

Matters

SPRING 2018



**CHANGES
AHEAD**

**Revised
Common Rule
Coming Soon**

SEE PAGE 3



**New Resident
Research Submission
Process**

SEE PAGE 6

**H**

Why Research Matters

Harry Colfer, MD, has been a practicing cardiologist in Petoskey since 1983. After joining the medical staff at McLaren Northern Michigan (formerly known as Northern Michigan Regional Hospital), he started the cardiac rehabilitation program, as well as the clinical research program.

1. What drove you to launch the clinical research program at McLaren Northern Michigan?

I had the opportunity to participate in a clinical trial comparing old and new treatment strategies for management of congestive heart failure at a time when the value of treating heart failure with ACE inhibitors was just being recognized. I could see that this would be an important study that could inform cardiologists about the best treatment for patients with congestive heart failure. At that time, our treatment for congestive heart failure was not very good and patients really suffered. I wanted to contribute to an effort that might improve care for this very symptomatic group of patients.

2. How has the clinical research program at McLaren Northern Michigan progressed over the years?

I believe that clinical trials have improved the quality of care for our patients through the more rapid adoption of evidence based care than would otherwise occur. Physicians who participate in clinical trials have exposure to key opinion leaders in the field from whom we can learn. Patients who participate in clinical trials can benefit from new therapies and clinical trial participants have been shown to have better outcomes as compared to patients not in clinical trials even if they do not receive the new treatment.



Harry Colfer, MD
CARDIOLOGIST,
INTERNAL MEDICINE
McLAREN NORTHERN
MICHIGAN
MICHIGAN HEART
& VASCULAR
SPECIALISTS

In this issue...

Revised Common Rule Coming Soon

PAGE 3

Self-Auditing for Quality Part 2

PAGE 4

New Resident Research Submission Process

PAGE 6

What's New?

PAGE 6

CONTINUED ON NEXT PAGE



Revised Common Rule Coming Soon

On January 18, 2017, the Federal Policy for the Protection of Human Subjects, or Common Rule, was updated for the first time since its publication in 1991. The explicit goal of these revisions—the result of collaboration between the US Department of Health and Human Services and 15 other Federal Departments and Agencies—is to reduce administrative burden and better protect subjects in the modern research context.

McLaren has been following the revised Common Rule activities very closely in the past year. Changes to the Common Rule were initially scheduled to go into effect January 19, 2018. That date has now been postponed and changes are now scheduled to go into effect on July 19, 2018.

Below is overview of the major regulation changes (also available on the MHC HRPP website):

- **Continuing Review**

No longer required for some minimal risk research including studies where the only remaining activity is the analysis of identifiable data/bio specimens or activity to obtain follow-up clinical data. IRB will still require an update every year through an Institutional Annual Status Report form. Remember that the requirement to submit modifications, reportable events, and final reports to the IRB has not changed. – **Effective July 19, 2018**

- **Informed Consent**

A new information section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not. Consent forms and discussions will now require a concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document. The IRB will not require re-consent, except when other significant changes are made. – **Effective July 19, 2018**

- **Exemptions**

New categories and clarification of existing categories. Effective July 19, 2018, the current federally-defined exemption categories for human subjects' research will change. Some exemptions may require "limited IRB review" (similar to an expedited review process). – **Effective July 19, 2018**

- **Single IRB-of-Record (sIRB)**

IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based). – **Effective January 20, 2020**

MHC IRB policies, procedures, and systems will be updated to transition to the New Rule.

.....

3. What is the significance of this research to you personally and professionally? Why do you believe that research matters?

As professionals, we have an obligation to provide the best care possible for our patients, communities and employers. To do this we need to be constantly learning and when possible adding to the knowledge about our profession. Research and clinical trials are an important means of meeting these obligations. To feel that I am contributing to the value of our profession through clinical research gives meaning to my work day beyond the satisfaction of serving my patients and providing for my family.





EQUIP Corner

Self-Auditing for Quality Part 2

By Patricia Ivery, QI and Education Specialist, McLaren Health Care

We ended part 1 of this article by introducing the **PDCA (PLAN, DO, CHECK and ACT)** model for quality assurance, which is often used by industry sponsors. The PDCA cycle is very similar to the FDA mantra for a quality system: “Say what you do; Do what you say; Prove it; Improve it .”

There are 3 key **PLAN** components to ensure and monitor quality in a clinical trial. First, ensure every research team member is trained and educated on human subject assurance, the protocol, applicable regulations (either or both the Common Rule and FDA regulations), internal SOPs, institutional policies and GCP guidelines – before the trial starts. Second, develop a self-audit tool. This tool lists quality indicators for different aspects of trial activities, i.e. consenting process, documentation in subject files, etc. The quality indicators define the “expected behavior or outcome” and are based on GCP guidelines, federal regulations and institutional policies. There is no need for investigators at MHC to create something from scratch, as a template self-audit checklist is available on the HRPP website. This template is very comprehensive, examining every aspect of a clinical trial. Use it as a guide and decide what aspects of the audit tool apply to your study. Third, get the research team on board with self-auditing for quality, which includes assigning the individual to conduct the audit and determining when the audit should be conducted.

PLAN to DO at least one self-audit during the course of a trial. A Duke University study found that performing a series of audits during the course of a study is more revealing and effective than conducting a single audit. Each site must decide the frequency, focus and number of the trials to self-audit.

If you don’t have the time and resources to conduct a comprehensive audit of every trial, tailor the self-audit to focus on specific area of research. Look at your history of deviations or sponsor monitor findings. Ask yourself, “is there a trend or repeated findings noted within an individual study or across all studies?” Other triggers to prompt self-audit include, high enrolling studies, high-risk studies, changes in processes/policy, or history of FDA warning letter. Whatever your plan, take action. Do what you said you were going to do.

No clinical research is free of quality issues during the life of a clinical trial. Once you have completed the audit you need to perform a quality control **CHECK** by looking at the self-audit findings and verify adherence or deviations from quality. Keeping a spread sheet or table displaying trends and problems throughout the

Brown Bag Series

Corrective Action Plans: How to Move Forward When the Unexpected Happens

April 10, 2018 • 12:00 noon - 1:00 pm

LIVE WEBINAR

Registration is required. Contact Markeda Richards via email at markeda.richards@mcclaren.org to be put on notification list.

Upcoming Education and Conferences

CAAHRPP Annual Conference

April 20 - 22, 2018 • Denver, CO

ACRP Annual Conference

April 27 - 30, 2018 • Washington, DC

MAGI Clinical Research Conference

May 20 - 23, 2018 • San Diego, CA

conduct of the trial will be helpful. Assess the scope, source and significance of any deviations you find by asking the following questions:

Did the deviation:

1. Occur once or multiple times?
2. Occur in one subject or multiple subjects?
3. Occur in one study or multiple studies?
4. Involve one staff member or multiple staff members?
5. Cause or have the potential to cause harm to subjects?
6. Impact or have the potential to impact the integrity of the data?
7. Occur after implementation of a new process or change in existing processes?

containment or correction. Significant findings are those deviations or problems that are: minor but happen frequently, impact the welfare and safety of subjects or affect the credibility of the data. Significant findings must be escalated up to the creation of a formal corrective action preventative action (CAPA) plan. Remember, all deviations from quality require a correction, but not all corrective actions require preventative actions.

Guidance on writing a CAPA plan can be found on the HRPP website, along with the Office of Research Compliance self-audit tool. The upcoming brown bag in April will focus on writing an effective CAPA. In addition, you are encouraged to contact the Office of Research Compliance for assistance in writing or reviewing your CAPA. Remember, an effective, documented and implemented CAPA makes your site favorable in the eyes of the sponsor and government regulators. It can make the difference between a study remaining open or being closed.

The PDCA cycle is a continuous cycle and the steps in the cycle are repeated. There is no end point, which ensures continuous quality improvement.

The next step in the PDCA cycle is **ACT**. Act on deviations from quality. Any findings that indicate actual or potential harm to subjects require immediate action. **If the problem is minor (not critical and not significant) and there's a solution that can be performed** immediately and sufficiently, then the quality event can be closed with an effective

Certifications and Acheivements



Charlotte Brown successfully passed the Society of Clinical Research Associates (SoCRA) Certified Clinical Research Professional

(CCRP) exam in October 2017.



Carol Wells Clinical Research Coordinator I Karmanos Cancer Institute at McLaren Bay Region
Start Date: January 15, 2018

In her previous position, Carol assisted cancer patients obtain financial support for cancer treatment through a foundation dedicated to the promotion of the control and cure of cancer.



Sarah Salich Clinical Research Coordinator I Karmanos Cancer Institute at McLaren Flint
Start Date: February 5, 2018

Previously employed as a Patient Service Representative at our Owosso Radiation.



Resident Corner

New Resident Research Submission Process

If you are a resident doing a scholarly project, you must meet with your faculty mentor, PhD researcher, and program director to discuss your project and determine its feasibility and type of study design. Beginning January 15, 2018 all scholarly projects must be planned, designed, and written using Protocol Builder and follow the process shown in figure 1 on the next page.

Please note that the IRB will not accept your eProtocol application until you first submit a “Request for human subject research determination” and the IRB has determined your project human subject research. This process will eliminate unnecessary IRB submissions and will streamline the quality of resident IRB submissions overall.

Figure 1, on the next page, describes the process residents must follow when planning and designing scholarly projects.

What’s New?

Feasibility Review Committee

McLaren Center for Research and Innovation has embarked on an initiative to create a more robust and formalized process to better determine true study feasibility. This initiative has resulted in the MCRI Feasibility Review Committee (FRC). Membership is growing, however, our current members are:

Mark Zainea, MD, Chairperson; Rebecca Avers; Ron Cosson; Rachel Dick; Tanya Gardner-Mosley; Jill George; Elvira Harrison; Kelly Kayner; Perr Meyer; and John Silveri. Ex-Officio members include: Hesham Gayar, MD; Lana Gevorkyan and Chandan Gupte.

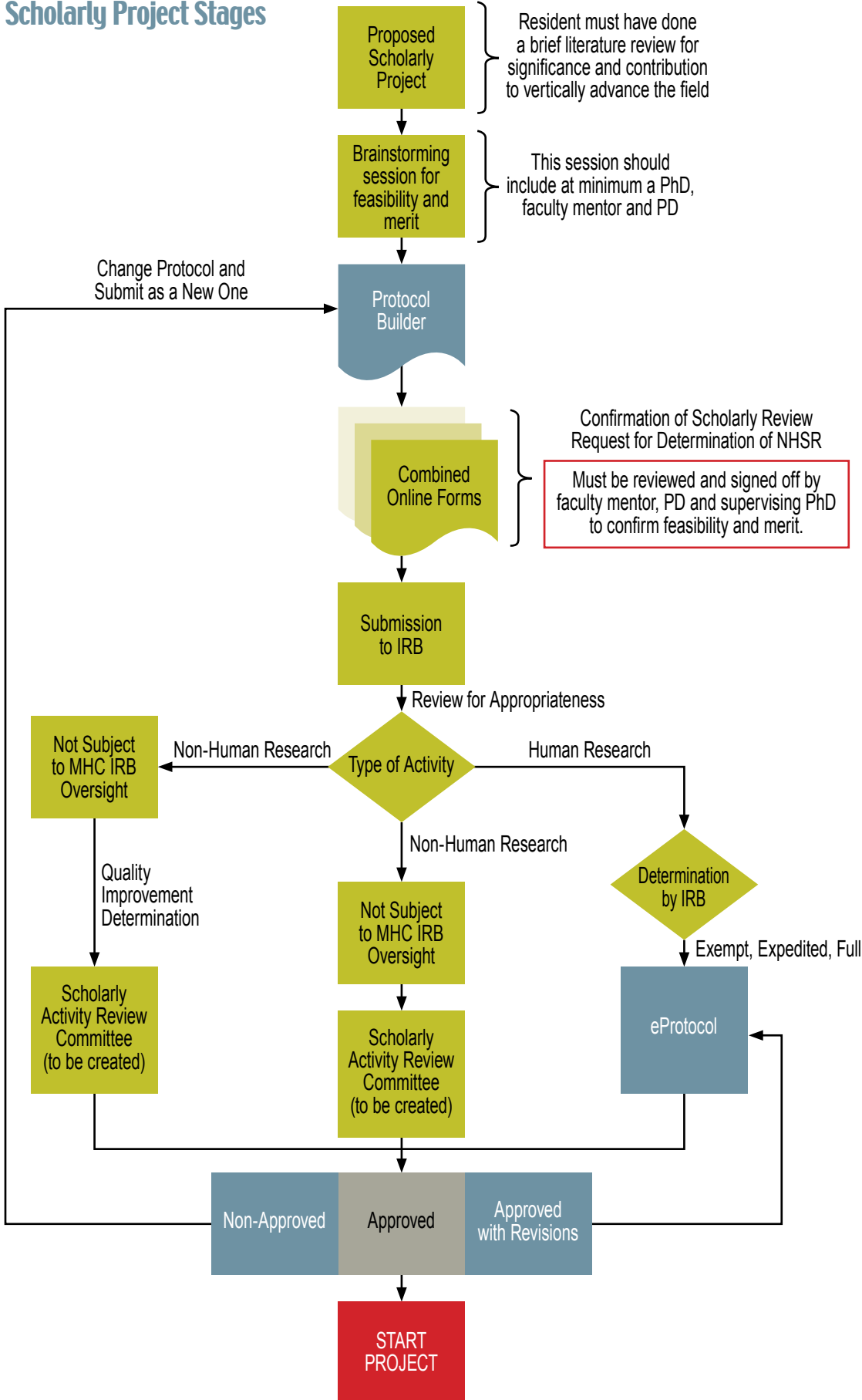
FRC meetings will be scheduled the last Tuesday of the month, and every MCRI study will go through this process. PRC, for those studies required to be reviewed for scientific merit, will still be held the following week on the first Tuesday of the month.

Neuroscience Research Council

McLaren’s Neuroscience Research Council (NRC) has been established to guide the service line’s research efforts in support of the mission and vision of our

CONTINUED ON PAGE 8

FIGURE 1
Scholarly Project Stages



For questions about this new process, Protocol Builder, or to get an account set up for Protocol Builder, please contact Dr. Carlos Rios-Bedoya, M.P.H., Sc.D., Corporate Director of Scholarly Inquiry at carlos.rios@mclaren.org.

What's New?

CONTINUED FROM PAGE 6

research program. NRC will function as the leadership body focusing on initiatives in neuroscience research, strategic collaborations, and will provide support to all neuroscience research activity across all subsidiaries of McLaren Health Care. NRC is composed of the following members:

Aniel Majjho, MD, Chairperson; Malaz Almsaddi, MD; Chaim Colen, MD; Avery Jackson, MD; Robert Levy, MD; Sunil Manjila, MD; Linda Peterson, MD; Bharath Naravetla, MD; Kalil Nasrallah, MD; Gregory Norris, MD; Veronica Sesi, DO; and Barbara Wolf, PhD. Ex-Officio members include: Hesham Gayar, MD; Michael McKenna, MD; Chandan Gupte; Lana Gevorkyan; and Jill George.

Introducing Multisite capability in eProtocol

As the McLaren research infrastructure has grown, we have seen an increase in the same study being conducted at more than one McLaren site. The process for submitting such studies was cumbersome, as each site was required to complete an IRB application. Recently, new functionality in the eProtocol system was introduced to simplify the process of submitting multi-site studies.

This new functionality provides an abbreviated site-specific submission form for McLaren investigators wishing to join studies

that are already open with the MHC IRB, shortening the submission process and increasing efficiency. The new process will also eliminate redundancy, as there will be no need to provide duplicative information when additional sites/investigators join existing studies. If you have any questions regarding this new capability, please reach out to the Research Integrity office at (248) 484-4953.

Revised Policies

The following categories of policies have been revised:

- Overview of the McLaren Health Care Human Research Protections Program
- IRB Governance and Operations
- IRB Reviews Process
- Informed Consent
- Human Subject Participants
- Operational Guidelines for the IRB
- The Research Team

A full list of current HRPP policies can be found on our website at: <http://www.mclaren.org/main/research-policies1.aspx>

McLaren Corporate Research
2701 Cambridge Court, Ste. 110
Auburn Hills, MI 48326

Office of Clinical Excellence
VICE PRESIDENT
Chandan Gupte
chandan.gupte@mclaren.org

Corporate Research Administration
CORPORATE DIRECTOR
Lana Gevorkyan
lane.gevorkyan@mclaren.org

Research Integrity (formerly HRPP)
hrpp@mclaren.org
(248) 484-4950

IRB ANALYSTS
Jodi Reetz
jodi.reetz@mclaren.org
Katherine Pittel
katherine.pittel@mclaren.org

RESEARCH INTEGRITY COORDINATOR
Markeda Richards
markeda.richards@mclaren.org

QI & EDUCATION SPECIALIST
Patricia Ivery
patricia.ivery@mclaren.org

McLaren Center for Research and Innovation
mclaren.org/Main/Research.aspx
(248) 484-4960

CORPORATE RESEARCH MANAGER
Jill George
jill.george@mclaren.org

REGULATORY SPECIALIST
Tanya Gardner-Mosley
tanya.gardner-mosley@mclaren.org

CONTRACT AND BUDGET SPECIALISTS
Rachel Dick
rachel.dick@mclaren.org

Karmanos Cancer Institute Clinical Trials Office

VICE PRESIDENT
Lisa Lange
langel@karmanos.org

DIRECTOR
Maureen Kelley
kelleym@karmanos.org

MANAGER
Elizabeth Bowie
bowiee@karmanos.org

CRC-REGULATORY
Vidya Yarlaga
yarlagas@karmanos.org

