McLaren HEALTH CARE		Policy Title:	Determination of Human Subject Research
Effective Date:	January 16, 2012	Policy Number:	MHC_RP0104
Review Date:	August 4, 2020	Section:	Research Integrity
Revised Date:	March 22, 2024	Oversight Level:	Corporate
Administrative Responsibility:		Corporate Manager of Research Integrity Institutional Official, HRPP	

1. Purpose

1.1. The purpose of this policy is to establish when an activity meets the definition of Human Subjects Research as defined by 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 and:

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

2.1.2. The research is conducted by an investigator employed by 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.

2.1.4. MHC is engaged in the research per OHRP's "Guidance on Engagement of Institutions in Human Subjects Research".

2.1.5. MHC personnel are identified as investigators or study personnel, or MHC facilities are identified as performance sites, in regulatory documentation for FDA-regulated studies (e.g., FDA Form 1572 or its equivalent for medical device research delegation of responsibilities log, etc.).

3. Definitions

3.1. Refer to Appendix I "Definitions"

4. Policy

4.1. Investigators and outside parties CAN NOT make the determination that the activity is not human subject research.

4.2. Research subject to regulation as defined in 45 CFR 46.102(e), 21 CRF 56.102(b) and 21 CFR 812.3 must be reviewed and approved, in compliance with all applicable regulatory requirements, **and** by an institutional review board (IRB) that operates in accordance with all pertinent federal requirements.

4.3. 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.

4.4. 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. The MHC IRB will determine if a proposed study meets either the Health and Human Services (HHS) or the Food and Drug Administration (FDA) definition of human participant research (clinical investigation). The study must meet the criteria for both research and human participants. If the study does not meet the definition provided below, a letter will be sent to the Principal Investigator (PI) stating the reason the project does not meet human participants review criteria.

4.6. 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. Investigators and outside parties CAN NOT make the determination that MHC is not engaged in human subjects' research that involves MHC in any way.

4.7. MHC IRB makes the determination whether MHC is involved in clinical investigations regulated by the FDA. Investigators and outside parties, such as sponsors, CROs, or coordinating centers, CAN NOT make the determination that MHC is not involved in FDA-regulated clinical investigations that involve MHC in any way.

4.8. Activities that are not human subjects research do not fall under the purview of the MHC IRB.

5. Procedure

5.1. Determinations whether MHC is engaged in human subjects' research or involved in FDA-regulated clinical investigations that involve MHC in any way must be made by the MHC IRB. Investigators and others (e.g., outside parties) may request a determination by contacting the MHC IRB office and providing all requested information.

5.2. The MHC IRB chair, or Corporate Research Manager will determine whether MHC is engaged in human subjects' research.

5.3. 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.

5.4. To obtain a determination the investigator must complete and submit to the MHC IRB the "Request for Determination of Non-Human Subject Research" application in the MHC IRB electronic system, however:

5.5. The investigator can move forward with submitting a human subject research application (exempt, expedited, full board) and bypass submitting a "Request for Determination of Non-Human Subject Research" application only if they are certain their project is human subject research i.e.,

Drug or device study and have met or do not violate all other department or ancillary committee requirements, i.e., Protocol Review Committee approval or GME department requirements.

5.6. In cases where it is not clear, if the investigator is not sure or investigator doesn't believe their project is human subject research then the investigator must complete and submit to the MHC IRB the "Request for Determination of Non-Human Subject Research" application in the MHC IRB electronic system.

5.7. The IRB staff will:

5.7.1. Advise PI and research staff in preparation and completion of the application process.

5.7.2. Perform pre-review of application and supporting documents to identify non-scientific issues for completeness according to IRB staff checklist.

5.7.3. If the IRB staff does not believe that the materials received are sufficient or the application incomplete, the Analyst may request that the PI make further clarifications and/or revisions.

5.7.4. If the PI does not respond within 60 days, the determination inquiry will be withdrawn.

5.7.5. Assign completed review to MHC IRB chair or designee.

5.8. 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.

5.9. 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.

5.10. The determination should be made within approximately 5-7 business days of receipt of a *complete* submission. Determination in cases where additional information is needed from the investigator may take additional time.

5.11. Determination whether an activity constitutes human subject research will be made using the "Human Subject Research Determination" IRB reviewer checklist.

5.12. After MHC IRB chair or designee makes determination, IRB staff would notify investigators of the determination via an outcome letter generated in MHC IRB electronic system if project determined to be *human subject research* or *not human subject research*.

5.13. For activities determined by the IRB chair or designee to meet either the DHHS or FDA definition of "*human subject research*," the principal investigator is advised to submit a human subject research application in MHC IRB electronic system for either chart review, exempt, expedited, full-board IRB review application, as appropriate.

5.14. The Investigator *must follow all instructions* in the determination letter. If a project is not human subjects research, and the investigator proposes to utilize a consent form for the study, no references to the project/ activity as "research" or IRB oversight can be included.

6. References

6.1. 21 CFR 50

6.2. 21 CFR 56

6.3. 21 CFR 46

6.4. 45 CFR 46

6.5. OHRP's decision Chart #1 "Is an Activity Research Involving Human Subjects?"

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

6.7. Appendix I "Definitions"

6.8. Appendix III: Medical Devices and Excluded Software Functionality

6.9. "Request for Determination of Non-Human Subject Research" MHC IRB electronic system

6.10. "Human Subject Research Determination" Reviewer Checklist

6.11. FDA Information Sheet guidance entitled "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)."

7. Previous Revisions: 8/3/12, 10/17/15, 8/4/20, 1/12/23

8. Supersedes Policy: MHC_RP0103_Determinations of Human Subject Research

9. Approvals:

MHC Institutional Review Board initial approval: 2/17/12, 1/14/21

MHC Institutional Review Board acknowledgment: 2/21/12, 11/6/15, 11/11/16

Signature on File *3/22/2024*

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