McLaren HEALTH CARE		**Policy Title:**	Exempt Review of Human Subject Research
Effective Date:	July 20,2012	**Policy Number:**	MHC_RP 0105
Review Date:	November 6, 2015	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	October 28, 2015	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to establish guidelines for McLaren Health Care Institutional Review Board (MHC IRB) to recognize and review human subjects' research that is exempt from federal regulations.

2. Scope

2.1. The Human Research Protections Program (HRPP) applies this policy to all proposed activities that meet definitions of "research" and "human subject," the Food and Drug Administration (FDA) definitions of "clinical investigation" and "human subject" and

2.1.1. The research is conducted by or under the direction of a MHC investigator in connection with his/her assignment.

2.1.2. The research is conducted by an investigator employed by a MHC or its subsidiary hospitals.

2.2. The research is conducted using any property, patient population, or facility of the MHC or its subsidiary hospitals. This policy applies to Principal Investigators, research staff, IRB Chair or designee and IRB Staff and Administrators.

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. The MHC IRB is responsible for determining whether a research activity is exempt from 45 CFR 46 and 21 CFR 56.

4.2. Determination of whether human subject research can be exempt is made by the MHC IRB Chair, designee or IRB Analyst who is also a member of the IRB, acting on behalf of MHC IRB.

4.3. Investigators or others within the organization may not make exemption determinations.

4.4. Human subjects research determined to be exempt are conducted in a manner consistent with the ethical principles set for by the Belmont Report.

4.5. The IRB Chair or designated reviewers are subject to the MHC HRPP policy *MHC_RP0126 "Conflicts of Interest: IRB Members"* when reviewing and making exemption determinations.

4.6. MHC IRB Members are notified of exempt determinations at the time of the fully convened meeting. Studies meeting the exempt criteria are reported on the agenda as informational only and are also documented in the meeting minutes.

5. Procedure

5.1. Investigators who believe that their project meets the federal criteria for exemption are required to complete an Exempt Initial Review Application using eProtocol electronic submission system and provide all required information and documents to the MHC IRB for review.

5.2. The review is performed by the IRB Chair, designee and/or IRB Analyst who is also a member of the IRB Committee, acting on behalf of MHC IRB.

5.2.1. The reviewer may request additional information from the PI to make determination or request changes in the research to meet the institution's ethical principles for human subject protection and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

5.2.2. This is communicated to the PI via eProtocol.

5.2.3. When all the necessary information is received from the PI, the reviewer will make the exemption determination when applicable.

5.2.4. The reviewer will use the *Reviewer Checklist "Exemption Determination Checklist"* to document the review and exemption determination.

5.3. If there are interactions with participants, the reviewer should determine whether there should be a consent process that will disclose such information as:

5.3.1. That the activity involves research.

5.3.2. A description of the procedure.

5.3.3. That participation is voluntary.

5.3.4. Name and contact information for the researcher.

5.4. If a request is made for a waiver of individual HIPAA authorization or alteration of individual HIPAA authorization, a Privacy Officer, who is also a member of the IRB Committee, will be assigned.

5.5. If a research meets the criteria for exemption, a Notice of Exempt Review is generated via eProtocol and available for the PI.

5.5.1. This notice indicates that they may not make changes to the research activity without first discussing the changes with the MHC IRB to ensure that the changes are within the parameters for exemption.

5.5.2. This notice indicates category(ies) under which the exemption is granted.

5.6. Once a research project is determined to be exempt, it is not reviewed again unless a modification application is submitted.

5.7. There is no continuing review process for exempt research, as long as the criteria for exemption remain satisfied.

5.8. This notice indicates that the project will be administratively closed once stated end date that is listed in the application arrives.

5.9. If a protocol does not meet the criteria for exemption, it is returned to the PI using eProtocol electronic submission system with notification of failure to meet the criteria.

5.10. The PI is asked to complete a Protocol Application for expedited/full board review.

6. Responsibilities

6.1. Investigator:

6.1.1. All Investigators proposing human subjects research, conducted at any McLaren subsidiary hospitals or by employees, students, or agents of MHC or its affiliates, believed to meet the federal criteria for exemption must submit an Exempt initial review application to MHC IRB using eProtocol electronic submission system.

6.1.2. Investigators must ensure the human subjects research:

6.1.2.1 Involves no more than minimal risk to subjects;

6.1.2.2 Is equitable in the selection of subjects;

6.1.2.3 If the research involves interactions with subjects, the circumstances of consent must minimize coercion and undue influence;

6.1.2.4 When applicable, informed consent process discloses that the activity involves research, a description of the procedures, that participation is voluntary, and the name and contact information of the PI;

6.1.2.5 Provides adequate provisions for protecting the privacy interests of subjects.

7. Exemption Criteria from Applicable Laws and Regulations:

7.1. DHHS Regulated and Investigator Initiated Research in which the only involvement of human subjects will be in one or more of the following categories (45 CFR 46.101):

7.1.1. Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

7.1.1.1 Research on regular and special education instructional strategies or;

7.1.1.2 Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

7.1.2. Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

7.1.2.1 Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

7.1.2.2 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, or reputation.

7.1.3. Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2), if:

7.1.3.1 The human subjects are elected or appointed public officials or candidates for public office; or

7.1.3.2 Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

7.1.4. Category 4: 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

7.1.4.1. "Existing" means data or specimens collected (i.e., on the shelf) at the time the research is proposed (i.e. submitted to the IRB). It includes data or specimens collected for research and non-research activities.

7.1.5. Category 5: Research and demonstration projects which are conducted by or subject to the approval of department or agency heads [this

reference is to government department or agency heads], and which are designed to study, evaluate, or otherwise examine:

7.1.5.1. Public benefit or service programs; or

7.1.5.2. Procedures for obtaining benefits or services under those programs; or

7.1.5.3. Possible changes in or alternatives to those programs or procedures; or

7.1.5.4. Possible changes in methods or levels of payment for benefits or services under those programs.

7.1.6. Category 6: Taste and food quality evaluation and consumer acceptance studies:

7.1.6.1. If wholesome foods without additives are consumed or

7.1.6.2. 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7.2. FDA-Regulated Research

7.2.1. The Chair or designee is responsible for making determinations of exemption from IRB requirement in accordance with 21 CFR 56.104(a)(b)(c)(d) as quoted below:

7.2.1.1. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981

7.2.1.2. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date."

7.2.1.3. Emergency use of a test article provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

7.2.1.4. Taste and food quality evaluation and consumer acceptance studies. If wholesome foods without additives are consumed or if the 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

7.2.2. The exemption at 21 CFR 56.104(c), the emergency use of a test article, is covered in separate policy *MHC_RP119_Emergency Use of Investigational Drugs or Medical Device.*

7.2.3. The exemption at 21 CFR 56.104(c) does not apply to human-subjects research regulated by the DHHS.

7.2.4. FDA-regulated research determined to be exempt from 21 CFR 56 IRB requirements is subject to 21 CFR 50 Informed Consent of Human Subjects.

8. Human Subject Research which are not exempt from federal regulations include the following:

8.1. Studies involving prisoners (Subpart C of DHHS regulations);

8.2. Survey or interview procedures with children (Subpart D of DHHS Regulations);

8.3. Observation of public behavior of children when the investigator(s) participates in the regulations);

8.4. Research involving deception;

8.5. Research involving fetuses;

8.6. Human in vitro fertilization;

8.7. Placing a subject at greater than minimal risk;

8.8. Data collected which meet the criteria for protected health information (PHI) when there is a direct or indirect link that would identify the participant;

8.9. Mentally disabled or cognitively impaired individuals, regardless of whether a legally authorized representation is required for informed consent.

9. Modifications to Exempt Research

9.1. In general, investigators are not required to submit modifications to the IRB once a research study is designated as exempt as long as those changes do not affect the exempt category or criteria for exempt determination (changing from exempt status to expedited or full review, changing exempt category).

9.2. Personnel changes must be submitted to the IRB via eProtocol.

9.3. An extension of proposed end date must be submitted to the IRB via eProtocol.

9.4. Modifications in procedures that would change the exempt category approved by the IRB include but are not limited to:

9.4.1. New knowledge that increases the risk level.

9.4.2. Use of any methods described in the expedited review categories that do not meet the exempt criteria (e.g., blood draws).

9.4.3. Surveying or interviewing children or observing public behavior of children and participating in the activities being observed.

9.4.4. Change in the way identifiers are recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that subjects can be identified.

9.4.5. Addition of an instrument, survey questions, etc. that would pose more than minimal risk to subjects.

9.4.6. Addition of an instrument, survey, etc. from which information obtained is recorded in such a manner that human subjects can be identified, 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, or reputation.

9.4.7. Addition of prisoners as research subjects.

9.4.8. Addition of other vulnerable populations that may pose more than minimal risk.

9.4.9. Under certain circumstances, addition of a funding source.

9.4.10. Addition of exempt category not previously approved by the IRB.

9.5. If there are plans to make any of the above changes, the investigator must contact the MHC IRB Office.

10. References

10.1. 45 CFR 46

10.2. 21 CFR 50

10.3. 21 CFR 56

10.4. MHC_RP126 “Conflicts of Interest: IRB Members”

10.5. MHC_RP119 “Emergency Use of Investigational Drugs or Medical Devices”

10.6. “Exemption Determination Checklist” form

10.7. Appendix I “Definitions”

11. Previous Revisions: August 6, 2012, August 10, 2015

12. Supersedes Policy: *MHC_RP0104_Exempt Review of Human Subject Research*

13. Approvals:

MHC Institutional Review Board Initial Approval: July 20, 2012

MHC Institutional Review Board acknowledgment: July 20, 2012,
August 10, 2015
November 6, 2015

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Michael McKenna, MD. **Date**
Executive Vice President/ Chief Medical Officer
Institutional Official of Research