McLaren HEALTH CARE		Policy Title:	Education and Training in Human Subject Research
Effective Date:	November 12, 2015	Policy Number:	MHC_RP0306
Review Date:	August 18, 2020	Section:	Research Integrity
Revised Date:	March 22, 2024	Oversight Level:	Corporate
Administrative Responsibility:	Corporate Manager of Research Institutional Official, HRPP		

1. Purpose

The purpose of this policy outlines the process and requirements for keeping McLaren Health Care (MHC) Human Research Protection Program (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 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 the 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 they are compensated for their contributions.

3. Definitions

3.1. Refer to Appendix I *"Definitions"*

4. Policy

4.1. McLaren Health Care is dedicated to excellence and integrity in research. MHC fosters excellence and integrity in research by ensuring 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.

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

Human Subject Research Training

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 Collaborative Institutional Review Board Training Initiative (CITI) every three years.

4.4. It is the responsibility of the Principal Investigator to ensure that all members of the research team have current CITI Human Subjects Research Training. Individuals who are required training has expired will not be able to engage in any research activities until this training is current.

4.5. Additionally, the CITI Human Subjects Research Training 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. CITI Human Subject Research training courses taken under a non-McLaren Health Care institution may be accepted. However, it is required to be affiliated with McLaren Health Care on the CITI website. This will ensure all McLaren required courses have been completed. If appropriate, CITI will ask the individual to complete any modules required by McLaren Health Care that were not required by the previous institution.

Additional Training

4.7. In addition to human subject research training, there are additional requirements:

4.7.1. All research Investigators and Academic/Faculty Advisors must complete mandatory **Conflict-of-Interest Training** through CITI every four years.

4.7.2. **Good Clinical Practice (GCP)** training is required every three years if the clinical trial is required to adhere to ICH-GCP E6 guidelines.

4.7.2.1. If the clinical trial is required to adhere to ICH-GCP E6 guidelines, it is the responsibility of the Principal Investigator to ensure that all members of the research team have up to date **GCP training**. Individuals who are required GCP has expired will not be able to engage in any research activities until training is complete.

4.7.2.2. McLaren Health Care IRB will accept GCP training from the following:

4.7.2.2.1. NIH https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

4.7.2.2.2. Industry sponsors (e.g., organizations, etc. registered with TransCelerate Biopharma Inc.'s GCP Training Mutual Recognition program)

4.7.2.2.3. Federal sponsors (e.g., NIH's NIAID GCP or National Drug Abuse Treatment Clinical Trials Network GCP)

4.7.3. Investigators conducting community engaged research must complete the CITI **Community-Engaged and Community-Based Participatory Research course**. It is the responsibility of the Principal Investigator to ensure that all members of the research team have completed the CITI Community-Engaged and Community-Based Participatory Research prior to engaging in any research activities.

4.8. The IRB has the authority to suspend or withhold approval from *any project* that involves study personnel who fail to meet mandatory training requirements.

4.9. Individuals whose work on human subject research protocols is limited, might be exempt from human subject research training, such as:

4.9.1. Chart/medical records department.

4.9.2. Secretarial and support staff.

4.9.3. Non-identifiable data analysis or statistical support.

4.9.4. Individuals not accessing or viewing identifiable human subjects PHI.

4.9.5. 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. Procedure

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 Research Integrity leadership will assist users with access to CITI.

5.1.2. CITI Course Assignment:

5.1.2.1. All Investigator and Research Staff will complete Biomedical and/or Behavioral/Social Basic Human Subject Research Course, as applicable.

5.1.2.2. As required Investigator and Research Staff will complete additional training:

5.1.2.2.1. Conflict-of-Interest Training through CITI

5.1.2.2.2. Basic Good Clinical Practice (GCP) training, four options:

5.1.2.2.2.1.1.1. Basic Good Clinical Practice (GCP) training (FDA Focus)

5.1.2.2.2.1.1.2. Basic Good Clinical Practice (GCP) training (Social-Behavioral)

5.1.2.2.2.1.1.3. GCP for Clinical Investigations of Devices (formerly called GCP Course for Clinical Trials Involving Investigational Medical Devices (international focus)

5.1.2.2.2.1.1.4. GCP for Clinical Investigations of Drugs and Biologics (ICH) (formerly called GCP for Clinical Trials Involving Investigational Drugs (international / ICH focus)

5.1.2.2.3. Community-Engaged and Community-Based Participatory Research

5.1.2.3. IRB members and HRPP Staff will complete the IRB Members Course.

5.1.2.4. Investigators will also complete the Conflicts of Interest (COI) Course.

5.1.3. Verification of Completion of CITI

5.1.3.1. The Research Integrity department administrative assistant and IRB staff are 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.

5.1.3.3. The IRB software, iRIS, monitors current certificate status of users training completed in CITI.

5.1.3.4. IRB staff will verify CITI training completion via CITI website if necessary.

5.2. Principal Investigator Training and IRB Approvals

5.2.1.1. While applications for new research protocols, modifications and continuing review will be accepted and reviewed:

5.2.1.1.1. Protocol submissions for new research protocols, modifications, and continuing review will not receive final approval until the Principal Investigator holds a current certification of CITI Human Subjects Research Training and/or GCP training if applicable.

5.2.1.1.2. All sub-investigators and members of the research team are required to complete the initial education requirement before conducting any research related procedures.

5.3. Renewal of Training and Continuing Education

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 nine modules of their choice.

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. Good Clinical Practice Training

5.3.3.1. All Investigators will receive a 90-, 60-, and 30-day email reminder from CITI to complete the refresher for GCP Training every four years.

5.3.4. Brown Bag Sessions

5.3.4.1. The research community will be notified of live sessions offered throughout the year via email and iRIS notifications.

5.3.4.2. Attendees of live sessions will receive research credit and CE/CME credit for attendance.

5.3.5. Customized Education

5.3.5.1. Tailor-made presentations or webinars on topics requested by anyone in the research community may be accommodated.

5.3.5.2. One-on-one or group training on the IRB electronic application system is available.

5.3.5.3. Requests can be made by email, phone, or via an online request form available on McLaren HRPP website.

5.4. Quality Improvement Initiatives

5.4.1.1. Educational programs or changes in HRPP processes to improve the quality of research conduct will be created and instituted, as outlined below.

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

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

5.4.1.1.3. Educate select groups [i.e., new resident orientation].

5.4.1.1.4. Other topics as found to be needed.

5.5. McLaren University

5.5.1.1. EQuIP will post select webinars to McLaren University.

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

5.6. HRPP Website

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

5.6.1.2. Research Integrity administrative assistant will update the HRPP website as needed to keep information current.

5.7. Research Matters Newsletter

5.7.1.1. QI and Education Specialist will submit quarterly articles to Research Matters Newsletter focused on protection of human subjects. The newsletter is available by email to the research community and is listed on the Research website.

5.7.1.2. QI and Education Specialist or designee may contribute to the quarterly MHC Corporate Compliance Newsletter for publication of articles on research compliance and regulatory news.

5.8. IRB Education

5.8.1. Required New IRB Member Training

5.8.1.1. IRB Member Course through CITI.

5.8.1.2. Meeting with the Corporate Manager of Research Integrity or designee and IRB Staff for an informal orientation session. At the session, the new member will be given an IRB Handbook (binder) that includes:

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

5.8.1.2.2. IRB Roster and meeting dates; Staff Contact List.

5.8.1.2.3. Instructions for using IRB electronic application system and Reviewer Checklists.

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

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

5.8.2. Continuing Education of IRB Members

5.8.2.1. 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.

5.8.2.1.1. Members are required to complete nine modules of their choice.

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

5.8.2.2.1. IRB Ed session during the convened IRB board meeting, conducted by either the EQuIP office, Corporate Manager of Research Integrity, or designee.

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

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

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

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

5.8.2.7. CITI Refresher modules.

5.8.2.8. Educational events at convened meetings.

5.8.2.9. Invitation to EQuIP Brown Bag sessions.

5.8.2.10. Newsletters.

6. Responsibilities

6.1. Corporate Manager of Research Integrity: The Manager determines which continuing education activities are mandatory for IRB members, staff, and the research community each year and tracks whether everyone has satisfied the requirements. The Manager will maintain the HRPP policies and procedures.

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

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

6.4. Research Integrity Professional Staff: The Research Integrity department Professional Staff will be expected to become Certified IRB Professionals (CIP) within two years of employment.

6.5. EQuIP Staff: The QI and Education Specialist will provide or arrange expert speakers for continuing education, as applicable.

6.6. Research Integrity Department:

6.6.1. Staff will update the website with all policies, guidance, links to federal regulations, or forms communicated by electronic announcement and newsletter to research the 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: 11/28/21, 7/14/21, 3/25/23, 7/14/23

9. Supersedes Policy: None

10. Approvals:

Signature on File *3/22/2024*

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