INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 01/14/2014
Revision No.: 2
Effective Date 07/01/2016

TITLE: Institutional Review Board Functions and Operations
FO 307 Human Subjects Research Determination

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The purpose of this policy is to describe the types of activities that qualify as human subjects research or clinical investigations and thus require the review and approval by the Institutional Review Board (IRB) prior to implementation and through study completion. In addition to federal regulations, all research conducted at Mercy Health regional sites complies with the Trinity Health Mission, Core Values, and Catholic moral/ethical principles, as delineated in the "Ethical and Religious Directives for Catholic Health Care Services." In this regard, IRB review and decision making gives special consideration for research participants' cultural, racial, social, religious, and economic circumstances.

GENERAL PROVISIONS:
In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any study that involves human subjects research. The federal regulations include a very specific determination for what constitutes research (45 CFR 46.102 (d)) and what is meant by human subject (45 CFR 46.102 (f)). The Office of the IRB will not make a formal written determination after a project has been completed.

DEFINITIONS:
DHHS/Common Rules
Research: means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subjects: means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Intervention: This includes physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- Interaction: This includes communication or interpersonal contact between investigator and subject

- Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
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FDA
Clinical Investigation: means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Human subjects (FDA guidelines for drug, food or biologic): means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

Human subjects (FDA guidelines for medical devices): An individual who participates in an investigation, either as a control or a subject on whom or on whose specimen an investigational device is used. A subject may be in normal health or may have a medical condition or disease (21 CFR 812.3 (p)) (Medical Devices). This definition includes the use of tissue specimens even if they are unidentified.

If the research involves any of the following, FDA Regulations, 21 CFR 50 & 56 apply and require IRB approval prior to implementation:
- Any use of a drug in research other than the use of an FDA approved Drug in the course of medical practice; or
- Any use of a medical device in studies where the purpose is to determine safety or effectiveness of the device; or
- Data will be submitted to or held for inspection by the FDA as part of a marketing permit.

Principal Investigator: A Principal Investigator may be a Mercy Health colleague or an employee at any site with which Mercy Health has signed an IRB authorization agreement.

REFERENCE:
21 CFR 56.102
45 CFR 46.102

ATTACHMENTS:
FO 307-A Human Subjects Research Determination Worksheet
FO 307-B Notice of Non-Human Subjects Research Determination

PROCEDURE: All Mercy Health Campuses

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<tr>
<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>Principal Investigator</td>
<td>1. Make a preliminary decision regarding whether his or her activities meet either the DHHS or FDA definitions of both &quot;research&quot; and &quot;human subjects&quot; or the FDA definitions of both &quot;clinical investigations&quot; and &quot;human subjects&quot;.</td>
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<td>2. Seek IRB review and approval of a protocol prior to initiating any clinical research or investigation that involves human subjects.</td>
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<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1. Review submission for completeness. Forward printed materials to IRB Chairperson or designee for determination of human subjects research.</td>
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IRB Chairperson (or designee)

1. Review submission and determine if human subjects research. Assign reviewer(s) as appropriate.
2. If human subjects research, determine type of review (i.e. expedited, exempt, full board).

CONCURRENT CONSENTS:

Institutional Official