McLaren HEALTH CARE		**Policy Title:**	Education and Training In Human Subject Research
Effective Date:	November 12, 2015	**Policy Number:**	MHC_RP0306
Review Date:	November 12, 2015	**Section:**	Human Research Protections Program
Revised Date:		**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy outlines the process for keeping HRPP staff, IRB members, investigators and their research staff educated regarding protecting the rights, safety, and privacy of human participants in accordance with federal regulations and MHC HRPP policy.

2. Scope

2.1. This policy applies to:

2.1.1. All members of the McLaren Health Care research community and its subsidiaries who engage in research with human participants. This includes faculty, post-doctoral appointees, residents, fellows, students (graduate and undergraduate) and research staff.

2.1.2. All individuals engaged in human subject research overseen by McLaren Heath Care Human Research Protections Program regardless of the research-funding source.

2.1.3. Non-MHC employees serving as consultants who contribute to the scientific development or execution of research in a substantive way whether or not they are compensated for their contributions.

3. Definitions

3.1. CITI – Collaborative Institutional Training Initiative (CITI Program): a web-based training program in human research subjects' protections that offer research education courses covering key regulatory and ethical areas.

3.2. Refer to Appendix 1 "Definitions" for additional definitions.

4. Policy

4.1. McLaren Health Care Corporation is dedicated to excellence and integrity in research. One way that MHC fosters excellence and integrity is to ensure that all individuals responsible for the design, conduct, and reporting of research involving human participants receive and maintain the training, education, and resources necessary to fulfill the obligation of ethical conduct of the research.

4.2. Because the IRB, Investigator, and research staff assume different roles and responsibilities in the conduct of human subject research, educational/training requirements will be established accordingly.

4.3. All members of the research community and key personnel engaged in the design & review of research, interaction or interventions with human subjects, and access to research subjects PHI will complete mandatory ***Human Subjects Research Training*** through CITI every three years. In addition:

4.3.1. All research investigators must complete mandatory ***Conflict-of-Interest Training*** through CITI every four years.

4.3.2. All new clinical research coordinators must complete the webinar series, ***"Seven Habits of a Highly Effective Research Coordinator"*** within 6 months of employment.

4.4. Individuals whose required *Human Subjects Research Training* has expired will not be able to engage in any research activities until training is complete.

4.5. The *Human Subjects Research Training* (CITI) requirement also applies to investigators and research team members conducting studies involving human subjects that are exempt from IRB review, as well as those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent.

4.6. The IRB has the authority to suspend or withhold approval from any project that involves study personnel who fail to meet mandatory *Human Subjects' Research Training* (CITI) requirements.

4.7. The Corporate Director of the HRPP will accept training provided by another affiliate as long as it meets the MHC training requirement. The Corporate Director of HRPP will review other training upon request to determine whether it meets the requirements of this policy. If other training is accepted by the HRPP, the individual will be required to complete MHC-required CITI training at the time of the next renewal.

4.8. Individuals whose work on human subject research protocols is limited, might be exempt from human subject training, but not inclusive to the following:

4.8.1. Chart/medical records department.

4.8.2. Secretarial and support staff.
4.8.3. Non-identifiable data analysis or statistical support.
4.8.4. Individuals not accessing or viewing identifiable human subjects PHI.
4.8.5. Individuals who provide services to the primary investigator that is inherent to their job role/description and typically performed for non-research purposes, but have no other role or responsibility for the research study [e.g. hospital lab drawing blood, pharmacist dispensing drug to the research staff, oncology certified RN administering the oncology study drug, ultrasound technologist performing echocardiogram study procedure].

5. Procedures

5.1. Accessing CITI

5.1.1. To start the CITI course, users will log onto the training site (http://www.citiprogram.org), register as a user, and select McLaren as their affiliate institution. (If already affiliated with another institution, individuals should also affiliate themselves with McLaren)

5.1.1.1. When requested, the HRPP Coordinator will assist users with access to CITI.

5.1.2. CITI Course Assignment:

5.1.2.1. Investigator and Research Staff will complete Biomedical and/or Behavioral/Social Course, as applicable.
5.1.2.2. IRB members and HRPP Staff will complete IRB Members Course.
5.1.2.3. Investigators will also complete the Conflicts of Interest (COI) Course.

5.1.3. Verification of Completion of CITI

5.1.3.1. The HRPP Coordinator is assigned the role of CITI Administrator for McLaren.
5.1.3.2. The Administrator has access to the training completion records for all McLaren users and uploads updates into eProtocol on a regular basis.

5.1.4. Training and Education Requirements

5.1.4.1. While new research protocols and applications for continuing review will be accepted and reviewed if the Principal Investigator holds a current certification of *Human Subjects Research Training* (CITI), all co-investigators and members of the research team are required to complete the initial education requirement before conducting any research related procedures.

5.2. Required Clinical Research Coordinators (CRC) Education [CRC may also be referred to as protocol coordinator, research nurse, or research associate, medical assistant assigned to role of research coordinator]

5.2.1. MCRI Research Managers will notify the Education and Quality Improvement (EQuIP) office of newly hired research coordinators.
5.2.2. The QI and Education Specialist will notify McLaren Leadership Development office to assign research coordinator to the 7 Habits of Highly Effective Coordinators series at McLaren University with a due date of 6 months from date of hire.
5.2.3. New research coordinators will use their McLaren Health Care issued password and user ID to access McLaren University.
5.2.4. Verification of Completion - The EQuIP office will monitor and record completion of webinars through automatic electronic report notification from McLaren University.
5.2.5. The EQuIP Office will notify the Corporate Director of HRPP of any research coordinator who has not completed the assignment.

5.3. Continuing Education of Investigators and Research Staff

5.3.1. Human Subjects Research Training

5.3.1.1. All CITI users affiliated with McLaren Health Care will receive a 90, 60, and 30 day email reminder from CITI to complete the refresher training for continuing education every three years.
5.3.1.2. At that time, individuals are required to complete 9 modules of their choice.
5.3.1.3. New research protocols and submission for continuing review will not receive final approval until the PI have submitted a satisfactory evidence of continuing education.

5.3.2. Conflict Of Interest Training

5.3.2.1. All Investigators will receive a 90, 60, and 30 day email reminder from CITI to complete the refresher for Conflict of Interest Training every four years.
5.3.2.2. New research protocols and submission for continuing review will not receive final approval until the PI has submitted satisfactory evidence of completion of COI training.

5.3.3. Brown Bag Sessions

5.3.3.1. Live 45-60 minute sessions offered throughout the year will be posted on McLaren HRPP website.
5.3.3.2. Attendees of live sessions will receive research credit in the ratio of 1 credit per 60 minutes.

5.3.4. Customized Education

5.3.4.1. Tailor-made presentation or webinars on topics requested by anyone in the research community.
5.3.4.2. One-on-one or group training on eProtocol.

5.3.4.3. Request can be made by email, phone, or via online request form available on McLaren HRPP website.

5.3.5. Quality Improvement Initiatives

5.3.5.1. Educational programs or change in HRPP processes to improve the quality of research conduct will be created and instituted due to but not limited to:

5.3.5.1.1. Problems or recurrent non-compliance identified in the research community.

5.3.5.1.2. Disseminate information on changes in institutional policies, regulations, or laws.

5.3.5.1.3. Educate select groups [i.e. new resident orientation].

5.3.6. McLaren University

5.3.6.1. EQuIP office will post select webinars to McLaren University.

5.3.6.2. A list of archived webinars will be listed on the HRPP website.

5.3.7. HRPP Website

5.3.7.1. Website will include HRPP policies, the HRPP Manual, HRPP Investigator Manual, link to archived webinars, and numerous resources.

5.3.7.2. HRPP Coordinator will update HRPP website as needed to keep information current.

5.3.8. Newsletters

5.3.8.1. HRPP coordinator will distribute quarterly newsletter focused on protection of human subjects to research community.

5.3.8.2. QI and Education Specialist will submit quarterly articles to MHC Corporate Compliance Office for publication on research compliance and regulatory news.

5.4. IRB Education:

5.4.1. Required New IRB Member Training

5.4.1.1. IRB Member Course through CITI.

5.4.1.2. Meeting with the HRPP Director or IRB Staff for an informal orientation session. At the session, the new member will be given an IRB Handbook (binder) that includes:

5.4.1.2.1. Belmont Report and 45 CFR Part 46 (Federal regulations relevant to the IRB).

5.4.1.2.2. IRB Roster and meeting dates; HRPP Staff Contact List.

5.4.1.2.3. Instructions for using e-Protocol and Reviewer Checklists.

5.4.1.3. New IRB members are required to complete the initial education requirement for IRB members before they may serve as Primary Reviewer.

5.4.1.4. IRB administrative staff will train IRB members on the SOPs, checklists, and worksheets as applicable.

5.4.2. Continuing Education of IRB Members

5.4.2.1. IRB Members are required to complete CITI refresher course and will receive a 90, 60, and 30 day email reminder from CITI to complete the refresher training for continuing education every three years.

5.4.2.1.1. Members are required to complete 9 modules of their choice.

5.4.2.2. Additional training might include, but not limited to:

5.4.2.2.1. IRB Ed session during the convened IRB board meeting, conducted by either the EQuIP office, Corporate Director of HRPP, or designee.

5.4.2.3. Updates on new/revised HRPP policies, process procedures, forms or reviewer checklist.

5.4.2.4. Attendance at the annual PRIM&R Conference or the biannual Michigan Research Ethics Conference [as funds allow].

5.4.2.5. Unlimited access to the IRB office resource library [books, regulatory guides, webinars on DVD, webinars on McLaren University].

5.4.2.6. Updates or new information that impact the Human Research Protections Program including emerging/changes in research regulations or laws and ethical and scientific issues.

5.4.2.7. CITI Refresher modules.

5.4.2.8. Monthly HRPP meetings.

5.4.2.9. Invitation to EQuIP Brown Bag sessions.

5.4.2.10. Newsletters.

6. Responsibilities

6.1. Corporate HRPP Director: The Director determines which continuing education activities are mandatory for IRB members and staff in a given year and tracks whether each individual has satisfied the requirements. The Director will maintain the HRPP policies and procedures.

6.2. Institutional Official: The IO will provide support to send as many members of the IRB as possible to attend the annual PRIM&R/ARENA conference or regional OHRP conferences on human research protections.

6.3. Primary Investigator: It is the responsibility of investigators to ensure them and their staff to maintain current certification in human research protection education while engaged in human subjects research.

6.4. HRPP Professional Staff: The HRPP Office Professional Staff will be expected to become Certified IRB Professional (CIP) within two years of employment.

6.5. EQuIP Office Staff: The QI and Education Specialist will provide or arrange expert speaker for continuing education.

6.6. HRPP Office:

6.6.1. HRPP Staff will update the HRPP website with all of HRPP policies, guidances, links to federal regulations, or forms communicated by electronic announcement and newsletter to research community.

6.6.2. Monitor mandatory training and education.

6.6.3. Maintain extensive and current knowledge of all aspects of human subjects' protections.

7. References

7.1. OHRP Guidance on Engagement of Institutions in Human Subjects Research October 16, 2008.

7.2. HRPP Manual

8. Previous Revisions: None

9. Supersedes Policy: None

10. Approvals:

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Michael McKenna, MD Date
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