McLaren HEALTH CARE		Policy Title:	Exempt Review of Human Subject Research
Effective Date:	July 20, 2012	**Policy Number:**	MHC_RP 0105
Review Date:	November 16, 2015	**Section:**	Research Integrity
Revised Date:	January 12, 2023	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager Research Integrity Institutional Official		

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 Research Integrity department applies this policy to all proposed activities that meet the Common Rule definitions of "research" and "human subject", or 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 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. MHC is engaged in the activity.

2.2. The research is conducted using any property, patient population, or facility of the MHC or its subsidiary hospitals, and engages MHC in the activity. 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. In order for a project to qualify as exempt from further review, the entire research project must fall within one or more of the six (6) specific regulatory

categories of Exemption, provided in Appendix A. McLaren Health Care has not adopted criteria number 7 and 8.

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

4.3. 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.

4.4. Limited IRB review must be conducted by the IRB Chair or an IRB member. The IRB Chair/member conducting limited IRB review may not disapprove research, only the convened IRB may disapprove research.

4.5. Investigators cannot exempt their own projects. A research project cannot start until after written concurrence is granted by the IRB. Retroactive "concurrence" or review is not permitted. Data collected prior to IRB Exemption concurrence may not be used and must be destroyed. Human subjects research studies determined to be exempt are conducted in a manner consistent with the ethical principles set forth by the Belmont Report.

4.6. The IRB chair or designee is subject to the MHC Research Integrity policy *MHC_RP0126 "Conflicts of Interest: IRB Members"* when reviewing and making exemption determinations.

4.7. 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

Submission, Screening and Assignment of Reviewer

5.1. Investigators who believe that their project meets the federal criteria for exemption will submit an exempt initial review application using the electronic IRB submission system and provide all required information and documents (e.g., the protocol and any consent or recruitment materials, if applicable) to the MHC IRB for review.

5.2. Investigators must ensure the human subjects research:

5.2.1. Involves no more than minimal risk to subjects;

5.2.2. Is equitable in the selection of subjects;

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

5.2.4. When applicable, informed consent process discloses that the information detailed in Section 5.7 below;

5.2.5. Provides adequate provisions for protecting the privacy interests of subjects and confidentiality of their data.

5.2.6. Once exempt status is approved Annual progress report are not required. However, a Study Closure form must be submitted to the IRB upon project completion.

5.3. Upon receipt of the application, designated IRB staff screen the application for completeness and accuracy.

5.4. The IRB staff member reviews the PI's exempt category selection for appropriateness. The designated IRB staff member either assigns submission to the IRB chair or designee.

5.5. 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 MHC IRB, will be assigned by IRB staff.

Modifications to Already Approved Exempt Research

5.5.1. Personnel changes must be submitted to the IRB via the electronic IRB system.

5.5.2. An *extension of proposed end date* must be submitted to the IRB via the electronic IRB submission system.

5.5.2.1. The study project will be administratively closed once stated end date that is listed in the application arrives and a modification to extend date has not been submitted to the IRB.

5.5.3. Investigators must submit proposed modifications to the IRB to confirm that exemption category and status are not affected. Modifications in procedures that would change the exempt category approved by the IRB include but are not limited to:

5.5.3.1. New knowledge that increases the risk level.

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

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

5.5.3.4. Change in the way identifiers are recorded (directly or indirectly).

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

5.5.3.6. Addition of an instrument, survey, etc. 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.

5.5.3.7. Addition of prisoners as targeted research subjects.

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

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

IRB Exempt Review

5.6. The review is performed by the IRB chair or designee and/or IRB analyst who is also a member of the IRB, acting on behalf of MHC IRB.

5.6.1. 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 protections and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This is communicated to the PI via the electronic IRB submission system.

5.6.2. The IRB will review the protocol to determine if all aspects of the protocol meet one or more of the Exemption categories. During the review process, careful consideration is given to review of the risks, benefits, provisions for confidentiality, participant's voluntary participation, and the process of informed consent.

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

5.6.4. The reviewer will use the *"Exemption Determination Checklist"* to document the review, whether and how the research qualifies for exemption (i.e., the justification for the determination), and continuing review determination and justification (for exemptions granted under limited IRB review).

5.6.5. The IRB reviewer ensures the research does not include any of the following:

5.6.5.1. Targeted enrollment of prisoners as they are excluded from the exemption categories (however, research aimed at involving a broader subject population that only incidentally includes prisoners may be allowed);

5.6.5.2. Survey or interview procedures which include children as subjects (exemption category #2 only);

5.6.5.3. The administration of educational tests to children and/or observation of public behavior involving children where the investigator directly participates in the activities being administered and/or observed (exemption category #2 only);

5.6.5.4. FDA-regulated research (exemption categories #1-5).

5.6.6. Studies granted exemption requiring limited IRB review will be placed on the expedited study report that is presented to the IRB at their convened meeting.

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

5.7.1. That the activity involves research.

5.7.2. A description of the procedure.

5.7.3. For Category 3 (benign behavior interventions in adults) that involves subject deception: A statement that subjects will be unaware of, or misled, regarding the nature or purposes of the research.

5.7.4. That participation is voluntary.

5.7.5. Name and contact information for the researcher.

5.7.6. How the participants information will be used, shared (if applicable), and protected.

5.8. If a research study meets the criteria for exemption, a Notice of IRB Review is generated via the electronic IRB submission system and available for the PI. This notice will state:

5.8.1. that no changes may be made to the research activity without first discussing the changes with the MHC IRB to ensure that the changes are within the parameters for exemption.

5.8.2. The category(ies) under which the exemption is granted.

5.8.3. For exemptions not requiring limited IRB review, when the progress report will be required for submission.

5.8.4. For exemptions requiring limited IRB review, whether continuing review or progress report will be required, and when.

5.9. Once a research project is determined to be exempt it is not reviewed again unless a change is proposed and a modification application is submitted, except when the exempt study requires limited IRB review.

5.10. Continuing review by the IRB is not required for exempt research except as noted below:

5.10.1. The IRB may determine that continuing review is required for a study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

Exemption Concurrence/IRB Correspondence –

5.11. When the IRB determines a submission meets criteria for Exemption status, IRB staff will send a letter to the investigator indicating the IRB acknowledges the Exemption request and states the category number under which the Exemption status was granted.

5.11.1. IRB staff will place this information on the minutes of the next IRB meeting.

5.11.2. If the protocol does not meet the criteria for Exemption status, the investigator will be notified and given the reasons for the IRB's decision. The investigator will be instructed to resubmit the protocol under the appropriate Expedited or Full Board review status.

5.12. IRB staff will process administrative closure once stated end date that is listed in the application arrives and PI has not submitted modification to extend project date.

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

5.14. The PI is asked to complete a full board / expedited application in the electronic IRB submission system.

5.15. FDA-Regulated Research

5.15.1. The chair or designee is responsible for making determinations of exemption for prior IRB review and approval in accordance with 21 CFR 56.104(a)(b)(c)(d) as quoted below:

5.15.1.1. 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.

5.15.1.2. 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."

5.15.1.3. 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.

5.15.1.4. 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.

5.15.2. 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.*

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

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

6. References

6.1. 45 CFR 46

6.2. 21 CFR 50

6.3. 21 CFR 56

6.4. MHC_RP0126 “Conflicts of Interest: IRB Members”

6.5. MHC_RP0119 “Emergency Use of Investigational Drugs or Medical Devices”

6.6. “Exemption Determination Checklist” form

6.7. Appendix I “Definitions”

7. Previous Revisions: 8/6/12, 8/10/15, supplement - MHC_0500 SOP Transition and IRB Review of Research Subject to Revised 2018 Common Rule For those studies receiving approval prior to the implementation of the Revised Common Rule (approved prior to January 21, 2019), the previous regulations apply. For more information regarding the regulations applicable to these studies, please see November 6, 2015 version., 1/18/19, 7/6/20, 12/14/21

8. Supersedes Policy: MHC_RP0104_Exempt Review of Human Subject Research

9. Approvals:

MHC Institutional Review Board Initial Approval: 7/20/12

MHC Institutional Review Board acknowledgment: 7/20/12, 8/10/15, 11/6/15, 1/18/19

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Signature on File *1/31/23*

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Justin Klamerus, MD, MMM Date
Executive Vice President/ Chief Medical Officer
Institutional Official of Research

Appendix A Revised Common Rule - Exempt Categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and 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 is met: i. 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.

   ii. 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, or reputation; or

   iii. 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 .111(a)(7).

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from 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, or 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 .111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief, 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 is 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 readily be 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 investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(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 non-research 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 private 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 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 website 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 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. 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).
   Research category 7 is not an option at the McLaren Health Care currently

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 of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (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 (d)(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.

   Research category 8 is not an option at the McLaren Health Care currently

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

Subpart B [pregnant women, fetuses, neonates]. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C [prisoners]. 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.

Subpart D [children].

a. The exemptions (1), (4), (5), and (6) of this section may be applied to research subject to subpart D if the conditions of the exemption are met.
b. Exemption (2)(i) and (ii) may only 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.
c. Exemption (2) (iii) may not be applied to research subject to subpart D
d. Exemption (3) may not be applied to research subject to subpart D