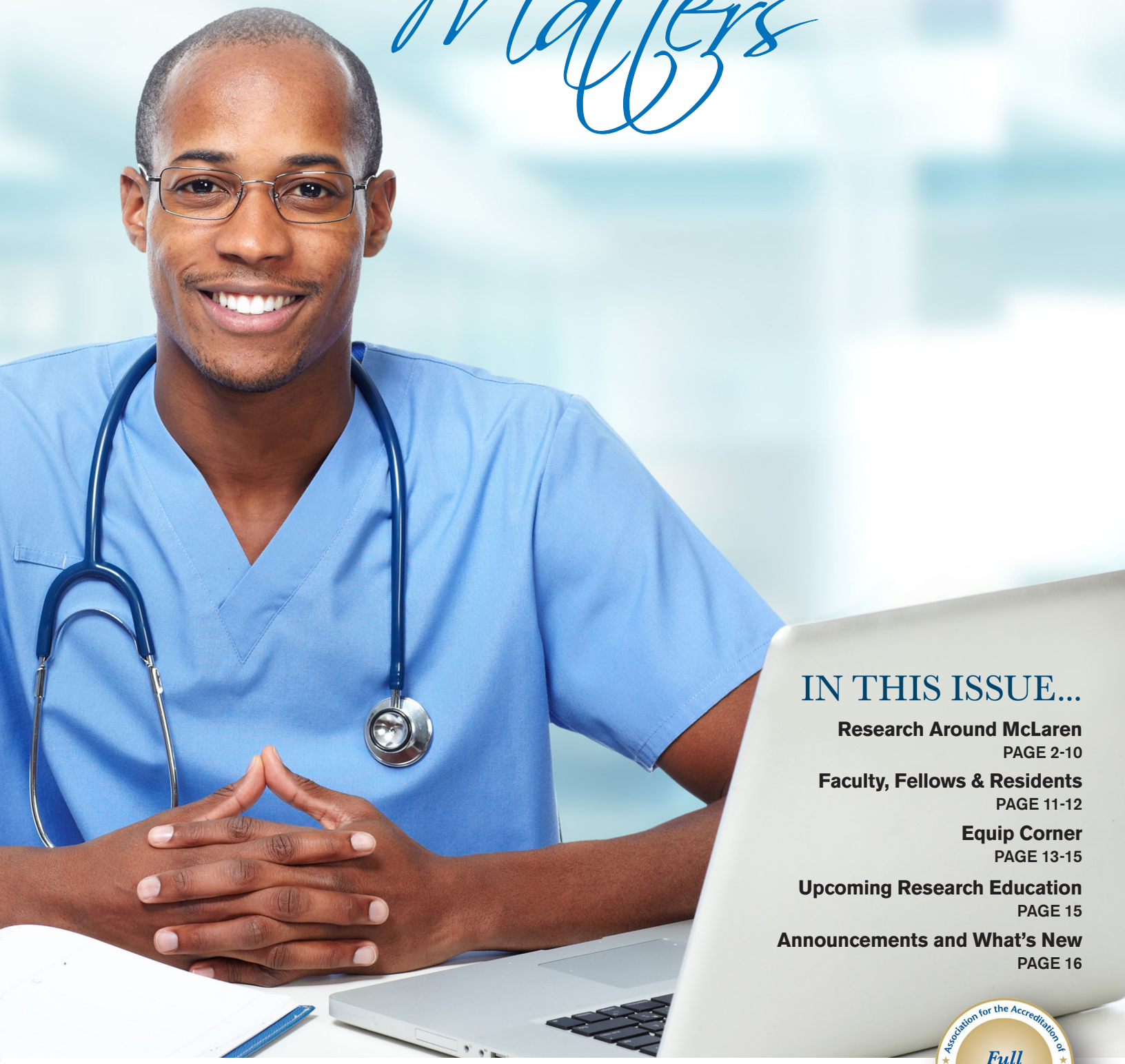
RESEARCH *Matters*

SPRING 2020



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Association for the Accreditation of Human Research Protection Programs, Inc. — *Full* Accreditation

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RESEARCH AROUND McLAREN

STUDY START-UP AT MCRI

New study opportunities come to McLaren through a variety of avenues. Sometimes you as the investigator may be approached by a colleague at a conference, a representative in the cath lab, or receive an email directly from a drug or device manufacturer, asking if you would be interested in participating in a clinical trial. Other times, study opportunities get funneled in through the staff at the sites, the management staff in the Administration Office or even cold calls to our general research line. Whichever way a study gets to us, McLaren Center for Research and Innovation has a systematic study start up management plan.

As soon as a new opportunity comes to our attention, it gets sent directly to the Corporate Research Manager in charge of study start up. The study is entered into to a tracking system, then the work begins. The manager reaches out to the sponsor, telling them who we are, what we have to offer and why they should choose McLaren as a research site. From this, we often get a Confidentiality Disclosure Agreement (CDA) from the sponsor. The CDA is executed on behalf of McLaren Health Care so our whole team can receive confidential study information. Once we have a CDA, the sponsor will provide us with a study synopsis, or brief description of the trial opportunity.

The manager sends this information out to the research coordinators at all active McLaren research locations: Macomb, Flint, Bay Region, Greater Lansing and Northern Michigan. The site staff review it and see if any of their local physicians would have a particular interest in conducting the trial. Once we identify interested investigators, the manager works with the sponsor and sites to get initial feasibility questionnaires completed. The sponsor often wants to do an on-site qualification visit to each site to complete their evaluation of our institution's capabilities. The sponsor will then use this information to determine if we are a suitable site for their study.

Once we are selected by the sponsor, we receive a contract and a budget and this starts the clock on our "study start up timeline". MCRI's goal is 90 days from contract receipt to IRB approval. Study sponsors expect a tight timeline to get studies enrolling as this process can be costly for them. The contract and budget specialist, in conjunction with McLaren's research legal team, begins reviewing the contract and budget while regulatory specialists begin drafting consents and collecting regulatory documents for the sponsor. Meanwhile, the Feasibility Review Committee, chaired by Mark Zainea, MD, gets to work with the site staff to tease out the operational details of the protocol. FRC exists to ensure that each site has the manpower, equipment, space and local hospital resources to adequately conduct the study. The study is also evaluated for financial impact to the institution.

In the background, MCRI's contract and budget specialists and regulatory specialists are working to get study budgets, contracts, consents and other related material reviewed, prepared and ready for final execution and IRB submission. Our research informatics team and research finance teams are also on high alert during this time to prepare our Clinical Trials Management System and patient payment system for the new study.

The final step before IRB submission is Protocol Review Committee. PRC, as chaired by Hesham Gayar, MD, reviews research protocols for scientific merit. This committee is charged with ensuring McLaren embarks on research that has value to the scientific community and can be of potential value to our patients. The committee is made up of primarily McLaren physicians who conduct peer reviews of research protocols. This is a wonderful forum for scientific discussion and research related collaboration.

CONTINUED ON NEXT PAGE

After PRC approval, the study can be released for IRB submission. Typically, once submitted, we can anticipate about 3 weeks to approval. Once the study is IRB approved, each participating site will have a Site Initiation Visit to ensure they are ready to begin enrollment. The SIV is conducted by the sponsor and includes detailed training on the study protocol, FDA regulations and responsibilities of the investigator and research team. This is also when study drug, devices or other study supplies will be shipped out to the study sites. Once the sponsor gives us the go ahead, we can begin the enrollment phase of the study.

The study start-up process is vital to the success of research at McLaren. Selecting studies that match our abilities and interests provides us a strong foundation to conduct valuable scientific inquiry and provide sponsors with high quality data. When we meet our contractual obligation with these high -profile industry leaders, they value McLaren as a partner in research and come back with future contracts. If MCRI continues to refine and improve our study start-up process, we can provide McLaren opportunity to grow research at our institution in ways we have yet to imagine.

ARTICLE SUBMITTED BY JILL GEORGE

CARDIOVASCULAR RESEARCH COUNCIL FORMATION

As cardiovascular research is such a large portion of our portfolio, the McLaren Center for Research and Innovation has reinvigorated the former Cardiology Research Council into the new and updated Cardiovascular Research Council (CRC). The council will be chaired by Dr. Nicolas Mouawad, vascular surgeon from McLaren Bay Region. The purpose of CRC is to provide a leadership body for all cardiovascular research through MCRI, as well as strengthening the program while aligning with the strategic objectives of corporate research. Cardiologists, Vascular Surgeons, Interventional Cardiologists and Thoracic Surgeons, as well as the corporate cardiovascular service line are represented on the CRC. Meetings of this group will be held every other month and the findings will be reported to the corporate level Research Advisory Board.

Nicolas Mouawad, MD

Dr. Mouawad stated his focus of this council will be to strengthen our multidisciplinary comprehensive cardiovascular care with the highest standards and best outcomes. He would like to continue to develop the collaboration with the subsidiaries and leverage the excellent care being delivered. Dr. Mouawad further states, “My goal is to increase cardiovascular research endeavors along the complete service line and be at the forefront of cardiovascular innovation and technology. I want to do this by continuing to contribute heavily to device-related and pharmacotherapeutic trials as we do have the patient volume and infrastructure to support this. Furthermore, I want to acknowledge these efforts by contributing to the scientific literature through publications and scholarly activity. It is an honor to work with such talented providers. We offer international caliber cardiovascular care here at McLaren and it is time we make it internationally known!”

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

Dr. Aniel Majjhoo, Medical Director of Neurosciences for McLaren.

PATIENT STORY

The Neuroscience Research team at McLaren Flint recently enrolled a patient into a stroke recovery study that focuses on sleep apnea management in preventing recurrent strokes. This patient suffered a stroke and had a history of Sleep Apnea. The study involves randomization between use of a C-PAP machine or no treatment. After overnight screening, the patient was randomized into the C-PAP arm of the study. When the research staff followed up with patient to discuss her test results and to deliver her C-PAP machine, courtesy of the study, the patient was elated. She cried tears of joy as she informed the team that her financial situation was such that she had historically been unable to afford a C-PAP, so she was not receiving the therapy she needed. The changes research makes in the lives of our patients is an incredible thing to be a witness to.

NEUROSCIENCE RESEARCH AT McLAREN

According to the National Institute of Health, 795,000 people in the United States will experience a new or recurrent stroke annually. That equates to one stroke being suffered every 40 seconds. Those that survive stroke are often left with serious long-term physical and cognitive disabilities. Stroke care, medication and missed days of work contributes to an estimated 34 billion US dollars annually.

As you may know, McLaren Stroke Network is the only program in Michigan where every stroke patient is seen by a stroke trained interventional neurologist in minutes, at any time of the day or night. This superior stroke care lends itself to McLaren's participation in neuroscience research. The McLaren Center for Research and Innovation has historically been focused solely on cardiovascular research. Branching out into neuroscience research has been very exciting for the team.

McLaren Neurointerventionalists Dr. Aniel Majjhoo, Dr. Bharath Naravetla, and Dr. Mahmoud Rayes serve as Principal and Sub-Investigators on the neuroscience studies. Dr. Majjhoo explained that all stroke patients are considered for one of the many studies that are currently enrolling.

McLaren is a member of the NIH funded StrokeNet. The purpose of StrokeNet is to conduct small and large clinical trials. These clinical trials focus to advance stroke treatment, prevention, acute intervention and recovery. McLaren Health Care has joined 200 hospitals in this research endeavor.

In addition to research with StrokeNet, McLaren is also participating in commercially sponsored drug and device trials. These trials largely focus on acute intervention in stroke care.

Neuroscience research at McLaren is growing at a rapid pace. In just the first quarter of the 2020 fiscal year, five studies at two McLaren sites (McLaren Flint and McLaren Macomb) have opened to enrollment. In addition to these studies, there are three more clinical trials in the start-up phase, as well as numerous neuroscience studies in the research pipeline.

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KARMANOS ADVANTAGE CAMPAIGN ON WJR HIGHLIGHTS RESEARCH IN THE NETWORK

On a cloudy grey afternoon last January, a well-spoken group of Karmanos employees crowded into a hushed studio on the Fisher Building's eighth floor.

After a few glances and pronouncers, the dulcet voice of Guy Gordon hit the microphone. "Hello and welcome to the Karmanos Advantage."

Gordon was recording a 60-minute show highlighting the power of the Karmanos Network for WJR News Talk 760 AM. Guests from Karmanos included Justin Klamerus, M.D., M.M.M., president, Karmanos Cancer Hospital & Network; Kiran Devisetty, M.D., medical director, Karmanos Cancer Network Radiation Oncology Research; Jaclyn M. Ventimiglia, supervisor, CTO Clinical Research; Delaney Erickson, clinical research coordinator; and Danyelle Howland, AGACNP-BC, nurse practitioner at Karmanos Cancer Institute at McLaren Lapeer Region. The group emphasized the availability of specialized oncology care throughout the network as part of the Karmanos Advantage ad campaign.

Devisetty, Ventimiglia, and Erickson focused specifically on the network's role in clinical trials. They emphasized teamwork and discussed the passion that both providers and patients share when participating in trials.

"Patients get excited about clinical trials because we're bringing tomorrow's treatment to today," Devisetty explained. "I talk about how the history of clinical trials brought us to where we are today. When (patients) have the opportunity to participate in helping the future patients, they get very excited about being part of something bigger than themselves. While we are helping them, they are helping future patients. Often the excitement of the entire team is almost infectious. When you have this team that is excited about clinical trials the patient also gets excited," Devisetty explained.

He went on to emphasize the importance of collaboration.

"It's never one person that can make a program succeed, it's the whole team that you assemble. When you bring in the excitement, when you bring in this energy, when you bring in the ideas … you say this is for the patient, this is for making medicine better."

Ventimiglia and Erickson provided an overview of the process that occurs when a patient begins exploring a clinical trial to make the general public aware of the attention to detail the clinical trials staff must apply.

"We go into a lot of depth when we're reading through the medical history," Erickson explained. "You have to make sure that the patient fits the criteria to a tee. Something like a heart attack that happened 30 years ago, may not clinically matter now; however, if the clinical trial would exclude that, it's my job to sift through the records and find that."

The hour-long interview also explored a variety of other topics including telemedicine, patient and provider relationships, community building and Karmanos' multidisciplinary approach. The program aired on January 30, 2020 and can now be streamed from http://www.youtube.com/KarmanosCancer.

Dr. Justin Klamerus, M.D., M.M.M. (top photo) and Dr. Kiran Devisetty, M.D. (bottom photo) speak with host Guy Gordon in studio for* The Karmanos Advantage *on WJR.

RESEARCH AROUND McLAREN

A STREAMLINED & COLLABORATIVE APPROACH FOR CLINICAL TRIAL PORTFOLIO MANAGEMENT

It's no secret; starting a clinical trial is complex.
Along with other cancer centers across the country, the Barbara Ann Karmanos Cancer Institute (KCI) faced a key obstacle before researchers could even begin: who starts the process? Incoming clinical trials were funneled through various departments and contributors including physician investigators, finance and coordinators. Inadvertently, this complicated the startup process and affected protocol activation timelines.

Observing this problem, the Karmanos Clinical Trials Office (CTO) identified the need for a centralized mechanism that could examine trial prioritization, feasibility, research team communication, multi-disciplinary team (MDT) assignment, trial suitability and CTO resources at an early point in the process. To organize resources and communication, the CTO New Study Committee (NSC) was created with the support of institutional leadership. The goals of the CTO NSC are to:

- Streamline the process for reviewing incoming clinical trials to ensure the trial can be feasibly and appropriately conducted at Karmanos
- Standardize MDT assignment and workloads
- Improve communication
- Centrally manage the trial portfolio

The CTO NSC is comprised of the CTO vice president, directors,

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CTO New Study Committee – Review Summary	2018		2019		TOTAL	
Total Number of Protocols Submitted	**129**		**89**		**218**	
Total Number of Protocols Committee Recommended Proceed	120	93%	85	95.55	205	94%
Total Number of Protocols Committee Recommended Not Proceeding	7	5.45	1	1.1%	8	3%
Total Protocols Withdrawn/Tabled/Pending Re-Review	2	1.6% 100%	3	3.4% 100%	5	2% 100%
Total Number of Protocols that Remained with the Submitting MDT	96	80%	71	83.5%	167	82%
Total Number of Protocols that Transferred to a Different MDT	24	20%	14	16.5%	38	18%

managers, supervisors and expert coordinators. The group meets each week to review incoming studies.

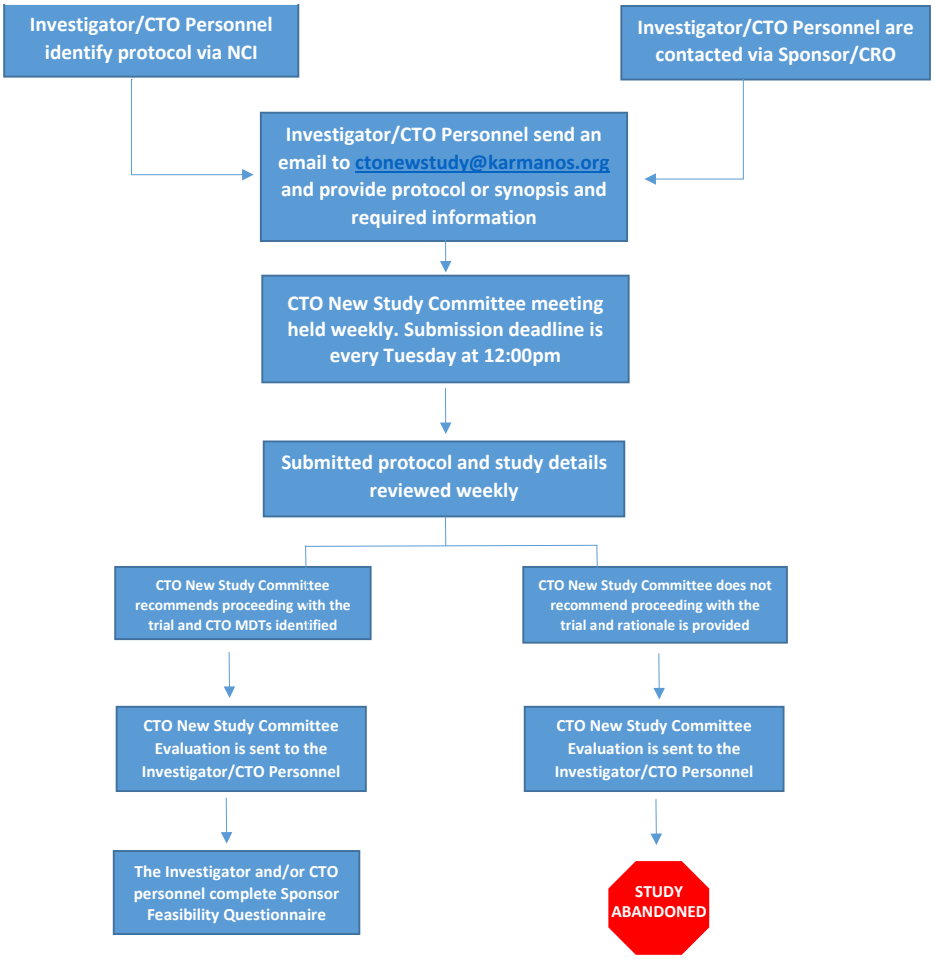
Before the meeting, an investigator or CTO personnel submits to the NSC utilizing a standardized email that identifies the minimum criteria for submission. Factors include protocol or synopsis, accrual to date, total target accrual, protocol population and expected Karmanos participation. Upon receipt of trial feasibility documents or National Cancer Institute (NCI) study activation notification, the study is added to the next CTO NSC agenda. At their weekly meeting, the Committee reviews the trial, assigns the appropriate CTO MDT staff and treatment area(s) and considers the trial for Network involvement.

The Committee recommends the path of the protocol, which allows for consideration of many outside factors including available CTO resources, competing trials and the institution's ability to make a significant contribution to the studies.

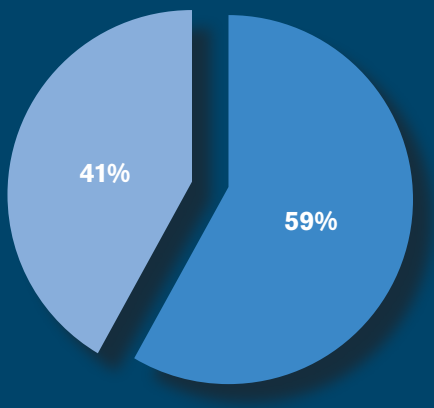
To document the review process and recommendations, the Committee utilizes a task list from OnCore®, the site's clinical trials management system.

The CTO NSC held its first meeting on June 21, 2018 and has reviewed 356 studies as of December 31, 2019. The formation of the Committee has resulted in earlier identification of unique trial requirements including biosafety, interventional radiology and unique testing. These are subsequently reviewed by Karmanos's Feasibility Review and Operations Committee. The NSC initiative has also led to increased tracking through the use of the OnCore® software platform. The team plans to continue optimizing as it moves forward.

High-Level Process Flow for Receipt and Review of Incoming Karmanos Trials Managed by the Clinical Trials Office

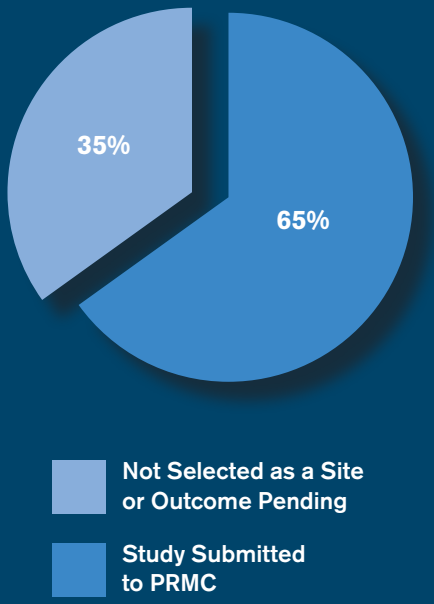


2018 STUDY OUTCOME SUMMARY



2019 STUDY OUTCOME SUMMARY

(As of April 2019)



RESEARCH AROUND McLAREN

KARMANOS RESEARCHERS EXAMINE THE IMPORTANT ROLE OF FINANCIAL ASSISTANCE IN PROVIDING NOVEL ORAL THERAPIES

Pharmaceuticals play a crucial role in treating patients, but what happens when the financial burden of novel oral therapies is too high for patients to bear?

Erlene Seymour, M.D., assistant professor, Karmanos Cancer Institute and Wayne State University School of Medicine and Lucius Daniel, clinical pharmacy specialist, set out to examine this question with their abstract, "High Dependence on Medicare and Foundation Grant Assistance Among Patients with Hematologic Malignancies Receiving Novel Oral Therapeutics." Their work explored the distribution of cancer care costs among insurers and patients based on the Karmanos Specialty Pharmacy (KSP) database. It also described the role of KSP in helping to alleviate the financial burden of novel oral therapeutics.

Before setting final patient cost-sharing and drug delivery, the Specialty Pharmacy streamlines prior authorization, determines patient cost sharing and automatically applies for additional financial assistance through co-pay cards or foundation grant funding. Seymour and Daniel evaluated the patterns of cost and need for additional funding since the Specialty Pharmacy was established by considering 201 prescriptions written for more than a dozen drugs among 96 patients.

Their data showed that the KSP reduced total patient drug costs by 79 percent through this additional financial assistance. In total, 36 percent of patients on novel therapies needed financial assistance.

The majority of patients had Medicare (50 percent), followed by private insurance (34 percent) and Medicaid (16 percent). Most of the provided assistance came through foundation grant funding (27 percent of all patients) with the remaining attained through manufacturer co-pay cards (9 percent of all patients).

The total claims costs for all prescriptions totaled just over $2

million. Medicare covered half this sum. Even so, Medicare patients encountered the greatest burden with 43 percent requiring foundation grant assistance and 16 percent acquiring high co-pays. There were 9 percent of patients who did not receive additional assistance but had high cost-sharing with prescription costs exceeding $100 per prescription.

Overall, the KSP attained more than $60,000 in financial assistance and provided an efficient process for fast authorization and drug delivery, which did not vary by insurance type or need for grants.

"The Karmanos Specialty Pharmacy implemented an efficient process of applying for financial assistance, which decreased total patient cost," said Dr. Seymour. "However, the fact that so many required assistance or continued to pay high co-pays emphasizes the need to cap these costs for our patients."

These findings were presented in an oral presentation at the American Society of Hematology Annual Meeting in Orlando, Florida and summarized recently in a December 2020 article published in the *American Journal of Managed Care*.

Table, Costs, Distribution of Financial Assistance, and Time to Drug Delivery by Insurance Type Through Karmanos Specialty Pharmacy

Insurance Type*	Total Costs				Financial Assistance		Patients with high cost >100 without financial assistance	Time from 1st prescription to prior authorization	Time from 1st prescription to delivery
	Insurer	Financial Assistance		Patient Cost	Foundation Grants	Co-Pay Cards		Median days (range)	Median days (range)
		Foundation Grants	Co-Pay Cards						
Medicare N = 52 pts	$1,118,464	$44,010	$0	$19,518	21 patients (40%)	0 patients	10 patients (19%)	0 (0-47)	5 (1-52)
Private N= 33 pts	$651,554	$8,937	$8,486	$4,290	5 patients (15%)	9 patients (29%)	1 patient (3%)	1 (0-23)	6 (1-35)
Medicaid N = 17 pts	$281,886	$0	$0	$1	0 patients	0 patients	0 patients	0 (0-48)	7 (0-56)

* Two patients switched insurance, N = 102

NEUROSCIENCE RESEARCH AROUND McLAREN

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In addition to increased volume of neuroscience studies, MCRI is days from opening our first clinical trial that involves emergency department treatment of stroke. It is a StrokeNet acute intervention trial that requires the intravenous investigational drug to be started in a tight timeframe for best outcomes. This trial, as well as many neuroscience trials requires a great deal of collaboration with other departments.

With this rapid growth in opening new studies comes a lightning fast uptick in patient enrollment. Neuroscience patient enrollment for the first quarter of the 2020 fiscal year is 8 times higher than the prior quarter. **In one study, McLaren is the second fastest enrolling site among both the international and North American cohorts!**

ARTICLE SUBMITTED BY PAM WILLS-MERTZ

RESEARCH AROUND McLAREN

RESEARCH CERTIFICATION EXAMINATION OFFERED AT KARMANOS CANCER INSTITUTE

Research professionals are encouraged to obtain research certification. Research certification provides research professionals with recognition and validation in their competency and expertise. Certification demonstrates knowledge, comprehension and skill in the ethical conduct of clinical research governed by research regulations and Good Clinical Practice (GCP) guidelines.

The Karmanos Cancer Institute Clinical Trials Office will host the Society of Clinical Research Associates (SOCRA) research certification examination on Tuesday, May 12, 2020, 8:00 a.m. – 12:00 p.m. The application deadline to register for the examination is March 31, 2020. Please visit the SOCRA website for further information about the research certification process and to register: www.socra.org.

KARMANOS RESEARCH CLINICIANS AND STAFF MUST COMPLETE EREG™ TRAINING

As has been previously communicated, the Karmanos CTO Regulatory team has gone live with our new electronic clinical trials management system, eREG™. This system was implemented in August 2019 and every new study moving forward will be managed in eREG™. This will enable research staff to electronically sign regulatory documents and confirm protocol training. All clinicians and staff engaged in research have received emails requesting completion of the required training via Forte Academy. If your training for eREG™ is still outstanding, please complete it as soon as possible to enable all MDTs to go live in the system. Please contact ctoereg@karmanos.org with any questions or requests for additional information.

The CTO Regulatory team would like to recognize and thank the following MDTs whose clinicians and staff have completed the required training and are currently live in eREG™: GI, GU, GYN, and Malignant Hematology.

SCHOLARLY PROJECT STAGES EXPLAINED, PART 2

McLaren's Division of Scholarly Inquiry in its efforts to encourage, promote, and support scholarly activity among residents/fellows and teaching physicians developed a scholarly project stages diagram/flowchart (Figure 1) over two years ago. Over these past two years, it has been modified in response to suggestions and recommendations from residents/fellows and teaching physicians. The updated diagram/flowchart should serve as the roadmap for scholarly activity from its conception to its IRB/SARC approval. Even when residents/fellows, teaching physicians, and PhDs are aware of this diagram/flowchart, some misunderstanding seems to exist. Part 2 of this series, we will describe and explain the aim and purpose of the diagram/flowchart if the scholarly project is determined by the IRB as Human Subjects Research *(Figure 1 Detail)*.

Human Research. The IRB sends a letter of determination to the Principal Investigator (PI) of the project informing the PI that, in this case, the proposed study has been determined to meet the criteria for human subjects' research. The aim of this step is for residents/fellows to guide residents to follow the human research path of the diagram/flowchart. The purpose of following this path is to begin writing the research protocol using the online tool McLaren provides to its residents/fellows for this task called Protocol Builder. To access

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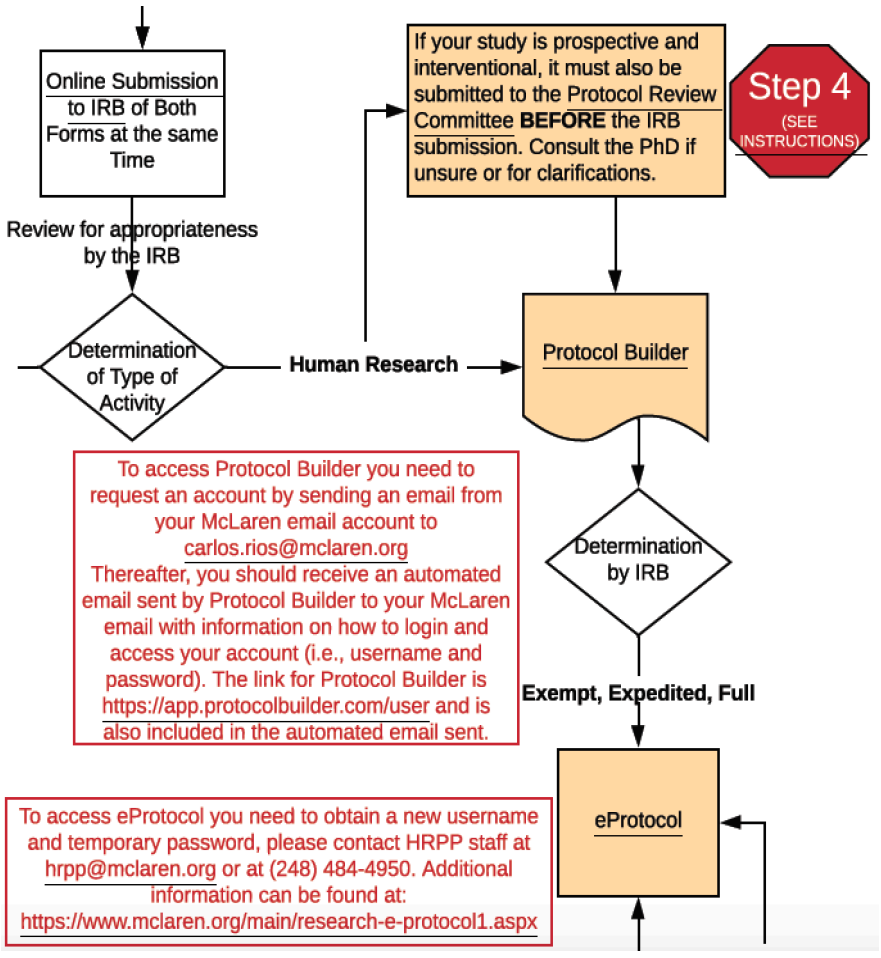
Figure 1 Detail



FACULTY, FELLOWS & RESIDENTS
SCHOLARLY ACTIVITY NEWS

Carlos F. Rios-Bedoya, ScD

In Part 3 of this series I will describe and explain the aim and purpose of the diagram/flowchart if the scholarly project is determined by the IRB as non-Human Subjects Research. The diagram/flowchart presented and discussed in this article is available upon request to a PhD. In the Division of Scholarly Inquiry, we have a commitment and responsibility to promote, expedite, facilitate, and support scholarly activity productivity among McLaren residents, fellows, and teaching physicians. For additional information or questions contact Dr. Carlos F. Ríos-Bedoya at carlos.rios@mclaren.org

SCHOLARLY PROJECT STAGES EXPLAINED

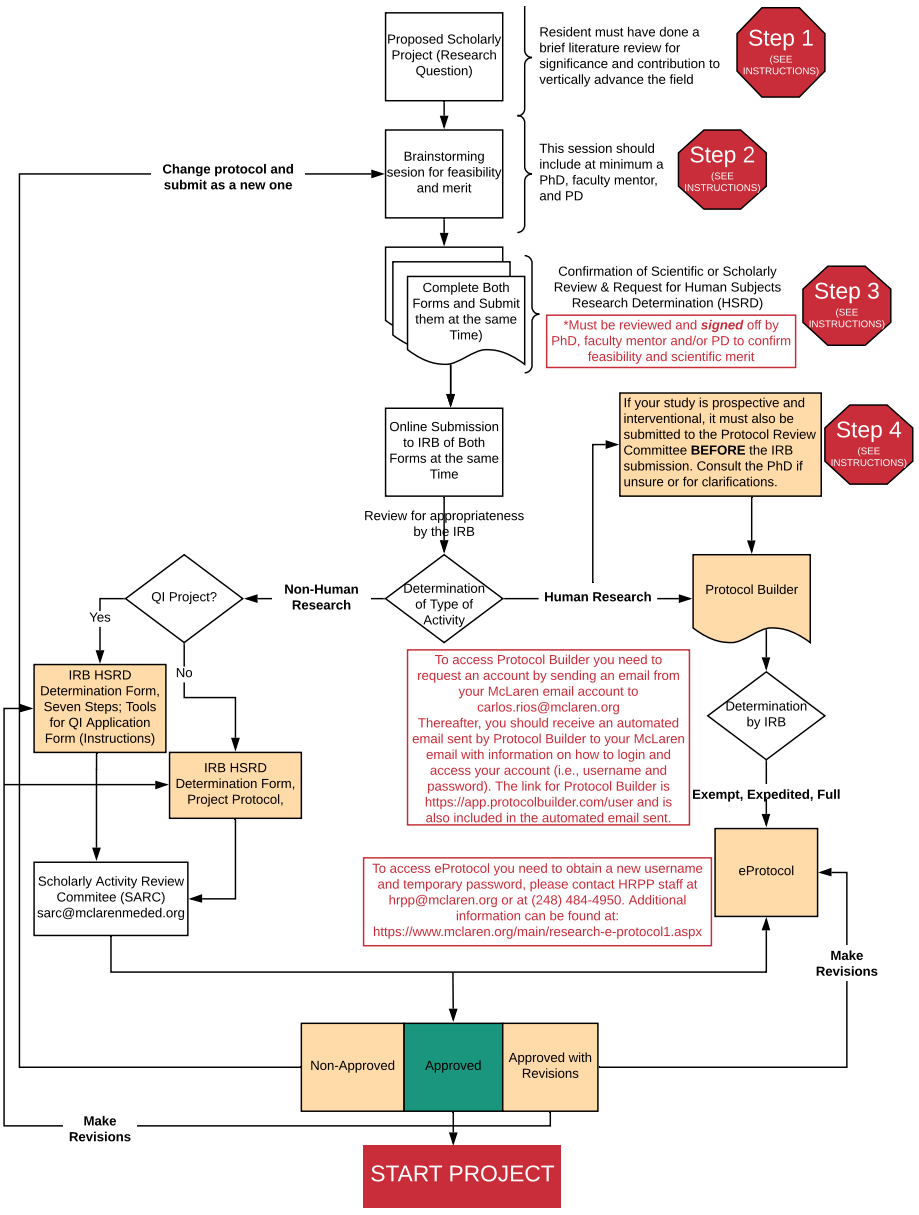
CONTINUED FROM PAGE 11

and use Protocol Builder an account must be created by Dr. Ríos-Bedoya. Therefore, the resident/fellow must email Dr. Ríos-Bedoya (carlos.rios@mclaren.org) requesting the creation of a Protocol Builder account. A copy of the IRB letter of determination must be attached to the email sent to Dr. Ríos-Bedoya requesting the creation of an account for Protocol Builders. Once the account is created, Protocol Builder will send an automated email to the McLaren email account of the resident/fellow notifying about the creation of the account and how-to login and access the newly created account. Dr. Ríos-Bedoya will also send an email to the resident/fellow McLaren email account notifying about the creation of the account that will also include links to videos on how to use Protocol Builder.

Determination by IRB. The aim of this stage is to determine the type of IRB review that the proposed project will go through. The purpose of determining the type of IRB review is for the IRB to assist the resident/fellow in selecting the proper IRB application form to use when submitting the research protocol for IRB review and approval. There are three different types of review with their corresponding forms. The types of review are exempt, expedited, and full. To get this IRB guidance, the resident/fellow should contact, preferable by phone, one of the IRB analysts.

eProtocol*. The next stage of the process requires again the use of another online system. This time is the IRB online application system called eProtocol. The resident/fellow needs to contact the IRB by email and request an account in Protocol Builder. The aim of this stage is for the resident/fellow to have access to the IRB online application submission system. The purpose of this stage is for the resident/fellow, under the guidance of the PhD and teaching physician, to electronically submit the research protocol and the correct application form to the IRB for review and approval. Once the application and protocol are submitted, the residents/fellows should wait for an IRB email with the letter of approval or with request for revisions and/or clarifications to the research protocol. The resident/fellow must wait for the IRB approval before moving forward with their scholarly project.

Figure 1 Scholarly Project Stages



**CLARIFICATION:*
By the time this issue of Research Matters *goes to press the IRB would be transitioning to a new online application submission system called iRIS. In the next part of this series I would be updating this section of the diagram/flowchart to describe the use of iRIS instead of eProtocol.*

EQuIP CORNER

Patricia Ivery

EXEMPT RESEARCH – WHAT DOES IT REALLY MEAN?

Much confusion exists surrounding what the word "exempt" means when a research project is deemed exempt. This article will cover the most frequently asked questions to clarify misunderstandings.

What is the difference between "exempt" research and "non-exempt" research?

"Exempt" research defines human subjects studies which present either no risk or no greater than minimal risk to subjects, meet specific federal criteria and fit into one or more exempt categories (see 45 CFR 46.101).

Non-exempt human subject research refers to research which meets the definition of research involving human subjects, and does not meet the criteria for exempt, but must remain compliant with regulations

Does an exempt study require IRB review?

Although the category is called "exempt," this type of research does require IRB review.

Certain kinds of research with human subjects are not eligible for exempt determinations. To qualify, research must fall into one of 8 (eight) federally defined exempt categories. McLaren IRB do not allow category 7 and 8 research to be conducted here. (see 45 CFR 46.101).

Some examples of Exempt Research are:

- Evaluating the use of accepted or revised standardized tests
- Surveying teachers, nurses, or doctors about a technique or an outcome
- Biospecimens or information is publically available
- Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

Research is not exempt if it:

- is greater than minimal risk *minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. or;
- involves administration or use of drugs or devices

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EXEMPT RESEARCH

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*** MINIMAL RISK** means that 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 of the general population or during the performance of routine physical or psychological examinations or tests." 45 CFR 46.102(i)

Who may determine that research is exempt?

Due to the potential for conflict of interest, the Office of Human Subjects Research (OHRP) recommends that investigators not be given the authority to make an independent determination that human subjects research is exempt. At McLaren Health Care the IRB is the sole regulatory body empowered to make this determination.

MHC IRB is responsible for determining whether a research activity is exempt from 45 CFR 46 and 21 CFR 56, and that investigators or others within the organization may not make exemption determinations. Other institutions may allow non-IRB members to make this determination, however, that is not the case here at McLaren.

Does an exempt study require continued IRB oversight or review?

Exempt research activity is exempt from 45 CFR 46 and 21 CFR 56. However, for certain exempt categories, a limited IRB review is required to determine that adequate provisions are in place to protect the privacy of subjects and the confidentiality of data.

The IRB will conduct limited IRB review during the initial review of the submitted project. In addition, investigators are required to submit changes to the IRB when the context or conditions of the original limited IRB review change. (e.g. if the location for the storage and protection of the data change). Continuing review is generally not required for exempt research subject to limited IRB review. However, the IRB may determine that continuing review is required for a study, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

When do I need to submit an amendment for exempt research? or What should investigators do when considering changes to an exempt study that could make it non-exempt?

Any proposed or anticipated changes in a study that was previously declared exempt from IRB review must be submitted via an amendment application, to the MHC IRB for approval prior to initiation of the change. The proposed amendment will then be evaluated for appropriate IRB review.

Can a study change cause a study to be no longer exempt?

Yes. Amendments or changes that alter the exempt category could flip a study or alter the determination from exempt status to non-exempt status. Therefore, it is very crucial that investigators inform the IRB of changes to their study plan. The MHC IRB must ensure that the changes are within the parameters for exemption.

Do I need to obtain HIPAA authorization for exempt research?

It depends. If the exempt research involves the use or disclosure of PHI, HIPAA rules applies. Investigators would either must either obtain HIPAA authorization or justify why the criteria for a waiver or alteration of HIPAA are met.

How long are exempt studies approved for?

Unlike non-exempt studies at McLaren, exempt studies do not expire on a yearly basis or have an expiration date. The study end date is based on the information supplied in the application. When an exempt study has ended, it is important to close the study with the IRB. The study "end date" is spelled out in the approval letter. Otherwise, once the "end date" has arrived, the IRB will administratively close the study. To extend the study "end date" the investigator must submit an amendment application prior to the study "end date".

In summary, researchers must always engage in practices which ensure privacy and minimize the risks to participants, regardless of the level of review. All the rights and protections afforded to human subjects in research are required in Exempt status cases.

If you think your proposal may be exempt from IRB review, you must still submit a non-human subject determination request to the IRB. The IRB staff will review the application and follow up with you if more information is needed to make a determination.

Remember exempt studies are so named because they are exempt from some of the federal regulations. However, they are not exempt from state laws, institutional policies, or the requirements for ethical research. In addition, exempt studies can still undergo routine audits to assess compliance by the Office of Research Compliance and QI.

LIMITED IRB REVIEW

The new provision for limited IRB review allows certain research to be categories as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for exemption, the study must meet the standards of the limited IRB review. When reviewing the exempt categories 2 and 3, the limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

UPCOMING RESEARCH EDUCATION

SOCRA Chapter Meeting
Meets every 4th Wednesday 3-4 pm at St. John Hospital & Medical Center. SOCRA continuing education credit available. Both members and non-members are welcome to attend.

For questions please contact Margie Romanoski at margaret.romanoski@ascension.org or (313) 343-6354.

ACRP Annual Conference
Seattle, Washington
May 1-4, 2020

MAGI Clinical Research Conference – East
Philadelphia, Pennsylvania
April 19-22, 2020

Clinical Research Nursing Conference
Newport Beach, California
May 7-8, 2020

Early registration open for:

29th Annual SOCRA Conference
Las Vegas, Nevada
September 25, -27, 2020

ANNOUNCEMENTS AND WHAT'S NEW


Lakeeshi Williams

Lakeeshi Williams joins MCRI as the new Contract and Budget Specialist. She comes to us from DMC Children's Hospital where she served as Data Analyst in the Clinical Research Budget & Contracts department. Lakeeshi brings three years of research budget experience, as well as many years of experience in business, banking, process improvement and operations. She holds a Master's Degree in Management, Strategy & Leadership from Michigan State University Eli College of Business.


Melissa Szemites

Melissa Szemites was recently promoted from her long-time research coordinator position to Corporate Research Manager. She has an extensive clinical and research background. In her coordinator role, Melissa successfully expanded research at McLaren Flint into the rapidly growing neuroscience area. She will utilize her strong skill set to strengthen and streamline operations at our various sites. Melissa holds a Bachelor's Degree in Nursing from the University of Michigan.


Katherine Butler

Katherine Butler has joined our research team at McLaren Bay Region as a Research Coordinator. She has a medical degree from Trinity College in Dublin, Ireland, and recently returned from 2 years in Singapore where she worked as a medical officer and researcher. Kate is excited to bring her medical expertise to MCRI and learn more about conducting sponsored clinical trials.


Marci Roberts

Marci Roberts is MCRI's newest Research Coordinator at our McLaren Flint site. Marci has extensive experience in running cardiovascular research trials. She has worked in private practice settings as a lead coordinator since 2005. Marci has proven success as a strong enroller and has spoken at both the SOCRA annual conference and MAGI National Conference. Marci looks forward to learning more about Neuroscience Research at Flint.


Cassandra O'Brien

Cassandra O'Brien has recently joined MCRI as a Research Coordinator at our McLaren Greater Lansing site. Cassandra has prior research experience coordinating orthopedic studies at a busy private practice. She has a master's degree in Family Life Studies from Spring Arbor University and a Bachelor's degree in Communication from MSU. Cassandra is excited to learn more about cardiovascular research trials at McLaren.

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