

RESEARCH

SPRING 2019

Matters

IN THIS ISSUE...

**Passion to Impact Public Health Drives
Research Focus of Vascular Surgeon**

PAGE 2

Neuro Research Expands at McLaren

PAGE 3

Taking Steps Toward Ending Disparities

PAGE 4

Changes for Radiation Oncology Research

PAGE 5

**Coordinator Role Encompasses Multiple
Responsibilities**

PAGE 6

New Revised Common Rule Has Arrived

PAGE 8



DOING WHAT'S BEST.®

RESEARCH AROUND McLAREN



Nicolas Mouawad, MD

“ IT IS REWARDING TO BE INVOLVED IN STUDIES THAT CAN IMPROVE HEALTH OUTCOMES AND IDENTIFY EFFECTIVE TREATMENTS FOR THE POPULATION AS A WHOLE. ”

– Nicolas Mouawad, MD

PASSION TO IMPACT PUBLIC HEALTH DRIVES RESEARCH FOCUS OF VASCULAR SURGEON

Nicolas Mouawad, MD, MPH, MBA, combines a love of medicine with a continuing quest for knowledge as one of McLaren’s more active research leaders. A board certified, fellowship trained vascular surgeon, Dr. Mouawad is chief of the Division of Vascular and Endovascular Surgery at McLaren Bay Region and medical director of its non-invasive Vascular Laboratory.

“My interest in research stems from a strong desire to give back in terms of impacting overall public health,” noted Dr. Mouawad, who holds master’s degrees in both public health and business administration. “It is rewarding to be involved in studies that can improve health outcomes and identify effective treatments for the population as a whole.”

Dr. Mouawad noted he was drawn to vascular surgery because of the comprehensive nature of the specialty.

“Everything in the body has a blood supply so, as a vascular surgeon, I am not relegated to one site or another,” he said. “I also enjoy the rapport I develop with my patients and the opportunity to perform both minimally invasive procedures as well as open procedures as appropriate.”

Dr. Mouawad is currently involved in three key research initiatives at McLaren Bay Region. He is the principal investigator for an upcoming national study called the Chocolate Touch Balloon Study. This study is investigating the efficacy of a balloon coated with the drug paclitaxel as compared with conventional balloons in restoring blood flow to the leg. The study has recently received IRB approval at McLaren and patient enrollment is underway.

Another national study coming soon is EVAS2, which is investigating the effectiveness and safety of a brand new device to treat abdominal aortic aneurysms. Dr. Mouawad noted there are fewer than 20 sites in the United States that will be involved in this study.

“McLaren Bay Region is extremely honored to be selected as a site for this study, largely due to the volume of aneurysms that we treat,” noted Dr. Mouawad, who is the principal investigator on this study.

A third study nearing the end of the IRB approval process is an international study called BEST-CLI. This study is comparing bypass surgery to stenting (endovascular) in the treatment of peripheral artery disease.

“Most of the country is involved in this study, including the vascular group at McLaren Flint,” he said.

Along with research that involves devices and procedures, Dr. Mouawad led an initiative that utilized financial and quality assurance data to demonstrate that developing a dedicated vascular team in the hybrid operating room increases efficiency and financial viability. He shared these results in a podium presentation for the Society of Clinical Vascular Surgery in March of 2018.

He has also authored or co-authored more than 45 peer-reviewed articles and presented his work at more than 60 international, national, regional and local conferences and symposia. Further, he serves as a reviewer for many medical journals, including *Annals of Vascular Surgery*, *Journal of Vascular Surgery* and *European Journal of Cardiovascular Nursing*.

NEURO RESEARCH EXPANDS AT McLAREN

As the physician team of neurologic specialists has expanded over the past year, so has the manpower to undertake additional studies related to neuroscience research.

Mahmoud Rayes, MD, a board certified and fellowship trained interventional neurologist, joined McLaren in August of 2018, working with fellow interventional neurologists Aniel Majjhoo, MD, and Bharath Naravetla, MD, in providing highly specialized services to patients suffering from stroke and neurological brain disorders. He has also enthusiastically joined these colleagues as an investigator on key research studies at McLaren.

“I have found that certain diseases and conditions can either frustrate or fascinate,” he said. “I don’t like to be frustrated. The draw of research for me is figuring out better ways to treat disease and impact patients’ lives for the better.”

One of Dr. Rayes’ key areas of interest is cryptogenic stroke, which is a stroke that has no known origin. He first became involved in research involving cryptogenic stroke at his previous practice in South Carolina and is continuing as a sub-investigator in the upcoming Arcadia study at McLaren, which is open to enrollment.



Mahmoud Rayes, MD

ARCADIA is a multicenter phase III trial that will study the role of abnormalities in the structure and function of the heart’s left atrium (atrial cardiopathy) in stroke patients, and test a medication that could prevent them from experiencing recurrent strokes.

Patients who experience a cryptogenic stroke are generally advised to take an aspirin daily. However, there is evidence that atrial cardiopathy can cause clots to travel to the brain in the same way as atrial fibrillation, and thus could be responsible for many of these cryptogenic strokes.

This trial will provide insight into whether atrial cardiopathy really is an important risk factor for stroke and will test the hypothesis that the anticoagulant apixaban is superior to aspirin for the prevention of recurrent stroke in subjects with cryptogenic ischemic stroke and atrial cardiopathy.

The trial is sponsored by the National Institute of Neurological Diseases and Stroke (NINDS) and involves 120 sites in the StrokeNet consortium, including McLaren.

Another upcoming trial is MOST (Multi-arm Optimization of Stroke Thrombolysis), which will study if combining t-PA with 2BA inhibitors makes the administration of t-PA more potent. Dr. Rayes noted this study should begin at McLaren within the next 3 months after IRB approval.

In citing other achievements in neuro research, Dr. Rayes noted that McLaren ranked third among all sites nationally for patient enrollment in the Target Intracranial Aneurysm Coiling Registry. This study is looking at outcomes of particular types of coils relative to specific technical and clinical measures. With patient enrollment complete, the study is now closed to additional patients and is in the clinical follow-up phase.

ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

For information on enrolling in a clinical trial please visit our website at <https://www.mclaren.org/main/research-trials1.aspx>. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

We have enrolling studies for the following conditions (not a complete list):

- Diabetes
- High Blood Pressure (Hypertension)
- Stroke
- Heart Attacks / Heart Failure / Heart Disease
- Kidney Diseases
- Lung Diseases
- Peripheral Artery Disease
- Carotid Artery Disease
- Mastectomy
- Various Cancers
 - Breast
 - Lung
 - Prostate
 - Multiple Myeloma
- Patients who underwent intracranial aneurysm coiling
- Drug study for patients with recent acute coronary syndrome

For a complete list of conditions, please visit our website listed above.

RESEARCH AROUND McLAREN

Faculty Director of OCHECE is Hayley Thompson, Ph.D. (third from left). Staff include (L-R) Voncile Brown-Miller, Sara Kim, Dr. Thompson, Knoll Larkin, Carie Francis and Lezina Topciu.

Photo by Timothy Haurert



TAKING STEPS TOWARD ENDING DISPARITIES

New outreach program engages communities across Michigan

There is no population group in America that cancer doesn't touch. But the disease hits some harder than others.

Numerous cancer health disparities affect groups defined by race, ethnicity, gender/sexual identity, geographic location, income and other factors.

For example, Hispanic women have higher rates of cervical cancer than women of other ethnic groups, according to the American Cancer Society. African American women have the highest death rate from this disease. People with lower education levels are more likely to die before age 65 from colorectal cancer than people with more education.

As a National Cancer Institute-designated Comprehensive Cancer Center, Karmanos Cancer Institute has always focused on eliminating cancer health disparities. Now, Karmanos launched a community outreach and engagement program called Michigan Cancer HealthLink to better integrate its efforts to tackle the problem.

The outreach efforts, coordinated by Karmanos' Office of Cancer Health Equity and Community Engagement (OCHECE), will cover a 46-county area across Michigan.

"We want to connect with people in communities where cancer is a huge issue," says Hayley Thompson, Ph.D., associate center director for Community Outreach and Engagement at Karmanos. "We're asking for their input on what research areas are important to them. Those ideas will inform the focus of our cancer health disparities efforts."

Through the OCHECE and HealthLink, Karmanos has formed Cancer Action Councils in partnership with community-based groups such as LGBT Detroit and ACCESS (Arab Community Center for Economic and Social Services). Council

“ THE MISSION OF THE OCHECE IS TO ELIMINATE CANCER HEALTH DISPARITIES IN MICHIGAN BY PROMOTING COMMUNITY-ENGAGED RESEARCH AND SUPPORTING FAIR ACCESS TO THE FULL CONTINUUM OF CANCER CARE FOR ALL POPULATIONS. ”

members include cancer survivors, caregivers and advocates. They identify research priorities and develop specific research questions relevant to cancer care and outcomes in their community, group or demographic.

In addition to the six councils located in Wayne County, other areas will include Mt. Clemens, Southfield and Burton, in the Flint area. By leveraging the reach of the Karmanos Cancer Network's 15 locations, councils will eventually extend across the state.

"The first three councils have identified 17 research areas and 81 specific research questions," Thompson says. "Some of those areas are cancer caregiving, the financial burden of cancer treatment, and family health history and genetic risk of cancer. With that input, we can connect the councils with people at Karmanos with expertise in those research areas."

Researchers are already taking steps to address council concerns. Mark Manning, Ph.D., assistant professor in the Department of Oncology at Karmanos and Wayne State University School of Medicine, is developing a smartphone app to help users collect and share their family health histories. Assistant Professor of Population Studies Lauren Hamel has developed a prototype of an app that generates a list of questions to help patients talk to their physicians about the costs of their cancer treatments.

"Karmanos physicians and researchers bring a certain expertise to cancer through their training, education and clinical experiences, but we know cancer patients and their families are also experts," Thompson says. "They're living with cancer on the front lines. They observe how cancer impacts their lives and communities in ways we don't necessarily see. Integrating their expertise with our clinical experience will result in stronger science and better cancer outcomes."

NEW CHANGES FOR RADIATION ONCOLOGY RESEARCH

The Karmanos Cancer Institute has made a significant investment into radiation oncology research that is translating into new and exciting treatments for our patients. Through a systematic program to coordinate resources and access, a robust array of clinical trials is being offered at twelve radiation oncology centers. This sustained excellence to the clinical research mission allowed Karmanos to be one of the top accrual sites for NRG CC001, a national clinical trial for patients with brain metastases in which they were randomized to standard of care whole brain radiation therapy or hippocampal avoidance whole brain radiation therapy. **Kiran Devisetty, MD**, the local primary investigator who also had the top accruals within the system, was subsequently named as a co-author on this seminal study. The paradigm shifting results received national attention as they were plenary presentations at both the American Society for Radiation Oncology (ASTRO) and Society for Neuro Oncology (SNO) 2018 annual meetings and the American Academy of Neurology (AAN) 2019 annual meeting. The final paper will be published in a high impact journal in the near future.

LEARN MORE

To learn more about a Cancer Action Council in your area or how to become involved in Karmanos' efforts to end cancer health disparities, visit cancerhealthequity.org.



Kiran Devisetty, MD
 Medical Director, Karmanos
 Cancer Network Radiation
 Oncology Research
 Clinical Assistant Professor,
 Wayne State University
 Clinical Associate Professor,
 Michigan State University
 Karmanos Cancer Institute at
 McLaren Flint

RESEARCH AROUND McLAREN



COORDINATOR ROLE ENCOMPASSES MULTIPLE RESPONSIBILITIES

Kelly Kayner calls it a “gift” to be able to work with patients who volunteer to participate in research studies through McLaren. She emphasizes to her patients that they are presenting future patients with a gift that keeps on giving as well.

“These people are truly medical heroes,” said Kelly, who is a research coordinator with McLaren Center for Research and Innovation at McLaren Bay Region. “They are helping to pave the way for potential new treatments and cures that will not only benefit them but their family members and future patients as well.”

Kelly, a bachelor’s level RN, is also a certified clinical research coordinator with the Association for Clinical Research Professionals. The passion Kelly exhibits for her role with the research team is evident through her enthusiasm, care and concern for not only the patients she works with but also for fellow colleagues on the research team.

She is one of 11 research coordinators who work for the McLaren Center for Research and innovation (MCRI) to facilitate non-oncology research studies across the McLaren system. This involves providing key information about a potential study to physicians and clinical staff as well as educating research participants and families.

“When we receive a potential study, our first priority is to determine how to provide the safest care for our subjects in a manner that is consistent with the study protocol,” Kelly noted in further describing the research coordinator’s role. “In order to do this, we meet with each department that may have a role in the study to assess their capabilities, concerns, and study support. Enthusiasm and education is essential at this level to assist in building a project team.”

Kelly explained that many different departments may come together to focus on the protocol specific requirements. Without the entire team involvement, the protocol does not make it to the site.

Working closely with the team members at the Corporate Research Administration Office is vital to the successful start-up of clinical trials at McLaren. Research coordinators assist the pre-award department with the budget planning by assessing how much time will be spent by each member of the team. They work with the research manager to determine the protocol’s feasibility and what resources are needed to execute the trial at their location. Coordinators also work with the regulatory specialists to facilitate submission and reporting requirements from the study sponsor, Institutional Review Board (IRB) and FDA.

Attending investigator meetings held by the sponsor of the study are just one of the ways research coordinators educate themselves on the important aspects of each trial. These sessions provide valuable information, training, and updates that the

“ WHEN WE RECEIVE A POTENTIAL STUDY, OUR FIRST PRIORITY IS TO DETERMINE HOW TO PROVIDE THE SAFEST CARE FOR OUR SUBJECTS IN A MANNER THAT IS CONSISTENT WITH THE STUDY PROTOCOL. ”

– Kelly Kayner

coordinator then brings back to educate the other members of the research team.

Kelly noted the enrollment phase is her favorite part of the study. When presenting a study to a patient, she takes time to educate the patient and their family on their disease process and the research-related commitment.

“We want them to have a full understanding so they have a comfort level with the research participation,” she said. “As clinical research is voluntary, our patients may choose to decline participation if they cannot commit to the clinical follow-up or research-related responsibilities. All research participants are required to sign an informed consent form before any research activity takes place.”

Other aspects of the research coordinator’s role includes follow up visits with research participants.

“During this time, our clinical skills are utilized,” Kelly said, noting this includes collection of subject’s data while completing tasks such as vital signs, EKG’s, collection of lab specimens, medication compliance, and adverse events. The data collected during this visit is then assessed by the principal investigator and provided to the sponsor after entry into the electronic data system.

Kelly stressed that coordinators are in a constant state of learning. For example, in order to send labs, they must be Saf-T-Pak certified. CITI (Collaborative Institutional Training Initiative) training is also essential for every member of the research team. Training such as CITI provides validation of good clinical practice, human subjects protection training, and other critical components of research to make certain that research is conducted in a manner that is compliant with the regulations and supports patient safety while providing exceptional data to the sponsor. In addition, each study has their own protocol specific training.

“My passion for research stems from knowing that I am helping to provide a product or service to a patient that may not be available otherwise,” she said. “When a patient might have lost hope, we may be able to give that back to them. Being a part of research means that patients may be getting health care that otherwise would not be available or affordable. Our patients put their trust in us, and we all become like family. It is very humbling and rewarding at the same time. I wouldn’t do anything else.”

“OUR PATIENTS PUT THEIR TRUST IN US, AND WE ALL BECOME LIKE FAMILY. IT IS VERY HUMBLING AND REWARDING AT THE SAME TIME. I WOULDN’T DO ANYTHING ELSE.”

– Kelly Kayner

KARMANOS CANCER INSTITUTE AND WAYNE STATE UNIVERSITY AWARDED PRESTIGIOUS GRANT

Karmanos Cancer Institute in Detroit and its academic partner Wayne State University received the prestigious LAPS Grant (Lead Academic Participating Sites) for the second time. The LAPS Grant is a national recognition honoring outstanding clinical and academic leadership who help advance cancer research.

A National Cancer Institute-designated comprehensive cancer center since 1978, Karmanos has consistently met and exceeded clinical trial enrollment accruals to advance science and help make new cancer therapies available to more cancer patients. In addition, Karmanos experts have played an important role in both scientific and administrative leadership roles, serving on national task forces and committees and authoring/co-authoring several abstracts and manuscripts. This outstanding achievement is a testament to the leadership, collaboration and commitment of our clinical, science and academic leaders.

Congratulations and thank you for your commitment to help end cancer.

EQUIP CORNER

THE NEW REVISED COMMON RULE HAS ARRIVED

By Marybeth McCarthy

On January 19, 2017, the Department of Health and Human Services (DHHS) published in the Federal Register the final rule to revise the Common Rule. This was the first revision since the time of original publication in 1991. On January 21, 2019, this revised Common Rule has finally come into full effect. The focus of this article is to review the significant changes and how those changes will impact current and future studies at McLaren Health Care.

What exactly is the Common Rule and Why Was it Changed

The DHHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy mandating the protection of human subjects or the “Common Rule”; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Regulations under the Common Rule covered research funded or supported by HHS.

The Common Rule regulations are separate from FDA regulations. FDA regulations have NOT changed; however, the FDA may harmonize their regulations to the Common Rule in the future.

The Common Rule was revised to ease administrative burdens on researchers, enhance human research protections through meaningful informed consent and modernize the regulations to be consistent with technological advances. In federal language, the new regulations are referred to as the “2018 Common Rule Requirements” and the expiring regulations are referred to as the “Pre-2018 Common Rule Requirements.” The major revisions to the Common Rule include changes in **informed consent, continuing review requirements, exemption categories, and clinical research definitions.**

Informed Consent Changes

Patients considering joining a research study are often overwhelmed with the decision-making process. The motive behind the changes and reorganization to the informed consent form (ICF) is to facilitate a potential subject or legally authorized representative in understanding the reasons why one might or might not want to participate in research. Simply stated, we want to aid in their comprehension. The primary change in the ICF is the inclusion of “**Key Information**” section*. This key information is required to be at the top of the informed consent, although the same information is detailed out elsewhere in the remainder of the ICF document (Figure 1).

Another change in ICF is the **addition of new basic elements** to the language (Figure 2).

A further change in the consent process includes a **modification in the “criteria for waiving or altering the informed consent.”** A waiver of informed consent for the secondary use of identifiable private information/biospecimens must justify why the use of identifiers is necessary to carry out the research. Also, the use of identifiable information/biospecimens to identify potential subjects (i.e., screening for recruitment purposes) is allowed without informed consent under certain circumstances.

Changes in the Requirement for Continuing Reviews

Under the previous Common Rule, non-exempt studies were required to undergo an annual, or continuing review by the IRB. Under the revised Common Rule, unless the MHC IRB determines otherwise, continuing review of research is not required for the following:

Figure 1.

*THE “KEY INFORMATION”

- A statement that the project is research and participation is voluntary
- A summary of the research, including purpose, duration, and list of procedures
- Reasonable, foreseeable risks or discomfort
- Reasonable, expected benefits
- Alternative procedures or course of treatment if any

- Research eligible for expedited review-minimal risk studies
- Research reviewed by the IRB in accordance with limited IRB review to ensure privacy and confidentiality are protected
- Research that has progressed to the point that it involves only data analysis or accessing follow up data

It is important to note the MCH IRB may still require continuing review of research that falls into the categories above when the following is applicable:

- Other applicable regulations require continuing review (e.g., FDA regulations have not changed)
- The research involves topics, procedures, or data that may be considered sensitive or controversial.
- The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability.
- An investigator has minimal experience in research
- An investigator has a history of non-compliance
- An amendment or report reveals new findings that require additional oversight

If the IRB determines that a continuing review is required in one of the above circumstances, this will be communicated to the investigator in the IRB determination letter. Even if a study does not require a continuing review the study team is required to:

1. Complete an **Annual Status Report**. This report lets the IRB know the study is still active.
2. Continue to submit modification applications such as changes to personnel, recruitment material, etc.
3. Report events such as UPIRSOs, SAE's, deviations.
4. Final report when the study is complete.

Take note, that when modifications, reportable events, or annual status reports are submitted, the IRB will evaluate if a continuing review is required.

New and Revised Exempt Categories

The revised Common Rule has added new exemption categories and clarified some of the existing categories. Also, new exempt determination processes will be applied in certain circumstances. In brief:

- Changes in category 1 and 2 were revised to place more restrictions on educational research.
- Category 3 replaces the previous category 3 exemption. This category covers benign behavioral interventions. Essentially, research involving benign behavioral interventions must be brief, harmless, painless, non-invasive, and not likely to impact/embarrass or offend subjects.
- Category 4 deals with the collection or study of existing data, documents, records, pathological specimens or biospecimens that were publicly available, and could not be identified. Changes in this category allow for **secondary research** for which consent is not required if one of the following criteria are met: use of publicly available identifiable private information or identifiable biospecimens OR the identity of the subjects cannot be readily ascertained OR research use of identifiable health information when that use is regulated by HIPAA OR analysis of data on behalf of a federal agency or department.
- Category 5 covers research conducted by or subject to the federal agency designed to study public benefit or service programs. New revisions category is designed to improve not just evaluate public benefit or service programs.
- Other categories: Category 6 is unchanged. Category 7 and 8 are new categories involving broad consent but, **not adopted** by McLaren Health Care.

Figure 2.

CHANGES IN BASIC ELEMENTS OF ICF LANGUAGE

- When research involves the collection of identifiable private information or identifiable biospecimens: Add a statement that identifiers might be removed, and these biospecimens may or may not be used for future research.
- If the project involves the use of biospecimens: Add a statement indicating whether biospecimen may be used for commercial profit, and the subject will share in that profit.
- If the project involves clinically relevant results: A statement whether the clinical results, including individual research results, will be returned to the subject, and if so under what conditions.
- If the project involves whole genome sequencing: A statement indicating that the research will or might include whole genome sequencing.

BROWN BAG SERIES

Statistics in Clinical Research: Understanding Protocols and Statistical References

Guest speaker Dr. Carlos F. Rios-Bedoya, Corporate Director of Division of Scholarly Inquiry
March 12, 2018 12-12:45

LIVE WEBINAR

Research Jeopardy How Much Do You Know About Conducting Research?

June 11, 2019 12:00-12:45

LIVE WEBINAR

UPIRSO

What Do I Need to Know?

September 10, 2019 12-12:45

LIVE WEBINAR

To register contact Marybeth McCarthy at 248-484-4987 or Marybeth.mccarthy@mclaren.org.

UPCOMING RESEARCH EDUCATION

MAGI Clinical Research Conference

Orlando, FL
March 3-6, 2019

ACRP Annual Conference

Nashville, TN
April 12-15, 2019

AAHRPP Conference

National, TN
May 21-23, 2019

SOCRA 28th Annual Conference

San Antonio, TX
September 27-29, 2019

New and Revised Terms

Clinical Trial – Per the Common Rule and NIH Policy, clinical trial means “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” The new requirement for this definition is that an informed consent form must be posted on a federal website after the clinical trial has closed to recruitment, no later than 60 days after the last study visit.

Human Subject – Redefined as a living individual about whom an investigator is conducting research:

- i Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- ii Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Interaction – communication or interpersonal contact

Intervention – physical procedures/environmental manipulations by which information or biospecimen are gathered.

Research – The Common Rule defines research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Activities, which meet this definition, constitute research whether they are conducted or supported under a program, which is considered research for other purposes. The definition of “research” has been expanded to list activities specifically deemed not to be research, such as scholarly and journalistic activities and public health surveillance

Changes for MHC Researchers

All human subject research approved on or after 1/21/19, regardless of the submission date, will be reviewed in accordance with the Revised Common Rule as applicable. Most studies approved before the 1/21/19 effective date of the new rule will remain under the old rule until its next continuing review. At that point, it will transition to the new rule. All studies at the time of the next continuing review or significant modification affecting the informed consent form will be required to update the informed consent form to meet the Revised Common Rule requirement. Existing approved exempt studies will experience no changes.

Other changes that will be forthcoming are revisions in our HRPP and investigator manual. Policies will also be updated to reflect the Revised Common Rule. Until all of our policies are updated review the Addendum to HRPP/IRB Policies - 2018 Common Rule MHC_RP0500 Transition and IRB Review of Research Subject to the Revised 2018 Common Rule available on our website.

Summary

This article addressed significant but not exhaustive explanation of changes to the Common Rule. For a more detailed description visit our web site or check out the resources listed below*. If you have any questions, e-mail us at hrpp@mclaren.org, or call us at (248) 484-4950.

Resources

- McLaren Research Integrity website
- McLaren University – Recorded Webinar: Revised Common Rule and Impact on Researchers
- CITI Program Final Rule Resources: <https://about.citiprogram.org/en/final-rule-resources/>
- OHRP references:
 - <https://www.hhs.gov/ohrp/education-and-outreach/Revised-common-rule/Revised-common-rule-q-and-a/index.html>
 - <https://www.hhs.gov/ohrp/final-rule-delaying-general-compliance-Revised-common-rule.html>

CASE REPORTS: NO IRB NEEDED BUT INFORMED CONSENT REQUIRED

The Division of Scholarly Inquiry recently received a couple of similar requests from a McLaren resident and a faculty to guide them on where to find a consent form for case reports they wanted to write and publish. At that time, this was an unusual request because federal IRB regulations do not require consenting individuals for case reports (one patient) or case series (three cases or less). To our surprise, the journals where they wanted to publish the case reports were requiring the consent forms from the patients. One of the journals even wanted the patient to review the manuscript and give consent before submitting it to the journal for review.

Most peer-reviewed and PubMed indexed journals are requiring now some type of consent form for case reports or case series. Most journals even provide their own consent forms if the author's institution does not have one to consent patients. Recognizing this new trend/requirement from peer reviewed journals and to assist residents/fellows/faculty in their scholarly activities, the Division of Scholarly Inquiry developed four initiatives.

1. **Awareness.** To create awareness among all McLaren residents of this requirement from peer-reviewed journals for case reports and case series. This article is part of creating that awareness.
2. **Reviewing current practices at McLaren.** To determine if McLaren subsidiaries include any type of consent form among all the forms patients have to sign when admitted to the hospital to receive treatment. We found that all McLaren subsidiaries include a paragraph in their General Consent to Admission and Treatment form that mentions the use of deidentified patient data for scientific, education, case reports, and teaching purposes. However, this form does not specifically address that this deidentified patient data could be used for presentations at scientific meetings or manuscript publications.
3. **Consultation with experts in the area.** To initiate conversations with several compliance and legal personnel to assess if this General Consent to Admission and Treatment form that patients sign meets the research and ethical requirements journals are evaluating before accepting manuscripts for publication. Email communications have started to gather the opinion of people with expertise in this area.
4. **McLaren's Consent Form Template for Case Reports and Case Series.** Lastly, to review several examples of consent forms for case reports and case series from research intensive institutions, hospitals, and journals. We have reviewed over ten different examples of consent forms and have adapted one of them that could be recommended as a standard template for McLaren subsidiaries if a new form is needed. This template is currently under review and if needed will be sent to McLaren's Corporate Compliance for approval.

In the Division of Scholarly Inquiry, we have a commitment and responsibility to expedite and facilitate scholarly activity productivity for McLaren residents, fellows, and faculty. For additional information contact Dr. Carlos F. Rios-Bedoya at carlos.rios@mclaren.org

FACULTY, FELLOWS & RESIDENTS SCHOLARLY ACTIVITY NEWS



Carlos F. Rios-Bedoya, ScD

ANNOUNCEMENTS AND WHAT'S NEW



Lindsey Packer

Lindsey Packer is the new Corporate Manager for Non-Oncology. Most recently, she joined MCRI as a research financial analyst. She brings extensive research experience from Mayo Clinic in Minnesota, where she worked as a research coordinator and then as a program coordinator. Her research experience and responsibilities ranged from conducting and managing

multi-site clinical-trials, to grant writing and managing research contracts and budgets, as well as fund management. She has been with MMG at McLaren, where she was an operations manager for outpatient ambulatory clinics in the Lansing region.



Amy Locher

Amy Locher joined the Karmanos Cancer Institute Clinical Trials Office in November 2018. Amy is providing medical oncology and radiation oncology Research Nurse support to our Karmanos Cancer Institute locations in Clarkston and Bloomfield Hills. Amy obtained her Bachelors of Science in Nursing (BSN) from Oakland University in Rochester, Michigan. Amy has over thirteen

years of oncology nurse experience in the outpatient radiation and medical oncology settings with the last year and a half focused on oncology clinical trials. Welcome Amy!



Carolyn Harrison

Carolyn Harrison, BA, CCRP joined the Karmanos Cancer Institute Clinical Trials Office in January 2019. Carolyn is providing medical oncology and radiation oncology Clinical Research Coordinator support to our Karmanos Cancer Institute at McLaren Central Michigan location in Mt. Pleasant.

Carolyn obtained her Bachelors of Arts in Integrated Physiology from the University of Colorado in Boulder, Colorado. Carolyn has eight years of research experience in regulatory affairs, data management and clinical research coordination in the areas of gastrointestinal, lung and endocrine oncology as well as blood and bone marrow transplant research. Welcome Carolyn!



Patricia Ivery

Patricia Ivery, RN, MSN is the new Corporate Research Manager for Research Integrity. Patricia joined McLaren 5 years ago as a Quality Improvement and Education Specialist within the department of Research Integrity [formerly known as HRPP]. Patricia brings a wealth of knowledge and experience from all facets of

research. She has a proven track record of success in the research field which will be invaluable in meeting the departmental goals and objectives. Some of Patricia's responsibilities will include management of the MHC IRB, Research Compliance and Research Education.

CTMS UPDATE

McLaren Center for Research and Innovation continues the integration of the IBM Clinical Trials Management System (CTMS) to support research operations across McLaren Health Care. This software allows clinical research administration to streamline current workflows and efficiently manage study progress and finances.

IBM CTMS for Sites has been successfully implemented at five clinical research locations: McLaren Greater Lansing, McLaren Bay Region, McLaren Flint, McLaren Macomb, and McLaren Northern Michigan. A post 'Go-Live' Health Check has been completed for all sites except for McLaren Northern Michigan, which is expected to be completed in March 2019. Continued utilization of CTMS will drive research best practices and facilitate consistency in research operations across McLaren Health Care.



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

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

Corporate Research Administration

ADMINISTRATIVE ASSISTANT
Tamara Leo
tamara.leo@mcclaren.org

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

CORPORATE RESEARCH MANAGERS
Jill George
jill.george@mcclaren.org

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

Vidya Yarlagadda
vidya.yarlagadda@mcclaren.org

CONTRACT & BUDGET SPECIALISTS
Stephanie Edwards
stephanie.edwards@mcclaren.org

Research Integrity
hrpp@mcclaren.org
(248) 484-4950

IRB ANALYSTS
Katherine Pittel
katherine.pittel@mcclaren.org

Markeda Richards
markeda.richards@mcclaren.org

QI & EDUCATION SPECIALIST
Marybeth McCarthy
marybeth.mccarthy@mcclaren.org

CORPORATE RESEARCH INTEGRITY MANAGER
Patricia Ivery
patricia.ivery@mcclaren.org

Karmanos Cancer Institute Clinical Trials Office

VICE PRESIDENT
Lisa Lange
langel@karmanos.org

DIRECTOR
Maureen Kelley
kelley@karmanos.org

MANAGER
Elizabeth Bowie
bowie@karmanos.org