McLaren HEALTH CARE		Policy Title:	Initial Review of Human Subject Research
Effective Date:	January 16, 2012	Policy Number:	MHC_RP0107
Review Date:	November 20, 2015	Section:	Human Research Protections Program (HRPP)
Revised Date:	November 2, 2015	Oversight Level:	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is to ensure the McLaren Healthcare Institutional Review Board (MHC IRB) and Principal Investigators (PI) conducting research at all MHC subsidiary hospitals meet the responsibilities associated with initial review for human subject research.

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 at least one of the following:

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. Refer to Appendix I "Definitions"

4. Policy

4.1. The MHC IRB is responsible for reviewing and approving research which meets the criteria outlined in the federal regulations, state and local laws and institutional policies and procedures. This policy affects all MHC IRB Members, MHC IRB Chair or designee, MHC IRB Staff and Administrators and PIs.

4.2. If an activity requires review by a MHC IRB, research may not be conducted until the MHC IRB has reviewed and approved the research study and the researchers have received electronic notification to print the approval letter and IRB-approved consent form(s) (if applicable).

4.2.1. Refer to *MHC_RP0104 "Determination of Human Subject Research"* for the policies and procedures on when a research study must be submitted to the IRB.

4.2.2. Refer to *MHC_RP0105 "Exempt Review of Human Subject Research"* for policies and procedures on the submission and review of exempt research.

4.3. To apply for approval of a research study, the PI must submit an initial application for expedited or full board review to the IRB.

5. Procedure

5.1. **Materials Required for Submission:** To evaluate the research study, the IRB members must have the initial application and all applicable supporting documents. The following supporting documents must be included whenever applicable:

5.1.1. Protocol or Research Plan

5.1.2. Instrument(s) or measures (e.g. survey(s), interview questions, questionnaire(s), case report(s), protocol)

5.1.3. Consent form(s) or script(s) for verbal consent (unless requesting waiver of consent)

5.1.4. Assent form(s) (if applicable)

5.1.5. Recruitment material(s), including advertisement(s) (if applicable)

5.1.6. Translation of instrument(s) and consent(s) provided to non-English speaking subjects

5.1.7. Letter(s) of permission from school administration to allow researchers to conduct research in individual schools

5.1.8. Health Insurance Portability and Accountability Act authorization form(s)

5.1.9. Investigator brochure(s)

5.1.10. U.S. Department of Health and Human Services (DHHS) approved sample informed consent(s) and complete DHHS approved protocol(s) for DHHS sponsored multi-center clinical trials

5.1.11. Package insert(s) if using a U.S. Food and Drug Administration approved drug/device/diagnostic test

5.1.12. Any other pertinent documents related to the proposed research study

5.2. Mechanism(s) for Submission: For research studies submitted to the MHC IRB, the initial application must be completed and submitted using the e-Protocol IRB online system. The initial application must be completed in full; all questions must be completed.

5.3. Submission Processing: The eProtocol will assign the initial application an IRB number, which is sent to the PI for reference in future communication with the MHC IRB.

5.3.1. The IRB staff checks for completeness (e.g., appropriate documents attached) and appropriate level and category for review.

5.3.2. IRB staff verifies current training for researchers listed on the application. IRB staff will notify the PI of any individuals without current training.

5.3.3. IRB Staff verifies whether a signed assurance page is submitted. IRB Staff will notify the PI if signed assurance page is missing and will require a receipt of the signed document before the approval letter can be issued.

5.4. Change in Review Level: Investigators indicate on the e- application which level of review (expedited or full board) they believe the research study falls into, but the IRB staff, IRB Chair, or members may change the category if the selection is not appropriate.

5.5. Materials Provided to IRB Members: Assigned reviewer(s) may access the initial application and supporting documents associated with the research study (e.g., consent, instruments) via the eProtocol IRB online system. Any document(s) not accessible online will be provided to the reviewer(s) via e-mail. IRB members will receive all documents as referenced in Section 5.1.

5.6. How Review is Conducted: For review procedures, see *MHC_RP0106 "Expedited Review of Human Subjects Research"* or *MHC_RP0108 "Full Board Review of Human Subjects Research".*

5.7. IRB Member Considerations

5.7.1. When reviewing initial applications, the criteria for IRB approval must be met to approve or recommend approval of the application.

5.7.2. An IRB may not approve a research study for more than one year. Typically, the approval period is 364 days. However, in studies where any of the following conditions are likely to prevail, the IRB may require review more often than annually:

5.7.2.1. Phase I trials

5.7.2.2. Clinical studies where risks to health are considered life threatening

5.7.2.3. Behavioral studies where stress to subjects could threaten health

5.7.2.4. Studies where data monitoring and security issues may warrant more frequent review

5.7.2.5. Others as the IRB sees fit

5.7.3. If the IRB Chair, member, or staff recommends that a protocol requires review more often than annually, it will be referred to the convened IRB. When the IRB determines review is needed more often than annually, that determination will be communicated to the researchers in writing and documented in the minutes.

5.7.4. When the researcher is the Lead Researcher of a Multi-Site study, the IRB evaluates whether the management of information that is relevant to the protection of participants is adequate.

6. Responsibilities:

6.1. Principal Investigator:

6.1.1. Provide the IRB with all relevant information regarding the conduct of the research.

6.1.2. Complete and submit the initial review application via e-protocol electronic submission system;

6.1.3. Provide current human subject protection education certification;

6.1.4. Provide all key personnel current human subject protection training certification;

6.1.5. Provide all applicable documents including;

6.1.5.1. Full Protocol/thesis/dissertation/project summary;

6.1.5.2. Informed consent document and/or assent form;

6.1.5.3. If applicable, short Form Informed consent document;

6.1.5.4. Investigator's Brochure(s);

6.1.5.5. Supporting documentation for IND/IDE or HDE;

6.1.5.6. Product labeling, packet insert or other information;

6.1.5.7. Patient information brochure or other information;

6.1.5.8. Advertisements;

6.1.5.9. Recruitment materials;

6.1.5.10. Any relevant grant applications;

6.1.5.11. Documentation for dual enrollment to demonstrate the PI of other study has agreed to allow for dual enrollment;

6.1.5.12. Interview or focus group questions;

6.1.5.13. Questionnaires or survey instruments;

6.1.5.14. Data abstraction or collection form(s);

6.1.5.15. Approval letter(s) from appropriate review committees (if applicable);

6.1.5.16. If applicable, Conflict of Interest (COI) Management Plan

6.1.5.17. Any other relevant study documentation which will allow the IRB to review the science and ethics of the study and make a determination regarding approval.

6.1.6. Provide any additional information or clarification requested by the convened IRB, IRB Chairperson, or designee, in a timely fashion, to assist in the determination of approval

6.2. IRB Staff:

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

6.2.2. Conduct a pre-review of the application and supporting documents to identify non-scientific issues;

6.2.3. Ensure scientific and scholarly review occurred;

6.2.4. Ensure all applicable documents have been provided;

6.2.5. Submit concerns to the study team for incomplete submissions, clarifications or minor changes to allow for review by the fully convened IRB or the IRB Chair or their designee;

6.2.6. Confirm study type (e.g., exempt, expedited, full board) is appropriate as submitted by the PI and request changes in accordance with federal regulations, state and local laws and institutional policies and procedures;

6.2.7. When applicable, schedule full board initial review applications to the next available convened IRB meeting;

6.2.8. Assign full board initial review applications to a primary and secondary reviewer(s) (if needed);

6.2.9. Ensure IRB has adequate representation during the evaluation of the proposed human subjects research;

6.2.10. Assign expedited and exempt applications to the IRB Chair or qualified reviewer for review;

6.2.11. Ensure there is no outstanding comments in the e-protocol system;

6.2.12. Pre-reviews the response to IRB concerns submitted by the PI and assigns the appropriate reviewer (IRB member or Chair) for further review and approval.

7. References

7.1. 45 CFR 46

7.2. 21 CFR 56

7.3. MHC_RP0104 “Determination of Human Subject Research”

7.4. MHC_RP0105 “Exempt Review of Human Subject Research”

7.5. MHC_RP0106 “Expedited Review of Human Subjects Research”

7.6. MHC_RP0108 “Full Board Review of Human Subjects Research”

7.7. Appendix I “Definitions”

8. Previous Revisions: August 8, 2012, March 22, 2013

9. Supersedes Policy: *MHC_RP0111_Initial Review of Human Subject Research*

10. Approvals:

MHC Institutional Review Board initial review: February 17, 2012

MHC Institutional Review Board acknowledgement: November 20, 2015

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

Date