McLaren HEALTH CARE		**Policy Title:**	Review and Management of Conflict of Interest in Research
Effective Date:	March 14, 2013	**Policy Number:**	MHC_RP0202
Review Date:	April 14, 2016	**Section:**	Human Research Protections Program (HRPP)
Revised Date:	March 16, 2016	**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is:

1.1.1. To describe the functions and responsibilities of the Research Conflict of Interest Committee.

1.1.2. To set forth principles, policies, and procedures to identify financial conflicts of interest and to eliminate or mitigate the potential adverse effects of such conflicts on the rights and welfare of participants and the objectivity with which a research study is designed, conducted and/or reported.

1.1.3. To describe Investigator's responsibility to disclose any Financial Interests related to their institutional responsibilities.

2. Scope

2.1. This policy applies to all individuals involved in research projects that are:

2.1.1. Submitted to and overseen by the McLaren Health Care Corporate Institutional Review Board (MHC IRB).

2.1.2. Make use of the space, facilities, materials, personnel, or other resources of McLaren Health Care.

3. Definitions

3.1. Compensation: Compensation means payments made by an organization to the investigator or the institution exclusive of the costs of conducting the research during the time the investigator is carrying out the study and for 1 year following the completion of the study. This includes, but is not limited to:

3.1.1. Income from seminars, lectures, or teaching engagements.

3.1.2. Income from service on advisory committees or review panels.

3.1.3. Grants to fund ongoing research.

3.1.4. Compensation in the form of equipment.

3.1.5. Retainers for ongoing consultation.

3.2. **Conflict of Interest:** A conflict of interest (COI) occurs when any financial arrangement, situation, or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings.

3.3. **Conflicting Interest:** An individual involved in research review is automatically considered to have conflicting interest when the individual's immediate family have any of the following:

3.3.1. Involvement in the design, conduct, or reporting of the research.

3.3.2. Ownership interest, stock options, or other ownership interest related to the research of any value exclusive of interests in publicly-traded, diversified mutual funds.

3.3.3. Compensation related to the research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research.

3.3.4. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.

3.3.5. Any other reason for which the individual believes that he or she cannot be independent.

3.4. **Financial Interest Related to the Research:** Financial Interest Related to the Research means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.

3.4.1. **Significant Financial Interest:** Significant Financial Conflict of Interest in human subject research include:

3.4.2. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

3.4.3. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

3.4.4. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months

preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3.4.5. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.4.6. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3.4.7. No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.

3.5. 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)).

3.6. 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. For the purpose of this definition:

3.7. 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.

3.8. 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.

3.9. Immediate Family Member: those with whom a Covered Individual is related by blood, law (e.g., adoption or guardianship), or marriage and others with whom the Covered Individual resides including but not limited to the following: spouse, domestic partner, parent, child, stepchild, sibling, grandparent, grandchild, or in-laws.

3.10. Institutional Conflict of Interest arises in human subjects’ research when a financial interest of MHC may affect or appear to affect the design, conduct, reporting, review, or oversight of the human subjects’ research. Institutional Conflicts of Interest are of significant concern when they create the potential for inappropriate influence over a human subjects’ research project, particularly to the integrity of the research and the safety and care of subjects enrolled in the research. All forms of potential

Institutional Conflicts of Interest related to human subjects' research require disclosure, evaluation and either management or elimination under this Policy. Such interests include but are not limited to: Licensing, technology transfer, and patents, Investments of the organization; and gifts, when the donor has an interest in the research.

3.11. Institutional Official (IO): The IO is responsible for ensuring that the HRPP at the Organization has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects' research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance.

3.12. Institutional Review Board (IRB): An IRB is a board designated by the Organization to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The IRB may be assigned other review functions as deemed appropriate by the Organization.

3.13. Investigator: An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the that team.

3.14. Non-financial Conflict of Interest: Non-financial conflict of interest may exist when an individual serves dual roles, such as health care provider and investigator. Other interests such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts, other than his/her own, may potentially affect the design of, decisions made, and/or action taken surrounding a specific study.

3.15. Ownership Interest: Ownership interest means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a non-publicly traded corporation), or any equity interest in a publicly traded corporation during the time the investigator is carrying out the study and for 1 year following completion of the study.

3.16. Patent: A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

3.17. Principal Investigator: The MHC IRB recognized term for the individual the IRB holds ultimately responsible for the design, conduct, and evaluation of human subject research activities.

3.17.1. The responsibilities of the Principal Investigator encompass the DHHS and FDA regulatory requirements for conducting human subject research activities.

3.18. 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.

3.19. **Royalty:** A royalty is compensation for an invention.

4. Policy

4.1. McLaren Health Care Corporation (MHC) is committed to conducting all research activities in accordance with the highest standards of integrity and ethics. It is MHC's policy to preserve public trust in the integrity and quality of research at the organization by minimizing actual or perceived conflict to interest in the conduct of research.

4.2. This policy meets the requirements of and responsibilities for compliance with:

4.2.1. Regulations pertaining to federally-funded research.

4.2.2. Accreditation standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

4.2.3. FDA requirements for Financial Disclosure by investigators.

4.3. The Research Conflict of Interest Committee is given responsibility, on behalf of the organization, to review Financial Interest disclosures, identify Financial Conflicts of Interest, and create Management Plans where appropriate.

4.3.1. This Committee functions as a subcommittee of the Corporate Conflict of Interest Committee.

4.3.2. This Committee is comprised of the following representatives: Corporate Director of Human Research Protection Program, Corporate Compliance Officer, subsidiary compliance representative(s), IRB representative(s), Research Nurse representative.

4.4. An individual who is involved in the oversight, design, conduct, and/or reporting of research is required to disclose to McLaren all Financial Interests (AND those of his/her spouse and dependent children) that are related to the institutional responsibilities.

4.5. An individual who is involved in the oversight, design, conduct, and/or reporting of research must adhere to this policy and management plan issued by the Research Conflict of Interest Committee.

4.5.1. The Research Conflict of Interest Committee is given the responsibility, on behalf of the organization, to review Financial Interest Disclosures, identify Financial Conflicts of Interest and create a Management Plans where appropriate.

4.5.2. These actions may involve referral to appropriate advisors outside the facility or obtaining advice from the McLaren Health Care's legal counsel.

4.6. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations.

4.7. After reviewing a significant financial interest in research, the Research Conflict of Interest Committee will communicate its conclusions, along with any management arrangements to be imposed, to the MHC IRB.

4.8. All relevant conflicts will be disclosed to research participants in a form to be determined by the MHC IRB.

5. Procedure

5.1. Disclosure of Investigator COI

5.1.1. Each Investigator will be prompted annually to disclose Financial Interests in accordance with MHC's annual conflict of interest disclosure process and as described in *MHC_CC0137_Provider Conflict of Interest and Business Integrity* policy.

5.1.2. The Investigator will also be prompted to disclose Financial Interests when the Investigator submits a protocol to the MHC IRB.

5.1.2.1. The IRB application asks protocol-specific questions regarding conflict of interest for the investigators, personnel, and their immediate families.

5.1.3. All disclosures will be made electronically (to the extent possible).

5.2. Committee Review of Financial Interest Disclosure

5.2.1. All Financial Interest disclosures will be made available to the Committee for review, in accordance with the requirements described below:

5.2.1.1. For each new project, the Committee will review all Financial Interest disclosures before the project begins. Specifically, for PHS-funded research, the Committee will review all Financial Interest disclosures before the expenditure of PHS funds.

5.2.2. For each Financial Interest, the Committee will determine:

5.2.2.1. Is the Financial Interest *related to* the research?

5.2.2.1.1. Financial Interest is *related to* the research if the Committee determines that the Financial Interest could be affected by the research.

5.2.2.1.2. Is in an entity whose financial interest could be affected by the research.

5.2.2.2. If the Financial Interest is *related to* the research, does it constitute a Financial Conflict of Interest?

5.2.2.2.1. A Financial Conflict of Interest exists if the Committee determines that the interest could *directly and significantly* affect the design, conduct, or

reporting of the research. In making this determination, the Committee will consider—and may ask the Investigator to provide—additional information related to the following factors:

5.2.2.2.1.1. Nature of the interest (e.g., consulting, equity interest, speaking fee, travel, etc.).

5.2.2.2.1.2. Value or amount of the Financial Interest.

5.2.2.2.1.3. The Investigator's role in the project, e.g., consenting/enrolling patients, data analysis, publication & reporting, etc.

5.2.2.2.1.4. Risk profile of the project (i.e., to project participants, to the organization, etc.).

5.2.2.2.1.5. Additional information regarding the relationship of the Financial Interest to the particular research project or program.

5.2.3. The Committee will contact the Investigator to provide additional information, if necessary, to assist with the Committee's review and determination.

5.2.4. The Committee may also seek additional information from MHC, to determine whether the research could create any new intellectual property rights.

5.2.5. If the Committee determines that an FCOI exists, the Committee will develop a Management Plan described in Section 5.4.

5.2.6. If the Committee determines that an FCOI exists with respect to a PHS-funded research project, MHC Human Research Protections Program will report certain information to PHS, as required by Federal Regulations.

5.3. Management Plan of COI

5.3.1. A Management Plan related to an FCOI in research will be developed by the Committee and implemented before the research project begins.

5.3.2. A possible Management Plan may include, but is not necessarily limited to, the following:

5.3.2.1. Public disclosure of the FCOI (e.g., when presenting or publishing);

5.3.2.2. Disclosure of the conflict to institutional committees, research or program participants (e.g., through consent documents), and data safety monitoring boards;

5.3.2.3. Modification of the research protocol;

5.3.2.4. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research (e.g., cannot conduct data analysis, restricted from recruiting human subjects and/or conducting the informed consent process);

5.3.2.5. Reduction or elimination of the Financial Interest (e.g., divestiture or sale of an equity interest);

5.3.2.6. Severance of relationship(s) that create the Financial Interest;

5.3.2.7. Appointment of an independent monitor capable of taking measures (e.g., review of data) to protect the design, conduct and reporting of the research against bias resulting from the FCOI; and/or

5.3.2.8. Appointment of an independent monitor to review the consent process or the appropriateness of clinical care provided to research/program participants, if applicable.

5.3.3. In determining the Management Plan for an FCOI related to human subject research, the Committee will consider, among other things, whether the Investigator will be allowed to participate in the following activities:

5.3.3.1. Subject recruitment;

5.3.3.2. Screening for inclusion/exclusion criteria;

5.3.3.3. The consent process;

5.3.3.4. Clinical evaluation of subjects during the research;

5.3.3.5. Reporting of data; and/or

5.3.3.6. Conducting data analysis.

5.3.4. In general, the Committee will permit the Investigator to participate in the foregoing activities only if *compelling circumstances* justify such participation.

5.3.5. Compelling circumstances may exist when, for example, the Investigator is the only individual at MHC with the expertise necessary to conduct certain study-related activities.

5.3.6. The Management Plan for an FCOI related to human subject research will be reviewed by the MHC IRB before the research project begins.

5.3.7. The MHC IRB may:

5.3.7.1. Approve with the Management Plan;

5.3.7.2. Make additional recommendations to the Committee with respect to the Management Plan; or

5.3.7.3. Determine that the FCOI cannot be managed sufficiently to protect the rights, safety and welfare of human subjects, in which case the MHC IRB and the Committee will determine appropriate steps to be taken, e.g., the research may not be conducted at MHC and its subsidiary hospitals, the Investigator may not be involved in the research study, or the Investigator must eliminate his/her FCOI before the research can take place at MHC and its subsidiary hospitals.

5.3.8. The Management Plan may specify the steps to be taken to monitor and verify the Investigator's compliance with the Plan (**Section 5.5.1, Monitoring of Compliance** below).

5.3.9. The Management Plan will be documented and must be reviewed and acknowledged by the Investigator.

5.4. New Disclosures and Interim Management Plans

5.4.1. Investigators and research staff must disclose any new significant financial interests within 30 days of acquisition or discovery.

5.4.2. If an Investigator who is new to a research project discloses a Financial Interest OR if an existing Investigator discloses a new Financial Interest, the Committee will, within thirty (30) days of the disclosure, review the Financial Interest and determine whether an FCOI exists; if so, the Committee will develop and implement, on at least an interim basis, a Management Plan.

5.4.3. In the case of PHS-funded research, the Committee will also determine whether reporting to PHS is required.

5.4.4. Depending on the nature of the Financial Interest, the Committee may determine that additional interim measures are necessary between the date of disclosure and completion of the Committee's review.

5.4.5. If a Financial Interest was not disclosed by an Investigator or, for whatever reason, was not previously reviewed by the Committee, the Committee will, within thirty (30) days of the Committee's receipt of the disclosure, review the Financial Interest and related information and determine whether an FCOI exists. If so, the Committee will develop and implement, on at least an interim basis, a Management Plan. In the case of PHS-funded research, the Committee will also determine whether reporting to PHS is required.

5.5. Compliance

5.5.1. Monitoring of Compliance

5.5.1.1. If the Committee issues a Management Plan, the Committee will monitor compliance with the Plan until its completion, or until the completion of the research project to which the Investigator's FCOI relates.

5.5.1.2. The Committee's monitoring activities may include annual or periodic Investigator self-certification of compliance; review of Investigator publications and presentations prior to issuance; or in-person meetings with the Investigator to review steps taken to implement the Plan.

5.5.2. Retrospective Review

5.5.2.1. Whenever there is noncompliance with the Management Plan, the Committee will conduct a retrospective review to determine whether, during the period of noncompliance, the research project was biased in its design, conduct and/or reporting.

5.5.2.2. Noncompliance may include, but is not limited to, failure to timely identification or management of an FCOI; failure to disclose a Financial Interest that the Committee determines to be an FCOI; or failure to review or manage an FCOI.

5.5.2.3. The retrospective review will be completed within ninety (90) days of the Committee's determination of noncompliance.

5.5.2.4. The Committee will determine the methodology for the review process, as well as the composition of the review panel and the documents to be reviewed.

5.5.2.5. The Committee will document the results of the review

5.5.3. Corrective Action

5.5.3.1. Depending on the nature of the FCOI, the Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the project between the date that the FCOI or the Investigator's noncompliance is determined, and the completion of the Committee's retrospective review.

5.5.3.2. Based on the results of the retrospective review, the Committee will determine what action(s) will be taken to manage the FCOI going forward.

5.5.3.3. If the Investigator failed to comply with the requirements of a Management Plan, the Committee may also recommend further corrective action based on applicable MHC policies and procedures (e.g., MHC IRB/Human Research Protection Program, Human Resources, Medical Staff, Corporate Compliance, etc.).

5.6. Reporting Requirements for PHS-funded research ONLY

5.6.1. If the Committee determines that an FCOI exists, and it is related to PHS-funded research, McLaren's HRPP will report such FCOI to the PHS awarding component (e.g., National Institutes of Health) prior to the expenditure of any funds for the award (i.e., the "initial report").

5.6.2. For all new FCOI and all FCOI that are identified subsequent to the initial report (e.g., upon participation of an Investigator who is new to the research project, or identification of an FCOI not previously disclosed), the McLaren HRPP will make the FCOI report to the PHS awarding component within sixty (60) days of identification or disclosure of the Financial Interest.

5.6.3. Each FCOI report will include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the Management Plan.

5.6.4. During the period of the PHS award, the McLaren HRPP will also submit an annual FCOI update. The annual update will include any changes in information regarding the previously disclosed Financial Interest (i.e. updated value of a previously disclosed equity interest) and any changes to the Management Plan.

5.6.5. Following the retrospective review, as described in Section 5.5.2. of this policy, the McLaren HRPP will submit an update to any previously submitted FCOI report, when/if applicable

5.7. Public Accessibility of Information for PHS-funded research ONLY

5.7.1. Information related to the FCOI of Senior Personnel for a PHS funded research project will be publicly accessible, so long as the Financial Interest is held by the Senior Personnel.

5.7.2. The McLaren HRPP will make this information available via a written response to any requestor within 5 business days of the request.

5.7.3. The written response will include, at a minimum, the following:

5.7.3.1. Project number;

5.7.3.2. Name of the Investigator with the FCOI;

5.7.3.3. Name of the entity with which the Investigator has the FCOI;

5.7.3.4. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

5.7.3.5. Value of the Financial Interest.

5.8. Committee Documents and Record Retention

5.8.1. All Committee meetings and communications will be recorded in writing.

5.8.2. All decisions regarding review of Financial Disclosures and determinations of FCOI and Management Plans will also be recorded in writing.

5.8.3. All such Committee documents will be retained by MHC HRPP, in accordance with *MHC_RP0114_IRB Documentation and Research Record Retention Policy*.

5.9. Education and Training

5.9.1. All Investigators required to adhere to this policy must complete Financial Conflict of Interest training. Training will include the following topics:

5.9.1.1. Financial Conflict of Interest: Overview, Investigator Responsibilities and COI Rules;

5.9.1.2. Institutional Responsibility as they affect Investigator;

5.9.1.3. Conflict of Commitment, Conscience, and Institutional Conflict of Interest;

5.9.2. Training will be required at least every 4-years and immediately in the event of any of the following:

5.9.2.1. McLaren Health Care FCOI policies change in a manner that affects Investigator disclosure/compliance requirements.

5.9.2.2. An Investigator is new to McLaren Health Care or its subsidiary organizations.

5.9.2.3. An Investigator is found to be non-compliant with this policy or a specific Management Plan.

5.9.3. If an Investigator is participating in PHS-funded research, he/she must – at a minimum – complete FCOI training prior to engaging in such research.

6. Reference:

6.1. 21 CFR Part 54

6.2. 45 CFR Part 50, Subpart F

6.3. 45 CFR Part 94

6.4. Public Health Service (PHS) Regulations

6.5. *MHC_RP0114_IRB Documentation and Research Record Retention*

6.6. *MHC_CC0137_Provider Conflict of Interest and Business Integrity*

7. Previous Revisions: **March 24, 2013, February 15, 2016**

8. Supersedes Policy: **Any subsidiary research conflict of interest policies.**

9. Approvals:

Research Conflict of Interest Committee initial approval: March 14, 2013
February 26, 2016
April 14, 2016

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

Date