TITLE: Institutional Review Board Functions and Operations
FO 302 Research Exempt for IRB Review

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: It is the policy of the Mercy Health Regional Institutional Review Board (IRB) that all activities involving the use of human participants in research be reviewed and approved by the IRB unless the Mercy Health Regional IRB Chairperson determines that the research meets the criteria for exemption established in federal policy. The federal policy that governs the use of human participants in research is 45 CFR 46, often referred to as the Common Rule and can be accessed at the following website: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. The purpose of this policy is to provide: (1) information to researchers about what human research activities are considered exempt from IRB review and approval; (2) the responsibilities of the researchers in the ethical conduct of human participant research since IRB oversight is not required; (3) the application process for research that is exempt and (4) information about changes made to the research study that would invoke the need for IRB review.

Federal regulations state that if research activities meet specific criteria, the activities may be determined to be exempt from initial and continuing review by the Institutional Review Board (IRB). The exemption determinations are made by the Mercy Health Regional IRB Chairperson. Exempt status does not, however, lessen the ethical obligations to human participants as articulated in the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) and in disciplinary codes of professional conduct. It is the Principal Investigator who assumes the responsibility for the protection of human participants in the research activities and ensures that the research is performed with integrity and within accepted ethical standards. Thus, depending on the circumstances, researchers performing exempt research may be required to make provisions to obtain informed consent, protect confidentiality, minimize risks, and discuss problems or complaints with the Mercy Health Office of the IRB. Principal investigators are also expected to ensure that they and all individuals performing the research have successfully completed the basic conduct of research training which can be accessed at: www.chiprogram.org.

Researchers are required to submit an application for exemption determination to the Mercy Health Office of the IRB.
Institutional Policy & Procedure

Exemption determination applications are typically reviewed within 10 business days from the date of the receipt of a complete application. Review and process time may increase if the application is incomplete, unclear or lacks all necessary information (e.g., complete application, grant application, data collection instruments, etc.) for the IRB Chairperson to make an informed decision about the determination of exemption for the research.

Once human participant research is determined to be exempt, the Office of the IRB staff will send an Exemption Determination notice to the Principal Investigator. The exempt determination is valid for the life of the research unless a change(s) is made that requires an additional review. Modification requests are required to be submitted only in limited circumstances and Continuing Renewal requests do not need to be submitted.

Research activities in which the only involvement of human participants will be in one or more specific categories, which are listed below in this policy, may be exempt from IRB review. Determination of exemption must be based on regulatory and institutional criteria and documented. Determination of exemption can only be made by the Mercy Health Regional IRB Chairperson.

GENERAL PROVISIONS:

1. Exempt Research Activities
   A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      i. Research on regular and special education instructional strategies,
      ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
      i. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
      ii. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

   C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if:
      i. The human participants are elected or appointed public officials or candidates for public office; or
      ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

   D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

   E. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
      i. Public benefit or service programs;
      ii. Procedures for obtaining benefits or services under those programs;
      iii. Possible changes in or alternatives to those programs or procedures; or
      iv. Possible changes in methods or levels of payment for benefits or services under those programs.

   F. Taste and food quality evaluation and consumer acceptance studies:
      i. If wholesome foods without additives are consumed, or
      ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Institutional Policy & Procedure

REFERENCES:
45 CFR 46.101
21 CFR 56.104, 105

ATTACHMENTS:
FO 302-A    Hold For Future Use
FO 302-B    Request for Claim of Exemption
FO 302-C    Worksheet: Exemption Determination
FO 302-D    Notice of IRB Exempt Approval

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
<th>Action</th>
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<tr>
<td>IRB Coordinator/IRB Specialist</td>
<td>1. Maintain and make available submission information regarding research that is exempt from IRB review.</td>
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<tr>
<td>IRB Chairperson</td>
<td>1. Review claims of exemption, confirm by signature and route to IRB specialist for issuance of letter of exemption and preparation for reporting to the IRB.</td>
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<td>2. Serve as a resource to IRB Coordinator for potential claims of exemption, as needed and requested.</td>
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<tr>
<td>IRB Coordinator</td>
<td>1. Assist in the review of claims of exemption as designated by IRB Chairperson, utilizing the IRB exempt review checklist.</td>
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CONCURRENT CONSENTS:
Institutional Official

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