McLaren

RESEARCH

Matters

SPRING 2017

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Association for the Accreditation of Human Research Protection Programs, Inc.
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Communication is Key Says MCRI's First System-Level Principal Investigator

Kalil Masri, DO, a cardiologist specialized in advance heart failure and pulmonary hypertension with Bay Heart & Vascular, is serving as the first System-Level Principal Investigator (PI) in cardiology at McLaren. His involvement with the CardioMEMS HF System Post Approval Study includes participants from McLaren Bay, Macomb, Northern, and possibly Lansing in the near future. As the multi-site research model is expanded throughout the McLaren system, Dr. Masri shares his top tip for ensuring the success of the project.

"Communication is essential. This should be a priority for everyone that is involved. Monthly meetings are a 'must' to provide feedback and insight from the entire team. It is important to understand the needs of each location so that we function as a team versus individual sites. This may take extra time and dedication, but the goal is to reach more patients, which is very rewarding."

He gives credit to the research staff for the amount of quality research that is conducted at McLaren Bay Region.

"As I said earlier, communication is essential. On a given day, you can find the research team educating hospital staff, patients and families, residents, etc. They provide physician meetings, training with the healthcare team, tip cards, etc. Kelly Kayner, Linda Jaskiewicz and Laura Powell work together well and really, it shows."

Serving as a System-Level PI has been a positive experience for Dr. Masri

"As a McLaren Bay Region physician, it has been nice to work closely with other physicians/staff within the McLaren organization. It is also great from a patient perspective, since we can reach far more patients when working from several locations than we can from one. We are working towards advancing medicine with the goal to increase their quality of life, so it is great to provide this opportunity to many more patients."

"Dr. Masri did a great job! [CardioMEMS] helps me get a good handle on the numbers. It has really helped me out."

– Research Participant

Begun in 2016, the active study with Abbot Vascular involves a post market device called CardioMEMS HF System. The device itself is a wireless, battery-less pressure sensor implanted into the pulmonary artery and transmits pulmonary artery pressure information to a secure website for physician review. Masri explained the CardioMEMS study will contribute to improving long-term outcomes in our patient population of heart failure.

"By participating in research, we are provided insight to the future of medicine. It is a great opportunity to be able to provide this to our patient population long before it may be available to the community."

It is the hope of the McLaren Corporate Research Program that this study will serve as a prime example for industry sponsors of the high quality research McLaren is capable of, and the kind of novel treatments the healthcare system is now able to offer patients all across Michigan.

In this issue...

Teaching the How and Why of Research

By Erin O'Connor, PhD

Research has been, and continues to be, a vital part of my career through my involvement in the MSUFAME Community Research Forum, McLaren Flint's Research Advisory Board, and as the Director of Scholarly Activity for the Family Medicine Residency. Medical students and residents don't often have as much education or experience in research, so I work to teach them basic concepts in project development, methodology, and applicability to practice. I think it's important to guide them towards research projects that they find more meaningful and personally interesting; the kind that will impact them now as well as later in their careers. Research is all about having an inquisitive mind and wanting to improve upon something or understand it better.

The tools I try to teach help create a foundation for learners to build upon throughout their careers, hopefully resulting in contributions to academic journals and national conferences. But more practically, a lot of what we do here in the residency involves quality improvement projects, which look at systematic procedures and how to better them.

For example, we did a study which looked at wait times in our family medicine clinic to understand where patients were spending the most time and what we could do to minimize this, resulting in improved provider and patient satisfaction. Most recently, we have been conducting research on those suffering from chronic pain and how new treatment approaches can impact the quality of their lives both physically and mentally.

I believe that integration and collaboration amongst specialties and departments produce the most interesting and ground-breaking research outcomes. It provides us with the opportunity to understand something more fully, and in doing so, make more meaningful changes to our practice. Research is what moves us forward and advances the fields of medicine and medical education. It's exciting and very rewarding to be a part of that process and hopefully have a positive impact on the future.

Why Research Matters

By Kathy Malfroid, McLaren IRB Community Member

Research is vitally important because the knowledge generated helps to improve our quality of life. Future generations will continue to improve building on our knowledge base. Research is a most valuable legacy.

It has been my privilege and pleasure to be a Community Member of the McLaren IRB for several years. My experience with "at risk" and "English as a 2nd language" population in my teaching career helps bring perspective to the vulnerable subjects area.

Having six children is an education in dealing with medical issues. To live with the advances in the last 60 years highlights the value of research. Both my husband and I are cancer survivors and owe a debt of gratitude to those who have dedicated their lives to advancing research.

Siddique Chaudhary, MD presenting at 2016 FAME

Resident's Corner
Case Reports/Case Series and Human Subject Research
What You Need to Know

By Jodi Reetz, IRB Analyst

The season of research consortiums and conferences such as FAME, ACP, and MOS is upon us. With that in mind, let's take a look at your responsibilities as a resident researcher and presenter. First and foremost, it is imperative that IRB approval is obtained before submitting or presenting projects to outside sources. Some of the most common questions we receive from residents are:

When am I required to seek IRB approval?

Whenever a proposed activity can be defined as research involving human subjects, IRB approval is required and must be obtained prior to initiating any research-related activities.

What is research involving human subjects?

Federal Regulations provide the following definitions for research and human subjects:

RESEARCH: a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. NOTE: Simply publishing or presenting a study does not make it research.

HUMAN SUBJECT: "a living individual about whom an investigator conducting research obtains: (1) Data through intervention or interaction with the individual, OR (2) Identifiable private information."

Remember

Investigators cannot make the determination whether or not a project is human subjects research. The IRB must make this determination.

Is a Case Report human subject research?

Per MHC policy MHC_RP0104 Determination of Human Subject Research, case reports are not considered research. Therefore, they do not require IRB approval or oversight:

CASE REPORTS: external reporting of an interesting clinical situation or medical condition of up to two patients. (3 or more patients constitutes a case series, which must be reviewed by the IRB). Patient information used in cased reports must have been originally collected for non-research purposes.

Note: If you are submitting a case report for FAME, the Guidance on Case Reports sheet found on our website can be uploaded to the FAME database in lieu of IRB approval.

Who is qualified to determine if my project is human subject research?

The MHC IRB is responsible for determining if a project meets the definition of human subject research. No other individual or entity can make this determination.

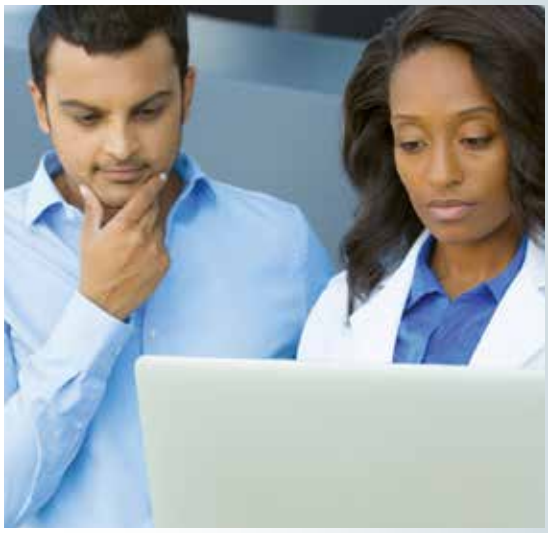
The investigator must submit a "Request for Determination of Non-Human Subject Research (available on our website on the IRB Forms page) in order initiate IRB review. Instructions are provided at the top of the form.

What if the IRB says my project IS human subject research?

The investigator must submit the project for further IRB review via the eProtocol online IRB submission system. Complete details regarding the IRB submission and review process can be found in the Resident Research section on our website.

Cerner's PowerTrials Connects Clinicians and Patients to Clinical Research

PowerTrials is a module within the Cerner Millennium EHR system, which is part of the ONE McLaren initiative. PowerTrials integrates prospective research into clinical care and ensures sharing of relevant data.



What does it mean to McLaren?

PowerTrials will help McLaren enhance patient safety, support study screening and enrollment and streamline research processes. Site staff across the system will be able to document study activity and access study documents from the PowerTrials module. Clinicians will be able to view relevant study information from their patient's medical chart. Research directors and managers can use oversight reports to track accrual metrics across all protocols or sites. Using PowerTrials will streamline research care and research billing throughout the McLaren research enterprise.

PowerTrials integrates research specific features into existing EHR workflows so research care and clinical care can be conducted using one system. By using the research account feature we can also delineate research charges from the standard of care to ensure accurate research billing.

McLaren plans to interface PowerTrials with a Clinical Trials Management Software, OnCore Enterprise. OnCore will support both Oncology and Non-Oncology research at all the McLaren subsidiaries including Karmanos Cancer Institute downtown.

The Power Trials leadership and Cerner Power Trials teams will work together on developing a detailed implementation plan. Updates will be provided as we move towards our go live dates, which coincide with the ONE McLaren timeline.

Are you participating in FAME?

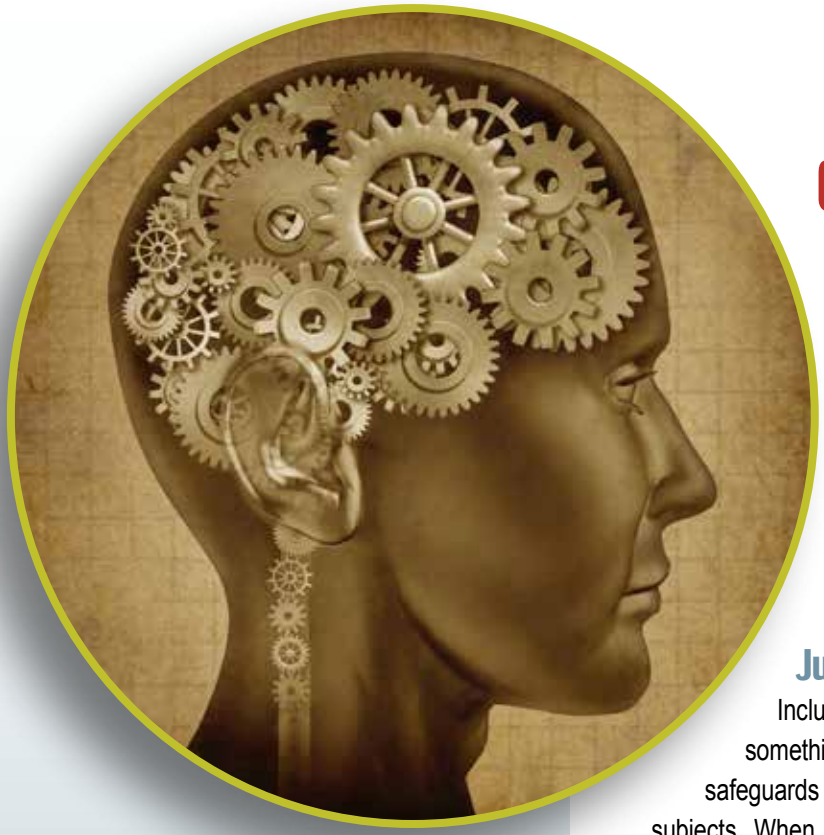
If you are submitting a case report for FAME, the "Guidance on Case Reports" sheet found on our website can be uploaded to the FAME database in lieu of IRB approval.

msufame

Protocol Review Committee

Protocol Review Committee (PRC) is a centralized review committee at McLaren Health Care made up of physicians across the system. The committee meets monthly via teleconference and conducts a thorough review of all prospective research trials at McLaren for scientific validity and feasibility. The meetings are typically the first Tuesday of each month, and run from 7:00 a.m. – 8:00 a.m. Principal Investigators are required to attend to present their study to the committee and answer any questions they have.

The PRC review should occur prior to your submitting to the IRB. All treatment/intervention studies must go through the Protocol Review Committee before submission to the IRB. An approval letter from the PRC will be required to be submitted with your IRB submission. If you are planning a prospective research trial at McLaren, or would be interested in joining the committee, please reach out to the Corporate Research Manager, Jill George, at 248-484-4969 or jill.george@mclaren.org



EQuIP Corner

Research Involving Decisionally Impaired Human Subjects PART 2

By Patricia Ivery, QI and Education Specialist

Justification for Enrollment

Including decisionally impaired individuals in a research study is something that should be given careful consideration, as additional safeguards must be included to protect the rights and welfare of these subjects. When creating such a research protocol, researchers must clearly identify what protections will be provided to these subjects, as the IRB is responsible for ensuring provisions are adequate prior to granting approval. It is important to remember that decisionally impaired subjects cannot be enrolled into a study until IRB approval has been obtained. The following issues should be considered when creating the research protocol:

- What is the justification for enrolling decisionally impaired persons as subjects in this research study?
- What is the likely degree of impairment of the subjects which affects their decision-making ability? (i.e. underlying pathological, psychological or other conditions)
- If the subjects have not been declared legally incompetent by the courts, how will capacity to consent to participate in research be assessed? Who will perform the assessment? How will the results be documented?
- When will the legally authorized representative (LAR) be approached relative to the subject's actual participation in the study?
- Who will approach the LAR about the prospective subject's participation in the study?
- How much time will be allotted to the process of consent?
- What is the location where informed consent will be obtained?
- Will a delayed consent procedure be used?
- How will it be determined that the LAR understands the information presented?
- Will there be a formal process of ongoing re-consent (over and above re-consent associated with changes in protocol?)
- Will the investigator ask the prospective subject to assent to participate in the research?

CONTINUED ON FOLLOWING PAGE

Brown Bag Series

Impact of Research on Ancillary Departments (i.e. Project Impact Statements)
April 11, 2017 • 12 - 12:45 pm
LIVE WEBINAR

What's New in Research at McLaren – Ask the Experts
June 13, 2017 • 12 - 12:45 pm
LIVE WEBINAR

Contact Markeda at (248) 484-4952

Upcoming Education and Conferences

ACRP 2017 Meeting & EXPO
April 29 - May 2, 2017 • Seattle, WA

AAHRPP Annual Conference
May 9 - 11, 2017 • Detroit, MI

- How will subject capacity to consent be reassessed throughout the study? If it is extremely unlikely that the subjects will regain capacity to consent, this should be stated.

Documentation of who is the legally authorized representative (LAR)

Since the publication of part 1 of this article, there have been changes to McLaren policy MHC_R0115 – Obtaining Informed Consent. Per the policy, a LAR is an individual or body authorized by a court of competent jurisdiction as the Legal Guardian of an incapacitated person, pursuant to a court order that grants the Legal Guardian the Authority to approve the ward's participation in medical research studies. The definition has expanded to also include a properly designated patient advocate, who has been given the authority to approve the patient's participation in medical research studies.

Patients may have an advanced directive identifying their wishes for medical care. However, the directive may not specifically address participation in research. Subsequent to IRB approval, consent must be obtained from a legal guardian or a legally authorized representative for those subjects that lack decision-making capacity. It is imperative that the researcher first determine and appropriately document the authority of the LAR to consent for research study. All documentation relevant to the LAR must be attached to and filed with, the informed consent document in the subject's research record.

Per the revised policy options for proof of LAR include:

1. A living will, advanced directive or legal document of authority over the decisionally-impaired adult.
2. Information related to the potential participant's wishes in regards to research.
3. If no legal documentation exists (i.e. advanced directive, durable power of attorney) proof of identity and, when possible, proof of relationship to the potential participant should be obtained. This could be, but is not limited to: driver's license, state ID, birth certificate, passport or proof of shared residence.

Consent – An Ongoing Process

Consenting for any research study is more than a signature on a form and it is not a one-stop-process. It begins with recruitment and continues until the end of participation in the study. If a subject has an LAR, the LAR will need to be a part of the consent process throughout the ward's participation in the study.

In some cases, a subject's impairment may be situational or temporary (e.g. reaction to a medication or secondary to a head injury). Therefore, procedures need to be in place to addresses a possible change in the status of a subject's impairment which may deem them capable of making their own decisions.

What's New?

Welcome to the Investigators at McLaren Greater Lansing! Lansing is our newest Non-Oncology Research Site and we are proud to include Drs. Gandhi, Shah, Mughal and hopefully many more. Are you a physician at McLaren Greater Lansing interested in doing research? Reach out to your local research associate, Katie Esckilsen at 517-347-1968 katie.esckilsen@mclaren.org and let's get going!

MCRI is proud to announce an exciting collaboration with Flint area vascular surgeon, Robert Molnar, MD, and his group at Michigan Vascular Center. We are thrilled for the opportunity to work with this highly skilled team on a ground breaking device trial at McLaren Flint.

Jill George

Staff Updates

Congratulations to Jill George in her new role as Corporate Research Manager for MCRI. Jill has been with McLaren Health Care for 4 ½ years as the oncology regulatory specialist. She has 16 years of research experience at different research institutions and brings with her a wealth of knowledge. Jill is responsible for facilitating, coordinating and the general oversight of research conducted through MCRI.

Neuroscience Research Gains Momentum at McLaren

In his work as an interventional neurologist, Aniel Majjhoo, MD, has the unique perspective of seeing the dramatic effects that technological and pharmaceutical advances make possible for brain attack (stroke) victims. In this rapidly evolving field, Dr. Majjhoo has a great appreciation for the research that makes these lifesaving treatments possible. His success in practice, along with his involvement in research, led to his appointment as Chair of the newly formed McLaren Neuroscience Research Council.

"McLaren definitely has an initiative to get more involved in research," notes Dr. Majjhoo. "They are seeing positive attributes from this effort. I see it as a plus being highly involved in any research project relating to stroke care. When it comes to the neurosciences, we have real talent here and are doing good work. Although we are just getting started, I see a lot of potential with more exciting things to come."

Currently, Dr. Majjhoo is looking forward to serving as principal investigator on two upcoming international randomized control trials; the Navigate ESUS proposed study at McLaren Macomb and Respect ESUS at McLaren Flint and McLaren Bay Region. Each of the studies follows patients who recently had a brain attack with no clear cause. These strokes are likely due to a blood clot and therefore, can be called embolic stroke of undetermined source, hence the abbreviation ESUS. Each study compares a prescription blood thinner with aspirin and is intended to show if patients given the prescription medication have fewer blood clots in the brain or in other blood vessels.

"In addition to randomized control trials, we would also like to conduct investigative studies. Creating the Neuroscience Research Council will help us achieve that goal."

Dr. Majjhoo has a positive outlook for the future of neuroscience care and McLaren's commitment to develop the Neuroscience Research Council.

"The reputation of a program is improved with the amount of research conducted. It is a win-win situation for both the patients and the program."

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