# Are you conducting research?

*Guide for Resident and Student Principal Investigators (PIs)*

McLaren
HEALTH CARE

# Human Research Protection Program (HRPP)

## AND

# McLaren Center for Research and Innovation (MCRI)

### Human Subjects Research Policy at McLaren Healthcare:

All non-exempt human subject research carried out at McLaren Health Care (MHC) and its subsidiary hospitals or under its auspices must be reviewed and approved by the MHC IRB prior to the start of research.

*http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0101_AuthorityofIRB.pdf*

# Who Are We?

The Human Research Protections Program (HRPP) and the McLaren Center for Research and Innovation (MCRI) provide the oversight and administrative facilitation of human research subject protection. Prior to the starting any research activity you must interface with these departments.

McLaren Health Care adheres to the Federal Regulations for the Protection of Human Subjects (DHHS OHRP* and FDA*).

# HRPP

The HRPP is the enforcer of the Federal regulations. It is made up of the following units:

- MHC Institutional Review Board ( MHC IRB)
- Office of Research Compliance and Quality Improvement
- Office of Education, Training and Resources

The IRB is responsible for reviewing all proposed research projects and related materials. It is an independent ethics committee designated to approve, monitor, and review biomedical and behavioral research involving humans. The purpose of their reviews is to assure, both in advance and periodically throughout the life of a research project, that appropriate steps are taken to protect the rights and welfare of humans subjects. The IRB's goal is to protect human subjects from physical or psychological harm.

*See* Resources *on page 15*

# MCRI

MCRI provides Investigators resources to (i) manage and conduct research (ii) assist with protocol development and (iii) assist with statistical analysis.

All research conducted through MCRI is reviewed for operational and financial feasibility. The pre and post-award activities for research are also managed centrally and includes contract review by the legal team, budget analysis, budget negotiations and management of post award funds.

As you read on you will learn how these two offices are involved in your research project, but first you must have a clear understanding of the definition of human subjects research.

# What Constitutes Human Subject Research?

The MHC IRB must determine if a project meets the regulatory definition of HUMAN SUBJECTS RESEARCH, ***not the student, not the resident, not the academic advisor***. They will start by answering two questions: Is it *research*? Does the project involve *human subjects*?

According to DHHS OHRP regulations at 45 CFR 46 .102 (d) or Federal policy for the Protection of Human Subjects:

**Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, **or** (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (i.e., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual; and which the individual can reasonably expect will not be made public (i.e., a medical record). In order for obtaining information to constitute research involving human subjects, private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Activities that meet the federal definitions for both **"research" and "human subjects"** must be submitted to the MHC IRB for review.

## Determination of Non-Human Subjects Research

If an investigator does not believe, or is not sure their research project meets the definition of human subjects research, they can complete the "Request for Determination of Non-Human Research" form. The completed form, which has been signed by the academic advisor, can be sent to the MHC IRB via email.

The MHC IRB staff will determine whether the activity meets the definition of human subject research, ***not the resident, not the student and not the academic advisor***.

*http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0104_DeterminationofHumanSubjectResearch.pdf*

## Examples of Research Reviewed by IRB

- Clinical studies involving use of drugs, biologics and medical devices
- Research projects involving collection of data through medical record review by viewing and/or recording any private health information (PHI)
- Research projects involving the collection of data from voice, video, digital, or image recordings made for research purposes
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for

non-research purposes (such as medical treatment or diagnosis).

- Research involving interventions such as collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Research involving interaction or observation of individual or group characteristics or behavior or research employing survey, interview

## The Process to Conduct Research at McLaren Health Care

After you have completed the preparatory steps (see *Getting Started* on page 12) you will be ready to submit your protocol application to the MHC IRB via the eProtocol system. There are three levels of review conducted by IRB: exempt, expedited and full board.

First, the research activity is assessed to determine the risk level. Minimal risk is defined as: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the routine performance of physical or psychological examinations or tests.

## Exempt

This category represents studies that present minimal risk to the research subject.

*http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0105_ExemptReview.pdf*

## Expedited

This category represents studies that present minimal risk to the research subject or minor changes in previously approved research approval period.

*http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0106_ExpeditedReviews.pdf*

### Full Board

This level of review is for all initial review applications submitted to the MHC IRB that are not eligible for the expedited review procedure. All research involving greater than minimal risk will also receive full board review.

*http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0108_FULLBoardReview.pdf*

Once submitted, an IRB analyst will conduct a pre-review of the study to ensure that all personnel have completed the required training and that all necessary documents are included with the submission.

## Review Timeline

Review times vary depending on completeness and clarity of submission materials, overall study submission volume, and IRB committee meeting dates. Please submit your application with ample time for the review process.

You can help the process by:

- Ensuring all required training is completed
- Submitting all documentation as requested
- Completing the application thoroughly
- Communicating with the IRB in a timely manner when questions are raised or further clarification is requested

## Informed Consent Process

Informed consent is an ongoing process that must occur before any clinical trial-related procedures are started. The process consists of a document and a series of conversations between the clinical trial participant and the Principal Investigator (PI) and/or designee, as appropriate. The tenets of the informed consent lie in the Belmont Report ethical principle, Respect for Person.


### Valid Informed Consent Form (ICF) Document

All informed consent forms must be approved by the MHC IRB before they can be presented to potential research subjects. In addition, the consent document must contain informational elements, as they apply to the study and are conveyed as part of the consent process.

## Elements of an Informed Consent

The elements include, but are not limited to the purpose, duration, risks, benefits, costs and additional expenses of the trial; a description of the trial procedures; alternative care options; confidentiality and statement of voluntary participation. (See IRB ICF template at

*http://www.mclaren.org/Uploads/Public/Documents/Corporate /irbInformedConsentTemplate.doc)*


## Clinicaltrials.gov Requirements

Some studies involving human subjects must be registered on the publicly accessible database clinicaltrials.gov. Please review requirements at clinicaltrials.gov. to determine if your research should be registered.

## Vulnerable Populations

Research involving vulnerable groups such as women, infants, fetus, children, or prisoners requires extra provisions of protection by the MHC IRB. Their consent forms and process will require additional steps that investigators must adhere to and are determined by the MHC IRB.

## HIPAA and Research

Protection of private health information (PHI) in the research setting has additional requirements. Unless your research study has a waiver of HIPAA, research subjects are required to sign a research HIPAA authorization document.


# Getting Started

*http://www.mclaren.org/Main/residentcornerirb.aspx*

**These steps are MANDATORY REQUIREMENTS before starting any research project**

## Step 1

Contact your faculty advisor and follow your subsidiary guidelines for faculty oversight of your project.

## Step 2

Obtain an eProtocol account to submit your project to the IRB. Contact HRPP@mclaren.org to obtain a user name and password in order to access eProtocol

## Step 3

Obtain Human Research Subject Protection Certification (CITI)

- Go to https://www.citiprogram.org
- Create a new user and password to gain access (If you do not already have one). If you have a previously completed CITI training, you must affiliate yourself with McLaren Health Care.
- Select **McLaren Health Care** as the institution you would like to be affiliated with. This is very important – because if you do not select the correct institution you will not be given the correct CITI Training modules.
- Complete the following with a score of 80% or higher:
  1. Biomedical Research Training Course
  2. Conflict of Interest Course

**Step 4**

Additional Assistance

- Need help with developing your research project
- Question about or gaining access to clinicaltrials.gov

**Contact MCRI at 810-342-1025**

# Whom to Contact

**Human Research Protection Program**

1198 N. Belsay Road, Bldg. #1
Burton, MI 48509
HRPP Main Line: (810) 342-1003
HRPP Fax: (810) 342-1514

Email: *hrpp@mclaren.org*

Web: *http://www.mclaren.org/main/HumanResearchProtectionsProgramHRPP.aspx*

**McLaren Center for Research and Innovation**

1198 N. Belsay Road, Bldg. #1
Burton, MI 48509
MCRI Main Line: (810) 342-1025
MCRI Fax: (810) 342-1293

Email: *hrpp@mclaren.org*

Web: *http://www.mclaren.org/main/ClinicalTrialsManagementProgram.aspx*

### Office of Research Compliance and Quality Improvement Office of Education, Training and Resources

Phone: (810) 342-1028
Fax: (810) 342-1514

Web: *http://www.mclaren.org/flint/OfficeofEducationTrainingandResources.aspx*

### eProtocol Technical Help

Phone: (810) 342-1003

Email: *hrpp@mclaren.org*

Web: *https://eprotocol-hrpp.mclaren.org/*

### CITI Technical Support

Call 305-243-7970 and select option #1

Email: *citisupport@med.miami.edu*

Web: *https://www.citiprogram.org/index.cfm?pageID=22*

# Resources

**MHC HRPP Policies & Procedures**
*http://www.mclaren.org/Main/IRBPoliciesProcedures.aspx*

**Guidance for Investigators**
*http://www.mclaren.org/Main/ForInvestigators.aspx*

**Investigator Handbook**
*http://www.mclaren.org/Uploads/Public/Documents/Corporate/HRPPInvestigatorHandbook.pdf*

**Office of Human Research Protections (OHRP)**
*http://www.hhs.gov/ohrp*

**U.S. Food and Drug Administration**
*http://www.fda.gov/*

**Code of Federal Regulations (21 CFR 56)**
*http://www.hhs.gov/ohrp/humansubjects/fda/index.html*

**Code of Federal Regulations (45 CFR 46)**
*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html*

**International Conference on Harmonization (ICH) E6 Good Clinical Practice: Consolidated Guidance**
*http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf*

**The Office of Research Integrity (ORI)**
*http://ori.hhs.gov/general-resources-0*

**The Belmont Report**
*http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html*

**Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule**
*http://privacyruleandresearch.nih.gov/pr_02.asp*


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