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

ORIGINATOR: IRB Chairperson

APPROVAL: [Signature]
IRB Chairperson

POLICY STATEMENT: It is the policy of the Mercy Health Regional Institutional Review Board (IRB) that all activities involving the use of human subjects in research be reviewed and approved by the IRB unless the Mercy Health Regional IRB Chairperson or designee determines that the research meets the criteria for exemption established in federal policy. The federal policy that governs the use of human subjects 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.htm1.

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 subjects 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 or designee. Exempt status does not, however, lessen the ethical obligations to human subjects 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 subjects 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.citiprogram.org.

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

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 or designee to make an informed decision about the determination of exemption for the research.
Once human subjects 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 subjects 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 be documented. Determination of exemption can only be made by the Mercy Health Regional IRB Chairperson or designee.

Use of the exemption categories for research subject to the requirements of subparts B, C, and D. Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

1) Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

2) Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

3) Subpart D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

GENERAL PROVISIONS:

Exempt Research Activities

1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact student’s opportunity to learn required educational content or the assessment of educators who provide instruction, such as:
   - Research on regular and special education instructional strategies,
   - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria are met:
   - Information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects; and
   - Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement or reputation; or
   - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111 (a)(7)

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from
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an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

B. Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, educational advancement, reputation; or

C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111 (a) (7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigators use of identifiable health information when that use is regulated under 45 CFR 160 and 164 subparts A and E for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501or for public health activities and purposes" as described under 45 CFR 46.512 (b); or

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable health information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal Department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies, that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or
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grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. 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

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB Review and makes the determinations required by 45 CFR 46.111 (a) (8)

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   (i) Broad consent for the storage, maintenance, and secondary research use or the identifiable private information or identifiable biospecimens was obtained in accordance with Sec 45 CFR 46.116(a) (1-4), (a)(6) and (d);
   (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
   (iii) An IRB conducts a limited IRB Review and makes the determination required by 45 CFR 46.111 (a) (7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (8) (i) of this section and
   (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Limited IRB Review

Under the revised Common Rule, exempt Categories 2, 3, 7, & 8 include a provision for limited IRB review.

For exempt categories 2 & 3, the requirement for limited IRB review is triggered when:
1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, AND
2. Any disclosure of the human subjects’ responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation

For exempt categories 7 & 8, Mercy Health will not be utilizing the broad consent categories.

Continuing review is not required for research approved under limited IRB review.

When changes to research are proposed that fall within the scope of the limited IRB review requirement (e.g., storage or maintenance, privacy and confidentiality), the changes must undergo limited IRB review and be approved before implementation (except when necessary to eliminate apparent immediate hazards to subjects).

Limited IRB review under exempt categories 2(iii), 3(i)(c), & 8 requires that the IRB determines that the criteria for IRB approval at 45 CFR 46.111(a)(7) is satisfied.
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45 CFR 46.111(a)(7): When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

The IRB should consider:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Limited IRB review must be performed by the IRB and can be performed using expedited procedures. Thus, the review may be performed by the IRB Chair or “one or more experienced reviewers designated by the chairperson from among members of the IRB”.

Exceptions to Availability of Exemptions

Certain kinds of research with human subjects are not eligible for exempt determinations because additional protection has been granted by federal regulations for vulnerable populations and FDA regulated research. Specifically, the following do not qualify for exempt status

Prisoners: Research involving prisoners as human subjects is not eligible for exemption. “Prisoners” are defined as “any individual involuntarily confined or detained in a penal institution”. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

FDA-regulated Research: Exempt research categories do not apply to research that involves FDA-regulated products (studies using investigational drugs, biologics, or devices for which the FDA has granted an investigational new drug [IND] or investigational device exemption [IDE], or non-significant-risk devices).

Minors (Children): Research involving minors may not be exempted, with one exception. If the research consists solely of observation of public behavior where the investigator does not participate in the activities being observed, the research may be eligible for exemption. All other research involving minors is not eligible for exemption.

REFERENCES:
45 CFR 46.101, 104, 111-117
21 CFR 56. 104

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>
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<tr>
<td>IRB Specialist/IRB Coordinator</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 or designee</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/IRB Specialist for potential claims of exemption, as needed and requested.</td>
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<tr>
<td>IRB Coordinator/IRB Manager</td>
<td>1. Assist in the review of claims of exemption as designated by IRB Chairperson or designee, utilizing the IRB exempt review checklist.</td>
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