participants at this institution and who perform related administrative duties. Initial and ongoing training is provided and documented by this institution through the Office of the IRB.
   C. Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities.
   D. Chairpersons will receive additional training in areas germane to their additional responsibilities.
   E. IRB staff will receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOP).
   F. IRB members and staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. Mercy Health will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

2. Documentation
   Training and continuing education shall be documented and added to the education records of the IRB as described in these policies and procedures.
REFERENCE:
21 CFR 56.107
45 CFR 46.107
OHRP IRB Guidebook
NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

ATTACHMENTS
GA 102-A  Bibliography & Resource List
GA 102-B  Hold for Future Use
GA 102-C  Hold for Future Use
GA 102-D  IRB SOP Review Sign Off

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
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<tr>
<td>IRB Chairperson</td>
<td>1. Establish training and educational requirements and content for IRB members and staff</td>
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| IRB Coordinator         | 1. Follow and assist in the implementation of the education training and requirements identified by the Chairperson.  
2. Based on requirements and budget, determine training & education schedule and syllabus.  
3. Schedule speakers, acquire outside publications, and schedule attendance at seminars as budget allows.  
4. Assist in maintaining documentation of all IRB Member and OIRB staff completed training, education and qualifications. |
| Institutional Official  | 1. Authorize the IRB Manager to set annual budget.                      |
| IRB Manager             | 1. Set annual budget for Office of the IRB.                            |
| IRB Specialist          | 1. Assist in providing IRB members with training/education materials.  
2. Notify IRB members as to available training materials & schedule. Send Training Documentation and reminders as needed.  
3. Assist IRB Coordinator in maintaining documentation of completed IRB Member training and education. |

CONCURRENT CONSENTS:
Institutional Official