HEALTH CARE

Human Research Protections Program Manual

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1 Purpose

The purpose of this manual is to provide an overview of this Organization's structure regarding the conduct, administration, and evaluation of the McLaren Health Care (MHC) Human Research Protections Program (HRPP). Standard Operating Policies and Procedures are created for day-to-day operations of the HRPP.

This HRPP Manual and all the Standard Operating Procedures are made available to all MHC investigators and research staff and are posted on the HRPP website (www.mclaren.org).

2 Executive Summary

McLaren Health Care, headquartered in Grand Blanc, Michigan, is a $6 billion (budget FY21), fully integrated health care delivery system committed to quality, evidence-based patient care and cost efficiency. The McLaren system includes 15 hospitals in Michigan and Ohio, ambulatory surgery centers, imaging centers, a 490-member employed primary and specialty care physician network, commercial and Medicaid HMOs covering approximately 640,000 lives in Michigan and Indiana, home health, infusion and hospice providers, pharmacy services, a clinical laboratory network and a wholly owned medical malpractice insurance company. McLaren operates Michigan's largest network of cancer centers and providers, anchored by the Karmanos Cancer Institute, one of only 51 National Cancer Institute-designated comprehensive cancer centers in the U.S.

As part of its Graduate Medical Education (GME) program, McLaren maintains academic affiliations with medical schools at Wayne State University, Michigan State University and Central Medical University. McLaren's six (6) GME campuses offer twenty-seven residencies and eight (8) fellowship programs that train over 650 future physicians annually. All GME programs at McLaren are overseen and managed centrally by the Department of Academic Affairs.

Until January 2012, McLaren hospitals conducted human research under their local Institutional Review Boards (IRBs) Some of the same projects were conducted at more than one hospital and were reviewed by more than one IRB. To reduce the burden of duplicate reviews and to save corporation time and resources, it was decided to develop a centralized IRB to review and make decisions concerning all human research conducted at McLaren Healthcare Corporation (MHC) through its subsidiaries. Moreover, as part of its strategic plan, McLaren Healthcare Corporation decided to develop a centralized Human Research Protection Program (HRPP) to ensure the protection of human subjects participating in research.

MHC is committed to protecting the rights and welfare of subjects in Human Research. McLaren's Human Research Protection Program is a centralized system to ensure the protection of the rights and welfare of subjects and compliance with the highest legal and ethical standards in Human Research. The McLaren's HRPP includes specific review and oversight of research activities involving human subjects; provision and development of training and policies for researchers; conduct of quality improvement and assurance activities; and the support of the compliance responsibilities of the covered institutions and investigators. The McLaren's HRPP is also committed to education of and outreach to persons interested in research.

3 Mission

MHC fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of MHC and its subsidiary hospitals. In the review and conduct of research, actions by the Organization will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as the *Belmont Report*). The actions of Organization will also conform to all applicable federal, state, and local laws and regulations. In order to fulfill this policy, the Organization has established a Human Research Protections Program (HRPP).

The mission of the HRPP is:

- To safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- To provide timely and high quality education, review and monitoring of human research projects; and
- To facilitate excellence in human subjects research.

The MHC HRPP is a multi-tiered program involving the Institutional Official (IO) of Research, Executive Management, McLaren Center for Research and Innovation (MCRI), the IRB, and investigators and research support staff. It is a system-wide program that ensures the safe and ethical conduct of human research participants by all investigators including physicians, nurses, staff, and students.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate and continually improve the protection of human research participants.
- Dedicate resources sufficient to do so.
- Exercise oversight of research protection.

- Educate investigators and research staff about their ethical responsibility to protect research participants.
- When appropriate, intervene in research and respond directly to concerns of research participants.

4 Institutional Authority

McLaren's Human Research Protection Program operates under the authority of the Organization policy " MHC_RP0201_Human Research Protection Program". As stated in that policy, the operating procedures serve as the governing procedures for the conduct and review of all human research conducted under the auspices of the McLaren Health Care Corporation. The HRPP policies and procedures are made available to all Investigators and research staff and are posted on MHC HRPP website (www.mclaren.org) and copies are available upon request.

5 Ethical Principles

McLaren and its subsidiaries are committed to conducting research with the highest regard for the welfare of human subjects. It upholds and adheres to the principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research* by the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (1979). These principles are:

1) **Respect for Persons**, which is ensured by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
2) **Beneficence**, which is assured by ensuring that possible benefits are maximized, and possible risks are minimized to all human subjects.
3) **Justice**, the equitable selection of subjects.

McLaren Human Research Protections Program (HRPP), in partnership with its research community, including researchers and research staff, IRB Members and Chair, IRB staff, the institutional official, employees and students, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted under its auspices.

6 Regulatory Compliance

The HRPP is responsible for ensuring compliance with federal regulations, state law and institutional policies. All human subjects research at MHC subsidiaries is conducted in accordance with the policy and regulations found in the Common Rule and 21 CFR 50 and 56. The actions of MHC subsidiaries will also conform to all other applicable federal, state, and local laws and regulations.

Regarding the Common Rule: Effective January 21, 2019, the MHC IRB began implementing the new requirements of the Revised Federal Policy for the Protection of Human Subjects, also known as the Common Rule, found in the Code of Federal Regulations at 45 CFR 46. Pre-existing studies (those approved prior to 1/21/2019) that require expedited or convened IRB review have since been transitioned to comply with the revised Common Rule. Studies that were determined to be exempt prior to 1/21/2019 remain under the pre-2018 Common Rule standards. Studies that were determined to be exempt on or after 1/21/2019 comply with the requirements of the revised Common Rule, including limited IRB review when applicable.

McLaren Health IRB commits to compliance with the International Conference on Harmonisation-Good Clinical Practices ("ICH-GCP") E6 to the extent ICH-GCP E6:

- is consistent with applicable federal regulations
- defined in clinical trial contract agreement with sponsors
- required by funding agency

7 Research Covered by the HRPP

MHC HRPP covers all research involving human subjects that is under the auspices of the Institution and has jurisdiction over all human-subjects research conducted at MHC and its subsidiary hospitals and clinics. 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 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.

The research may be externally funded, funded from internal sources, or conducted without direct funding.

An activity is covered by the HRPP when:

- It is considered ***"human subject research"*** – as defined in any one of the following:
  - FDA regulations
  - DHHS regulations or other Common Rule regulations
  - Other federal agencies, when applicable

and

- McLaren (or its employees or agents) is ***engaged*** in the research – as defined by OHRP rules of Engagement of Institutions in Human Subjects Research (http://www.hhs.gov/ohrp/policy/engage08.html) or substantively involved in the conduct of FDA-regulated research (e.g., McLaren facilities are performance sites, or McLaren employees or agents are investigators).

8 Research Not Covered by the HRPP

MHC does not currently engage in any of the following types of human research activities. If it were to contemplate such research, appropriate policies and procedures would be developed for:

- International Research
- Research conducted or funded by the Veteran Administration (VA)
- Research conducted or funded by the Department of Defense (DOD)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Education (ED)
- Research conducted, funded, or subject to oversight by the Environment Protection Agency (EPA)
- Research involving *in vitro* fertilization
- Research involving non-viable neonates
- Research Involving neonates of uncertain viability
- Research that plans to or is likely to involve prisoners as subjects
- Planned Emergency Research

9 Written Policies and Procedures

MHC Standard Operating Policies and Procedures for Human Research Protection detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by MHC IRB. This is not a static document. The policies and procedures are annually reviewed and revised by the Corporate Manager of the HRPP and the Institutional Official (IO). The IO will approve all revisions of the policies and procedures.

The Corporate Manager of the HRPP will keep the Organization's research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through campus electronic mailing lists. The policies and procedures are made available to all Investigators and research staff and are posted on the HRPP website and copies will be available upon request. Changes to the policies and procedures are communicated to PIs and research staff through memorandum quarterly

Newsletters, e-mail announcements or using the MHC HRPP website or iRIS (electronic IRB submission system). Changes to the policies and procedures are communicated to IRB members and IRB staff through IRB meetings, email announcements, or using the MHC HRPP website.

10 HRPP Organization

The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. It consists of various individuals and committees such as: the Institutional Official, the Manager of the HRPP, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Conflict of Interest, Privacy Board), investigators, IRB staff, research staff, health and safety staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

The following officials have primary responsibilities for implementing the HRPP:

10.1 Institutional Official

The ultimate responsibility of the HRPP resides with the Institutional Official (IO) of the program. The President of McLaren Health Care delegated authority and responsibility to establish, maintain and oversee the McLaren Human Research Protections Program to the Executive Vice President, Chief Medical Officer of McLaren Health Care Corporation, who serves as the IO for the protection of human research subjects. The IO delegates operational responsibilities of the HRPP to the VP of Clinical Excellence and Research.

The IO is primarily responsible for setting the level of the institutional culture of the ethical obligations of compliance, for instilling respect for human research participants and ensuring effective system-wide communication and guidance on human subject research.

The IO is responsible for ensuring that HRPP has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subject's research.

The IO understands the institution's responsibilities under the Federalwide Assurance (FWA), assures the protection of human subjects of research, and assures that the MHC IRB is knowledgeable about the local research context and will comply with the terms of the FWA. The IO ensures that the IRB is the sole entity that can grant approval for non-exempt research activities involving human subjects, (i.e., no one within the institution may approve such human-subjects research that has not been approved by the IRB.). The IO is legally authorized to represent HRPP.

The IO is also the signatory of the FWA for the McLaren Health Care Corporation and assumes the obligations of the Institution's FWA. IO is ultimately responsible for overseeing the protection of human subjects

participating in research conducted at each hospital, by the MHC employees or agents, and research approved by the MHC IRB. .

The IO is also legally authorized to execute documents and instruments with respect to the McLaren's HRPP, including MHC IRB and with respect to the human subject research conducted at each subsidiary hospital. Each subsidiary hospital's Board of Trustees agreed with this decision which reflects in a Letter of Resolution for their hospital.

The IO holds ultimate responsibility for:

- all areas of research compliance including but not limited to conflict of interest, scientific misconduct and non-compliance in research involving human subjects;
- oversight of the Institutional Review Board (IRB);
- ensuring respect for the authority of the IRB and its decisions and must ensure that the IRB is free from inappropriate influence;
- oversight over the conduct of research conducted by all MHC subsidiary hospital investigators;
- assuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- assuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
- oversight of the development and implementation of an educational plan for IRB members, staff and investigators;
- Support for evaluation of Conflict of Interest, and;
- Support for Community Outreach.

10.2 Corporate Manager of Human Research Protection Program

The Corporate Manager of the HRPP is selected by and reports to the Institutional Official (IO) and is responsible for:

- Developing, managing, and evaluating policies and procedures that ensure compliance with all state, and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program;
- Advising the IO on key matters regarding research at MHC and its subsidiary hospitals;
- Implementing the institution's HRPP policy;

- Submitting, implementing, and maintaining an approved FWA through the Department of Health and Human Services Office of Human Research Protection (OHRP);
- Ensuring compliance with the FWA, federal regulations, state statutes, local laws, IRB decisions, institutional policies, and ethical principles for protecting human research participants;
- Ensuring that MHC IRB is listed on Institution's FWA and ensuring that MHC IRB maintains current registration with OHRP;
- Managing the finances of McLaren's HRPP;
- Assisting investigators in their efforts to carry out organization's research mission;
- Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program;
- Developing training requirements as required and as appropriate for investigators, subcommittee members and research staff, and ensuring that training is completed on a timely basis;
- Serving as the primary contact at MHC for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies;
- Serving as the primary contact at MHC between research community and public at large on issues related to protecting human participants in research;
- Overseeing the Conflict-of-Interest Committee;
- Day-to-day responsibility for the operation of the HRPP office, including supervision of HRPP staff;
- Responding to researchers and staff questions;
- Working closely with the Chair of the IRB and on the development of policy and procedures, as well as organizing and documenting the review process;
- In consultation with the IO, notifying federal agencies and sponsors regarding compliance issues, and;
- Instituting corrective action plans based upon audit findings.

10.3 IRB Chair

MHC Institutional Official (IO), in consultation with the Corporate Manager of HRPP, appoints a Chair and Vice Chair of the IRB to serve on the MHC Corporate IRB. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chair should be a highly respected individual, from within the Organization, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions, e.g., the Vice Chair and Corporate Manager of the HRPP Office.

The IRB Chair advises the Institutional Official and the Corporate Manager of the HRPP Office on IRB member performance and competence.

The performance of the IRB Chair will be reviewed on an annual basis by the Manager of the HRPP Office in consultation with the Institutional Official. Feedback from this evaluation will be provided to the Chair. Evaluations serve to validate performance, identify areas which need improvement (both in function and knowledge), and make changes when appropriate.

If the Chair is not acting in accordance with the IRB's mission, is not following these policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair, he/she may be removed.

10.4 IRB Vice Chair

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority and duties as the Chair. The performance of the IRB Chair will be reviewed on an annual basis by the Manager of the HRPP Office. Evaluations serve to validate performance, identify areas which need improvement (both in function and knowledge), and make changes when appropriate.

10.5 IRB Members

IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed.

Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at the MHC subsidiary hospitals.

In addition, the IRB will include members who are knowledgeable about and have experience working with vulnerable populations that typically participate in this Health System research.

The performance of the IRB Members will be reviewed on an annual basis by the Manager of the HRPP Office. Evaluations serve to validate performance, identify areas which need improvement (both in function and knowledge), and make changes when appropriate.

Individuals from the MHC Office of Contract and Grants may not serve as members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may, however, provide information to the IRB and attend IRB meetings as guests.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

10.6 The Investigator

The investigator is the ultimate protector of the human subjects who participate in research. The investigator is expected to abide by the highest ethical standards and for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. The investigator may not commence human-subjects research prior to obtaining IRB approval. All subjects must give informed consent and the investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility. In addition to complying will all the policies and standards of the governing regulatory bodies, the investigator must comply with institutional and administrative requirements for conducting research. The investigator is responsible for ensuring that all research staff complete appropriate training and must obtain all required approvals prior to initiating research. When investigational drugs or devices are used, the investigator is responsible for providing written procedures for their storage, security, dispensing and disposal.

10.7 McLaren Legal Counsel's Office

The McLaren HRPP relies on the MHC Corporate Counsel for the interpretations and applications of State law and the laws of any other jurisdiction where research is conducted as they apply to human subjects' research.

Legal Counsel at MHC advises on human-subjects research issues and legal requirements; research compliance matters; research integrity and related misconduct investigations; conflicts of interest questions. Their work related to human subject protection includes, for example, drafting IRB Authorization Agreements, Letters of Resolutions, Investigator Agreements, advising on project-specific issues (e.g., child, who can serve as a legally authorized representative or guardian, informed consent, confidentiality), counseling on privacy requirements, assisting in investigations of alleged noncompliance, advising on liability issues, and generally interpreting and advising on new and existing legal requirements and conflicts between applicable laws. When there are any conflicts between federal or national law and other applicable laws, the Legal Counsel will determine the appropriate resolution.

McLaren Legal Counsel has a close working relationship with McLaren's Human Research Protections Program. Frequent conversations, meetings, and e-mail exchanges take place on a wide range of research issues on protection of human subjects.

10.8 Other Related Units:

10.8.1 McLaren Center for Research and Innovation (MCRI):

The McLaren Center for Research and Innovation has a centralized clinical trial infrastructure which streamlines operations while maintaining efficiencies and conducting research in compliance with federal and state regulations.

The MCRI is designed to provide centralized management of all the activities associated with research from pre-award to post-award and includes:

1) The centralized clinical trials office,
2) The office of research protocol feasibility,
3) The office of research contracts and budget negotiations and
4) The office of research fund management.

All clinical trials that are conducted through the MCRI are required to follow the MCRI contract review process.

10.8.2 Office of Budgets and Contracts

It is McLaren HRPP's Policy that any research conducted under the auspices of the Institution is conducted in accordance with federal guidelines and ethical standards.

Certain research agreements with federal, foundation, or non-profit sponsors (except registries and exempt studies) conducted at or through MHC subsidiaries will be reviewed by the Office of Budgets and Contracts through the MCRI. Certain contracts are reviewed by another entity in which the Investigator reports.

Moreover, McLaren's HRPP requests a copy of the contract to ensure that the protocol, consent form, and contract is consistent. Additionally, MHC IRB application will ask a set of questions to ensure that: no subjects are enrolled unless CTA and the MHC IRB approved consent form are in agreement.

10.8.3 Pharmacy

A pharmacist from one or more of the McLaren subsidiary hospital pharmacies serves on the MHC IRB.

It is McLaren HRPP's policy that when conducting clinical research using medications and investigational drugs, all MHC employees comply with all applicable federal and state statutes, rules and regulations and Health Systems policies regarding approval and use including procurement, storage, administration/dispensation, disposal, reporting, and record keeping requirements.

McLaren's pharmacies typically do not engage in the ordering/providing, dispensing, or compounding of drugs used in research, unless the drug is controlled substance, in which case the item is ordered/received by the Pharmacy and re-issued in appropriate quantities to researchers for human studies, pursuant to a study-specific and patient-specific medication order developed by the Pharmacy in collaboration with the Researcher.

PIs are typically responsible for the accountability of medications and drugs used in their clinical investigation, but may delegate these duties to an appropriate McLaren Pharmacy. When using McLaren's Pharmacy, the Manager of Pharmacy is primarily responsible for the accountability of all investigational drugs; however, all pharmacies are authorized to dispense according to policy and procedure. The PI works closely with the Pharmacy Staff to ensure that protocol procedures are followed.

All McLaren pharmacies are available to provide guidance to Investigators in relation to the management of the study drugs.

10.8.4 All members of the Organization

All individuals within the MHC and its subsidiary hospitals have the responsibility to:

- Be aware of the definition of Human Subject Research.
- Consult the IRB where there is uncertainty about whether an activity is Human Subject Research.
- Not conduct Human Subject Research or allow Human Subject Research to be conducted without review and approval by an IRB designated by the Institutional Official.

- Report allegations of undue influence regarding the oversight of the Human Research Protections Program or concerns about the Human Research Protections Program to the Institutional Official.
- Report allegations or funding of non-compliance with the requirements of the Human Research Protection to the IRB

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

10.8.5 Relationship between Components:

The MHC IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects regulations.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution(s). However, those officials may NOT approve research if it has not been approved by the IRB.

10.8.6 Protocol-specific coordination:

The **Initial IRB Application** form, which must be submitted with every protocol, requires Principal Investigators (PIs) to indicate institutional support that may be required for the research, including, but not limited to:

- Nursing
- Medical Records
- Lab
- Pathology
- Surgery
- Finance
- Pharmacy
- Radiation Oncology
- Medical Oncology
- IP
- OP
- Radiology
- Other

For any departments that are indicated, a letter of support (Project Impact Statement) must be included and the Department's Manager or Manager must sign the form. The protocol will be reviewed by the IRB staff in the HRPP Office to ensure that all necessary documents are included.

Final IRB approval will not be given until all necessary documents are received. The IRB may request review and consultation with any of the above-listed or other organizational committees or components even when such review or consultation is not technically required by policy.

11 HRPP Operations

In addition to the leadership structure described above, the McLaren HRPP office is staffed by two IRB Analysts, a Quality Improvement (QI) and Education Specialist, and an HRPP Coordinator. The HRPP Support Staff must comply with all ethical standards and practices.

HRPP Staff reports to the Corporate Manager of HRPP, who has day-to-day responsibilities for its operations. The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis.

11.1 IRB Analyst

- IRB Analyst will review research protocol submissions to assure compliance with federal, state, and institutional regulations and policies pertaining to the Human Research Protections Program;
- IRB Analyst will be responsible for ensuring the timely notification, processing, review, and disposition of all IRB activities including unanticipated problems related to research, protocol amendments, continuing review, and protocol deviations;
- IRB Analyst will review researcher's responses to IRB Stipulations and determine the adequacy and completeness of responses, requesting additional material or information in order to address concerns;
- IRB Analyst will ensure timely processing of protocols eligible for review using expedited procedures;
- IRB Analyst will coordinate IRB meetings and review activities: prepare relevant materials and necessary correspondence, including agendas in accordance with internal policy and compose high-quality, and regulatory compliant minutes after each IRB meeting;
- IRB Analyst will maintain electronic database for IRB required training for all key study personnel involved in human subject research;
- IRB Analyst will participate in federal and internal audits and inspections as pertain to the IRB and HRPP department, and;
- IRB Analyst will participate in continuing education to promote research ethics and the protection of human subjects.

11.2 Quality Improvement (QI) and Education Specialist

- Responsible for providing on-going support and education to the clinical research community at MHC and its subsidiary hospitals to ensure compliance with applicable institutional, FDA, OHRP, HIPAA, and GCP requirements and guidelines;
- Facilitate the execution of training programs, workshops, and conferences for Investigators, IRB members and Research Staff throughout the corporation and its subsidiary hospitals;
- Plan and conduct internal audits of HRPP program and all clinical research office/investigators to determine compliance with federal regulations and HRPP Policies and procedures;
- Evaluate findings, identify areas of improvement, and prepare and distribute reports;
- Assist Corporate Manager of HRPP with AAHRPP Accreditation and renewal process, and;
- Complete special projects as assigned by Corporate Manager of HRPP.

11.3 HRPP Coordinator

- Provide general administrative support to the Manager of HRPP department and staff as needed; this includes answering phones, scheduling appointments, and arranging travel;
- Compose and type routine correspondence and/or reports;
- Provide assistance with development of written guidelines to improve communication and understanding of human research requirements;
- Arrange and monitor quorum at Board meetings, track IRB attendance, and report significant absences under direction of the Manager of HRPP;
- Maintain required information about Board members for regulatory compliance;
- Help facilitate and organize the training and education of IRB members and researchers as instructed;
- Assist with IRB meeting preparation;
- Take minutes during the convened IRB meeting;
- Maintain department filing system;
- Act as a receptionist for the department which might include varies administrative tasks;
- Coordinate the daily activities associated with the processing of research protocols and all facets of protocol review management and regulatory compliance;
- Assist HRPP Quality Improvement (QI) and Education Specialist in identifying areas of focus for education topics and help coordinate webinars/workshops and conferences focused on current issues affecting protection of human subjects in research;

- Lead special projects identified and assigned by the Corporate Manager of HRPP, and;
- Assist in program development, implementation and evaluation as requested by the Corporate Manager of HRPP.

11.4 Selection, Supervision, and Evaluation of HRPP Supporting Staff

Selection Process

All HRPP staff who support the IRB and HRPP are selected by the Corporate Manager of HRPP under MHC Human Resources policies and procedures.

Depending on the position to be filled, qualifications to be considered in the selection of HRPP staff include prior experience in IRB administration or another position within an HRPP (e.g., study coordinator), or, at the assistant or clerical levels, a desire to learn and be an active participant in the regulatory, ethical, and procedural aspects that support an HRPP.

Supervision

HRPP staff is supervised by the HRPP Manager.

Evaluation

HRPP staff is evaluated on an annual basis as outlined in policy MHC Annual Evaluation of the Human Research Protection Program.

12 HRPP Resources

Resources for the HRPP are allocated to the individual McLaren's entities engaged in human-subjects research overseen by the McLaren's HRPP. Such resources include, but are not limited to:

- Staffing commensurate with the size and complexity of the research program;
- Appropriate office space to permit private conversations and to hold meetings, equipment, material, and technology;
- Adequate financial support;
- Resources for the production, maintenance, and secure storage of HRPP and IRB records;
- Resources for auditing and other compliance activities and investigations of non-compliance;
- Access to legal counsel;
- Support for educational opportunities related to human research protections for IRB members, relevant administrative staff, and all members of the research team;
- Support for evaluation of Conflict of Interest, and;

- Support for Community Outreach.

MHC periodically evaluates key functions of the HRPP, such as the number of IRBs, the Conflict-of-Interest Committee, EQuIP, educational activities, sponsored programs, and other departments impacted to make adjustments such that key functions of the HRPP are accomplished in a thorough and timely manner.

Thus, the adequacy of personnel and non-personnel resources of the HRPP program is assessed on an annual basis by the Corporate Manager of the HRPP with the HRPP staff and are reviewed and approved by the IO.

The resources provided for the IRB and HRPP Office will be reviewed during the annual budget review process.

13 Human Research Protection Program Components

13.1 McLaren's Corporate Institutional Review Board (IRB)

MHC Corporate IRB has one on-site IRB, appointed by the Institutional Official (IO). The IRB prospectively reviews and makes decisions concerning all human research conducted at MHC subsidiary hospitals' facilities, by its employees or agents, or under its auspices. The IRB is responsible for the protection of rights and welfare of human research subjects at the MHC and its subsidiary hospitals. It discharges this duty by complying with the requirements of the Common Rule; state regulations, the FWA(s); and institutional policies.

The MHC Corporate IRB is supported and managed by the HRPP. If applicable, the organization may rely upon the IRB of another organization provided that a written agreement has been established between the 2 IRBs. In addition to the above, this organization may rely upon the IRB of another organization provided the following is true:

- The IRB is the IRB of an AAHRPP accredited organization where:
    - This Health System's investigator is conducting research with another organization and has a written agreement between the 2 IRBs.
    - Corporate IRB will rely upon the IRB of another institution for review of collaborative research on a case-by-case basis. When this occurs, a single project reliance agreement is executed by the parties

The MHC Corporate IRB has the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the organization. All Human Research must be approved by an IRB designated by the Institutional

Official. Officials of this organization may not approve Human Research that has not been approved by the IRB.
- Suspend or terminate approval of Human Research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

IRB Chair, IRB Vice-Chair, IRB members, and IRB staff have the responsibility to follow all applicable Human Research Protections Program policies and procedures..

13.2 Research Conflict of Interest Committee

It is McLaren's policy to preserve public trust in the integrity and quality of research by reducing actual or perceived conflict of interest in the conduct of research. Managing conflicts of interest is essential to ensuring integrity in our business decisions and maintaining the public's trust in McLaren Health Care and all those connected with it.

McLaren maintains a Research Conflict of Interest Committee (RCOI). The purpose of the RCOI is to establish an effective process to identify, report, and resolve employee conflicts of interest. The specific functions and authority of the RCOI Committee is to handle matters that present potential conflicts of interest with respect to institutional interests and with respect to all employees of McLaren Health Care and its subsidiary organizations.

RCOI Committee members serve in various roles and disciplines from across MHC. The RCOI Committee meets as necessary to develop, management plans, and update policies and procedures for compliance with federal regulations.

13.3 Education and Quality Improvement Program (EQuIP) Quality Improvement

Education and Quality Improvement Program (EQuIP) supports and promotes ethical and compliant research practices at McLaren Health Care.

Part of the McLaren Human Research Protections Program (HRPP), EQuIP is a program dedicated to the research community to enhance the quality of human research and support improvement of the HRPP. EQuIP offers a variety of educational and study-related services and activities designed to ensure investigators, research staff, and the IRB are compliant with regulations,

guidance, institutional policies, and best practices for human research protections. *EQuIP is a wholly separate entity from the MHC IRB.*

Work activities of EQuIP will be determined through a semiannually work plan developed jointly by the Corporate Manager of HRPP and Quality Improvement (QI) and Education Specialist.

13.3.1 Post Approval Monitoring Activities – QA/QI Reviews, For-Cause Audits and PI-Requested Reviews

The QI and Education Specialist will conduct QA/QI reviews of human subject research studies. QA/QI reviews are part of a McLaren Health institutional-wide research education initiative, designed to help investigators identify standards of excellence and potential areas for improvement to enhance the quality of human subject research at McLaren and its subsidiaries.

The objectives of the QA/QI review are:

1. Verify that safeguards protecting the rights and welfare of research participants are in compliance with all applicable federal, state and local laws and regulations as well as ethical standards in human research.
2. Identify any possible safety issues for study participants and non-compliance in research conduct.
3. Provide feedback and help investigators identify any risks and initiatives to prevent potential problems that may arise during the study conduct.
4. Provide education on applicable human subjects' regulations, laws and policies that apply to research conduct. If necessary, create a corrective action preventative action plan for the investigator.
5. Provide information, resources, and tools to study team members that will assist with implementing day-to-day study activities.
6. Provide confidential discussion and correspondence, which does not become part of the IRB records or files.
7. Report potential serious or continuing non-compliance to the IRB, HRPP Corporate Manager, Institutional Official, and applicable regulatory agencies.

The QA/QI reviews are either randomly selected from an open list of protocols in the IRB database or selected for specific reasons such as, but not limited to high-risk research, first time investigator, red flags noted by IRB analyst during their reviews or research involving vulnerable populations. Any study involving human subjects, including medical and non-medical studies and those that have received exempt determination, may be selected for routine QA/QI review.

Under certain circumstances the IRB may request or direct a for-cause audit when there are concerns of serious non-compliance, continuing non-compliance or about whether the rights and welfare of participants enrolled in a particular research protocol are being adequately protected.

The PI may request and QA/QI review of their research study as a means for assurance in their research conduct or preparation for an external sponsor or regulatory agency.

Potential study areas that are reviewed/audited includes, but not limited to:

- Review of Regulatory and Compliance and Documentation
- Review of IRB Documentation
- Review of Informed Consent Process and Documentation
- Subject Study Records and Documentation
- Review of Data and Safety Monitoring Plan
- Review of Protocol Adherence and Protocol Violation Reporting
- Review of Serious Adverse Event and Unanticipated Problem Reporting
- Review of Recruitment methods and Compensation
- Conducting other monitoring or auditing activities as deemed appropriate by the IRBs.
- Inspecting storage facilities for IP devices or biological samples
- Review subject study records including medical records
- Review all regulatory including FDA documents, when applicable
- Observe any aspects of the research process/procedures including the consenting process
- Review recruitment, enrollment, and compensation methods
- Clinical Trial Agreements
- External Site Audits and Compliance Reviews

External directed audits and periodic compliance reviews will be conducted at non-Organization sites, where the McLaren's IRB serves as the "IRB of Record," to assess compliance with federal, state, and local law, research subject safety, and IRB policies and procedures

13.3.2 IRB Review and Compliance Audits Concurrent IRB Review with Investigator QA/QI Review

For each QA/QI review or audit conducted, regardless of selection type, the IRB will automatically undergo review. The IRB review might include, but is not limited to:

- IRB Files;
- Review IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures;
- Review the IRB database to assure all fields are completed accurately;
- IRB Approvals, Modifications, and Continuing Reviews;
- IRB Review of Informed Consent – required elements, and;
- Data and Safety Monitoring Plans.

- **IRB Meeting Minutes**
- Review of the IRB minutes to determine that adequate documentation of the meeting discussion has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as other risk/benefit ratio and consent issues that are included in the criteria for approval;
- Assess the IRB minutes to assure that quorum was met and maintained;
- Assess privacy provisions, according to HIPAA, have been adequately reviewed, discussed and documented in the IRB minutes, and;
- Evaluate the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review.

- **IRB Members**
- HRPP Corporate Manager will review the workload of IRB staff to evaluate appropriate staffing level;
- HRPP Corporate Manager will review evaluations by the IRB members;
- Observe IRB meetings or other related activities;
- IRB Metrics, and;

- Review the appropriate metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process.

13.3.3 Other EQuIP Quality Improvement Activities

- Metrics of EQuIP Activities
- Assist with AAHRPP Accreditation Process
- Conduct surveys to evaluate effectiveness of various aspects of the McLaren's HRPP
- Identify, review, analyze, report, and disseminate new and pertinent regulations and guidelines
- Identify needed improvements to HRPP policies, procedures, and guidelines

13.3.4 Corporate Manager of HRPP and Compliance Reviews

All internal quality assurance and audit reports, both research-related and HRPP-related, will be reviewed by the Manager of HRPP and the Institutional Official (when necessary) to determine if systemic changes are required in the HRPP to prevent re-occurrence. If so, a corrective action plan will be developed, implemented and evaluated by the Manager of HRPP and IO (when necessary).

Annually, the Corporate Manager of HRPP will define at least one targeted measure of operational efficiency and effectiveness and at least one targeted measure of compliance within the HRPP. In order to evaluate whether the targeted measures are being achieved, the Corporate Manager of HRPP (or delegate) collects and records data every 6-month. At the end of each year, the Corporate Manager of HRPP evaluates whether the respective goals were achieved and adjusts the affected processes to correct any deficiencies.

- **Reporting and Disposition**

  The results of all internal quality assurance activities and audit reports are reported to the Corporate Manager of HRPP.

  If an audit or review finds that subjects in a research project have been exposed to unexpected serious harm, the reviewer will promptly report such findings to the Manager and the IRB Chair for immediate action.

13.4 Education and Quality Improvement Program (EQuIP) Education

The Education and Quality Improvement Program (EQuIP) is committed to ensuring that research personnel, IRB members, and staff and other persons charged with the protection of research participants receive and maintain the training and education necessary to fulfill their obligations in the research enterprise.

EQuIP is a program dedicated to the research community to enhance the quality of human research and support improvement of the HRPP and offers a variety of education and study-related resources. The primary tasks of this office include, but are not limited to:

- **Required Human Subjects Research (HSR) Training**

  All IRB members, IRB staff, and others involved in the review of Human Research, Investigators and research staff must complete the online Collaborative Institutional Training Initiative (CITI) human subjects' online training program.

  Required Clinical Research Coordinators (CRC) Education
  CRC may also be referred to as a protocol coordinator, research nurse, research associate, or a medical assistant assigned to role of research coordinator. MCRI Research Managers will notify the Education and Quality Improvement (EQuIP) office of newly hired research coordinators. The QI and Education Specialist will notify McLaren Leadership Development office to assign the CRC to the 7 Habits of Highly Effective Coordinators webinar series on McLaren University with a due date of 6 months from date of hire. New research coordinators will use their McLaren Health Care issued password and user ID to access McLaren University.

  Verification of Completion - The EQuIP office will monitor and record completion of webinars through automatic electronic report notification from McLaren University. The EQuIP Office will notify the Corporate Manager of HRPP of any research coordinator who has not completed the assignment.

  Continued Human Subjects Research (HSR)Training
  Initial CITI training is only valid for a three-year period, after which time a refresher CITI course or additional training must be completed. Investigators must submit evidence of continuing education prior to the expiration of their training certification.

New research protocols and applications for continuing review will not receive final approval until principal investigators have submitted satisfactory evidence of continuing education.

Required Individuals

Human Subject Research training requirement applies to all individuals involved in the conduct of human subjects research regardless of pay status, appointment type and length of time at this organization, including, but not limited to:

- Investigators;
- Study coordinators;
- Research assistants;
- Other members of the research team;
- All members of the research office whose responsibilities include involvement with human research;
- All IRB staff, all IRB voting members;
- Members of other research committees or subcommittees that review research involving human subjects.
- Investigators and research team members conducting studies involving human subjects that are exempt from IRB review
- Those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent.
- Nonscientist members (e.g., clergy, lawyers, community representatives, subject advocates) may require individualized training to ensure comprehension of their responsibilities as an IRB member.

Individuals exempt from HSR training

HSR training requirement does not apply to:

- Secretarial support staff
- Individuals who provide services for the research study in the course of their routine clinical duties (e.g., an x-ray technician who performs a chest x-ray, or clinical laboratory technician who performs a routine blood count), but have no other role or

responsibility for the research study, are not required to complete HRPP human research protection training.

Individuals with Previous Training

CITI Human Subject Research training course taken under a non-McLaren Health Care institution may be accepted. However, we will require affiliation* with McLaren Health Care on the CITI website. CITI will review the modules previously completed and the date(s) taken. CITI will ask the individual to complete any modules required by McLaren Health Care that were not required by your previous institution.

Special Circumstances

If the IRB of an affiliated academic institution or other external organization serves as the IRB of record for some of the offices of this Health System, the external IRB members are to be encouraged to complete HRPP required human subjects protection training or its equivalent. McLaren's HRPP is not required to track such training.

Individuals outside of MHC (e.g., phlebotomists, x-ray, and laboratory technicians) who are not MHC's or subsidiary hospitals' employees and whose work occurs exclusively outside this Health System must meet their own institutions' requirements for training.

- **Additional Training Requirements**
    - **Conflict of Interest Training for Investigators**

      All research primary investigators, sub or co-investigators and academic advisors are required to complete COI training through CITI prior to the start of any study activities. COI training certificate is good for three years.

    - **Good Clinical Practice Course**

      If clinical trial is required to adhere to ICH-GCP E6 guidelines, you must complete Good Clinical Practice (GCP) training. is required every three years. GCP training is an additional separate training and is not basic human subjects protection training. GCP principles are specific to clinical trials and include international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials. Refer to clinical trial contract/agreement, sponsor or funding agency to determine if your research protocol is required to adhere to ICH-GCP E6 guidelines. Individuals engaged in the conduct

of a clinical trial (per the NIH definition) must complete a Good Clinical Practice (GCP) training. CITI GCP course options in CITI course are:

- **Good Clinical Practice for Clinical Trials with Investigational Drugs and Devices (US FDA Focus)**. This course includes references to FDA regulations and guidance. In addition, this course meets the minimum criteria for ICH GCP training as recognized by TransCelerate BioPharma to allow mutual recognition of GCP training among trial sponsors and NIH requirements (https://about.citiprogram.org/news/citi-program-gcp-training-complies-with-nih-policy)

- **Good Clinical Practice Social and Behavioral Best Practices for Clinical Research**
  This course is suitable for social and behavioral investigators and staff who must be trained in GCP. The *GCP – Social and Behavioral Research Best Practices for Clinical Research* course introduces GCP principles and discusses how they apply to clinical trials using behavioral interventions and social science research.

- **GCP for Clinical Investigations of Devices** *(formerly called GCP Course for Clinical Trials Involving Investigational Medical Devices (international focus)*
  This GCP Device Basic course is intended for research personnel involved in investigations of devices. It includes FDA regulations and guidance as well as International Organization for Standardization Guidelines ISO 14155:2020. It also provides an overview of investigator obligations in conducting clinical investigations of devices, as well as managing investigational devices according to GCP requirements, monitoring, audits and inspections, and informed consent for clinical investigations.

- **GCP for Clinical Investigations of Drugs and Biologics (ICH)** *(formerly called GCP for Clinical Trials Involving Investigational Drugs (international / ICH focus)*
  This course is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training, or for researchers involved in studies where compliance with ICH is required (for example, most industry-funded studies). This course meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Good Clinical Practice training is valid for a 3-year period, after which time a Refresher GCP Course must be completed. Alternative GCP training review - Submit a request for acceptance of alternate GCP training in lieu of the options above and email documentation of past training.

- **Engaged and Community-Based Participatory Research**

Investigators conducting community engaged research must complete the CITI Engaged and Community-Based Participatory Research.

- **Optional iRIS Training**

Initial research application submission and all subsequent IRB submissions must be done through the iRIS system. Existing McLaren

users use their McLaren credentials to log in to iRIS (user ID and password). When a user logs into iRIS for the first time, there may be a delay before they may fully use iRIS. After logging in for the first time, the System Administrator will have to manually set a role and department for the user. Navigation and completion instructions are built into the iRIS system. More information can be found on the McLaren iRIS webpage at https://www.mclaren.org/main/iris-research. However, if one-on-one or group training is preferred, the EQuIP office can accommodate this request.

- **IRB Education**
    - Initial Education

      IRB staff will also train IRB members on the SOPs, checklists, and worksheets applicable to IRB members including regulatory and guidance requirements.

    - Continuing Education

      To ensure that oversight of human research is ethically grounded, and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members and Investigators throughout their involvement in human subject protection and research.

      In addition to initial training requirements, IRB members and staff must also satisfy continuing education requirements on an annual basis. HRPP uses the following activities as a means for offering continuing education to IRB members and staff:

        - Regular in-service training at IRB meetings;
        - Training workshops;
        - Copies of appropriate publications;
        - Identification and dissemination by the HRPP Manager of new information that might have affected the human research protections program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;
        - Unlimited access to the HRPP Office resource library, and;

- Distribution of the “Medical Ethics Advisor” prior to each IRB meeting.

Members and staff who are unable to attend education sessions will be provided with the opportunity to make-up any training that they missed. If a make-up session is not possible (e.g. a webinar or conference), then an equivalent educational opportunity will be offered at the discretion of the Manager.

The activities for continuing education vary on a yearly basis depending on operating budget and areas of need, as determined by the HRPP Manager. The Manager 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. IRB members who have not fulfilled their continuing education requirements will not be allowed to attend IRB meetings until they are fulfilled. Continuing noncompliance will result in the individual not being renewed as an IRB member

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.

The HRPP Office Professional Staff is required to complete the entire CITI Course in the Protection of Human Research Subjects. Staff will be expected to attend PRIM&R or OHRP training on a regular basis.

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

Investigators who also serve as the IRB Chair, IRB members, or IRB Office staff will satisfy the training requirements for IRB members and staff described above.

- **Ongoing Continuing Education**

  EQuIP will provide additional continuing education to the research community through:

  - Live Brown Bag Webinar Series for research community at large.
  - Recorded educational offerings through McLaren University.
  - Custom talks and presentations upon request.
  - Institute educational initiatives based on compliance activities.

- **Educational Resources**

  EQuIP will provide additional education and resources to the research community through:

  - Development of tools and templates to maintain and organize studies.
  - Promote education through articles in the Research Matters and Corporate Compliance Newsletter.
  - Assist Investigators with IRB submissions (per request).
  - Assist Investigators with regulatory documents that are required for study initiation (per request).
  - Face-to face meetings with new researchers as needed and/or requested.

- **Expected Knowledge**

  All research staff is expected to:

  1. Be knowledgeable of federal regulations, laws, good clinical practice guidelines, and institutional HRPP policies that are applicable to the conduct of their research study.

  2. Know where to find information on federal regulations, laws, and institutional HRPP policies that are applicable to the conduct of their research study. Assistance with locating such information can be found on the HRPP website or calling the HRPP office for directions.

14 Participant Outreach

McLaren Health Care Corporation is committed to ensuring that educational opportunities are offered to research participants, prospective research participants, and community members who will enhance their understanding of research involving human participants at MHC and its subsidiary hospitals.

The following procedures describe how McLaren fulfils that responsibility.

14.1 Responsibility

It is the responsibility of the Corporate Manager of HRPP to implement the procedures outlined below.

14.2 Outreach Resources and Educational Materials

1. MHC dedicates a section of the research website to research participants entitled “Research Participant Corner”. This webpage provides basic information about research to help inform decision-making about participation, a glossary of research terms, FAQs, history, and contact information for Research Integrity and the IRB.
2. MHC provides links within its Research Participant Corner webpage to information from OHRP and FDA that provide information to the public about research and research participation.

14.3 Evaluation

MHC HRPP periodically evaluates its outreach activities and makes changes when appropriate. These evaluations take place in an informal, ongoing manner. All IRB staff, members and Chair/Vice Chair will report both positive and negative feedback about all HRPP outreach activities to the Corporate Manager of HRPP. The Manager will then track the input and any changes made to improve outreach activities. In order to formally evaluate its outreach activities, the Corporate Manager will determine:

1. The specific community outreach activities being used.
2. Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these evaluations.

The Corporate Manager of HRPP will administer surveys annually to determine the adequacy of outreach activities. The survey will assess:

1. The scope, the content, and the adequacy of outreach activities and resources.
2. Whether the research community is using the HRPP website resource “Research *Participant Corner”.*
3. Whether the research community is using other educational materials to inform prospective participants about their rights and welfare as research participants.
4. Whether additional resources are needed to improve participant outreach activities.

The results of the survey will be used to establish both the adequacy of current outreach activities and any additional resources that may be needed to meet the needs of the research community regarding participant outreach.

15 Questions and Additional Information

The HRPP Office wants your questions, information, and feedback.

Contact and location information for the HRPP Office is:

Name: Patricia Ivery RN, MSN, CHRC
Title: Corporate Manager of Human Research Protections Program
McLaren Healthcare Corporation

2701 Cambridge Court, Suite 110
Auburn Hills, Michigan 48326
Office: 248-484-4955
Email: Patricia.Ivery@mclaren.org

16 Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the Institutional Official, HRPP Manager, IRB Chair, or directly to the HRPP Office at HRPP@mclaren.org

The HRPP has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or designee.

To make such reports, contact:

Name: Patricia Ivery RN, MSN, CHRC
Title: Corporate Manager of Human Research Protections Program
McLaren Healthcare Corporation

2701 Cambridge Court, Suite 110
Auburn Hills, Michigan 48326
Office: 248-484-4955
Email: Patricia.Ivery@mclaren.org

17 Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, (i.e., federal, state or institutional. Random audits may also be conducted).

18 Disciplinary Actions

The IO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO such actions are required to maintain the Human Research Protections Program.

19 Approval and Revisions to the Plan

This Human Research Protections Program Plan is to be approved by the Institutional Official. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements.

The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official, the Corporate Manager has the authority to amend this plan as deemed necessary.

Approved:

Signature on File 4/7/2023

_____ _____

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

Previous versions: 11/29/11, 12/10/12, 10/07/2013, 08/13/2015, 10/20/2015, 2/12/16, 12/03/2021