McLaren HEALTH CARE		Policy Title:	Determination of Human Subject Research
Effective Date:	January 16, 2012	**Policy Number:**	MHC_RP0104
Review Date:	November 11, 2016	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	November 08, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to establish when an activity is Human Subjects Research and meets the regulatory definitions of "research" or "clinical investigation" and "human subjects" and when the institution is engaged in research.

2. Scope

2.1. The Human Research Protections Program (HRPP) applies this policy to all proposed activities that meet the 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.
2.1.3. The research is conducted using any property, patient population, or facility of the MHC or its subsidiary hospitals.

3. Definitions

3.1. Human Subject: A human subject as defined by the Common Rule is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (45 CFR 46.102(f)).

3.2. Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information.

3.3. Human Subjects as Defined by FDA: An individual who is or becomes a participant in a clinical investigation (as defined below), either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject/participant also includes any individual on whose tissue specimen an investigational device is used or tested.

3.4. Human Subjects Research: any activity that meets the definition of "research" and involves "human subjects" as defined by either the Common Rule or FDA regulations.

3.5. Research: The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

3.6. For the purposes of this policy, **a systematic investigation** is an activity that involves a retrospective or prospective study plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

3.7. Research as defined by FDA regulations:

3.7.1. 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 Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)].

3.7.2. Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)].

3.7.3. Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal

Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

3.7.4. Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21CFR 56.102(c)].

3.8. Research as Defined by DHHS: A systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

3.9. Research Under the Auspices of the Organization: Research under the auspices of the institution includes research conducted at this institution, conducted by or under the direction of any employee or agent of this institution (including residents and students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involving the use of this institution's non-public information to identify or contact human subjects.

3.10. Refer to Appendix I "Definitions" for additional definitions.

3.11. Examples of activities that are not considered research under the above definitions:

3.11.1. Quality Assurance/Improvement: Activities whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes. Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research.

3.11.2. Case Reports: The external reporting (e.g., publication, poster, or oral presentation) of an interesting clinical situation or medical condition of up to two patients. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

3.11.3. Public Health Surveillance: A series of ongoing systematic activities, including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice closely integrated to the dissemination of data to those who need to know and linked to prevention and control.

4. Policy

4.1. Research subject to regulation as defined in 45 CFR 46.102(e), 21 CRF 56.102(b) and 21CFR812.3 must be reviewed and approved, in compliance with

all applicable regulatory requirements, by an institutional review board (IRB) that operates in accordance with all pertinent federal requirements.

4.2. All research determined to be human subjects research must apply protections for human participants as mandated by applicable laws and regulations, and standards set forth in federal, state, and local laws and institutional policies.

4.3. The MHC IRB utilizes the Office for Human Research Protections (OHRP) guidance entitled "Guidance on Engagement of Institutions in Human Subjects Research" to determine when the institution is engaged in human subjects research activities.

4.4. All proposed research activities must be submitted to the MHC IRB for review and approval. Investigators must have an IRB approved study prior to the commencement of any human subject research.

4.5. MHC IRB makes the determination whether an activity constitutes research involving human subjects. Investigators CAN NOT make the determination that the activity is not human subject research.

5. Procedure

5.1. Determination whether an activity is research involving human subjects must be made by the MHC IRB. The investigator shall not make the determination that the activity is not human subject research.

5.2. The investigator must complete the "*Request for Determination of Non-Human Subject Research*" form and send it to MHC IRB via e-mail. Based on the definitions listed in this document, the MHC IRB chair, or designee, will determine whether the activity meets the definition of human subject research based on federal regulatory definitions, 45 CFR 46.102(d), 21 CFR 50, or 21 CFR 56.

5.3. The MHC IRB chair or designee may consult with MHC IRB members for their determination when needed, e.g. expertise in the field of study. The MHC IRB chair, designee, staff, or MHC IRB members may contact the investigator for additional information as needed. The determination should be made within three to five business days of receipt of the question. Determination in cases where additional information is needed from the investigator may take additional time.

5.4. Activities that meet the federal definitions for both "research" and "human subjects" as outlined in this document must be submitted to the MHC IRB for review via the e-Protocol electronic submission system. Based on the answers provided, the system will generate questions regarding human subject research as investigators continue through the application pages.

5.5. Determination whether an activity constitutes human subject research will be made using the "*Human Subject Research Determination"* checklist.

5.6. Documentation of all determinations made through the MHC IRB Office will be recorded and maintained in the MHC IRB Office.

5.7. Upon MHC IRB determination, the Investigator will be notified in writing.

5.8. A copy of the submitted materials and determination will be kept on file at the MHC IRB office

6. Responsibilities

6.1. PI is responsible for:

6.1.1. Consulting with the MHC IRB for a determination of human subject research versus non-human subject research;

6.1.2. Requesting confirmation that an activity does not constitute human subjects research from the MHC IRB Office.

6.2. IRB Office is responsible for:

6.2.1. The MHC IRB chair, or designee, will determine whether the activity meets the definition of human subject research based on federal regulatory definitions, 45 CFR 46.102(d), 21 CFR 50, or 21 CFR 56.

6.2.2. IRB staff will notify investigators of the determination in writing.

7. References

7.1. 21 CFR 50

7.2. 21 CFR 56

7.3. 21 CFR 812

7.4. 45 CFR 46

7.5. Office for Human Research Protections (OHRP) guidance entitled "Guidance on Engagement of Institutions in Human Subjects Research".

7.6. Appendix I "Definitions"

7.7. "Request for Determination of Non-Human Subject Research" form

7.8. "Human Subject Research Determination" Reviewer Checklist

8. Previous Revisions: August 3, 2012; October 27, 2015

9. Supersedes Policy: *MHC_RP0103_Determination of Human Subject Research*

10. Approvals:

MHC Institutional Review Board initial approval:	February 17, 2012
MHC Institutional Review Board acknowledgment:	December 21, 2012 November 6, 2015 November 11, 2016

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