RESEARCH *Matters*

Summer 2022

IN THIS ISSUE...

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

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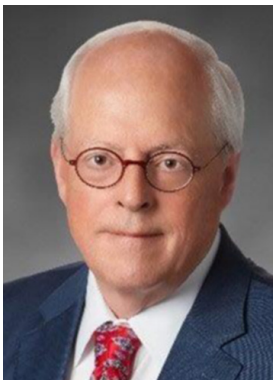
RESEARCH AROUND McLAREN

MICHAEL MCKENNA, MD

A LEGACY OF COMMITMENT TO ADVANCING RESEARCH

Central to Dr. Michael McKenna's legacy at McLaren Health Care was his commitment to advancing research across the system.

"Dr. McKenna is the reason the Center for Research and Innovation exists at McLaren," noted Chandan Gupte, Vice President of Clinical Excellence and Research at McLaren Health Care. "He was a strong advocate for the value of research in attracting skilled physicians to our system and in enhancing overall quality of care. From the start of his tenure at McLaren, he was very insightful about how research could provide a strong foundation to take our health system into the future."



Michael McKenna, MD

> "HE (DR. McKENNA) HAD THIS UNWAVERING ABILITY TO SEE SYSTEM NEEDS AND THEN BRING PEOPLE TOGETHER TO SHARE THEIR EXPERTISE AND BUILD ON A COMMON VISION TO MOVE THE ORGANIZATION FORWARD."
>
> *– Dr. Justin Klamerus*

According to Gupte, Dr. McKenna had four tenets that served as his compass: Safety, Service, Quality and Research.

He ingrained in those who worked with him that if you follow safe practices, it will lead to the best quality and the best patient experience, which will attract the best physicians to practice medicine and participate in research, which will then perpetuate that cycle of enhanced safety, quality and service.

Gupte noted when Dr. McKenna joined McLaren Health Care as Chief Medical Officer in 2013, research activity was primarily conducted at the subsidiary level. He made it his mission to lead the organization in centralizing the research structure under a corporate division and expanding access to both physicians and patient participants.

Dr. Justin Klamerus, who calls Dr. McKenna his mentor, praised him for realizing the importance early on of providing a common structure for research across service lines. This approach began with cancer research and was extended to the cardiovascular, neuroscience and other service lines.

"He had this unwavering ability to see system needs and then bring people together to share their expertise and build on a common vision to move the organization forward," noted Klamerus, who recently assumed the Chief Medical Officer position held by Dr. McKenna. "He clearly understood the role of research in learning to treat and prevent disease and the need to share with the community new drugs and devices that can lead to improved patient outcomes."

Dr. McKenna was a strong proponent of expanding access to clinical trials for patients who might not otherwise have the chance to participate in these studies. The broad geographic footprint of McLaren supports that goal perfectly, as clinical trials have been pushed out to subsidiary sites outside of major urban settings.

"Dr. McKenna talked a lot about the power and impact of research in developing new therapies to fight disease, especially as it relates to cancer," Klamerus noted. "During his own brief battle with cancer, he and his wife expressed gratitude for the research studies conducted at Karmanos and for the new class of therapies that are available as a result of some of those studies."

As co-chairman of the Research Advisory Board, Dr. McKenna championed many programs and initiatives that took the research function to a new level. Among these were the establishment of the Research Foundation at McLaren, which awards grants to physicians to fund their research studies. He also advocated for Information Technology support to enhance research capabilities and efficiencies.

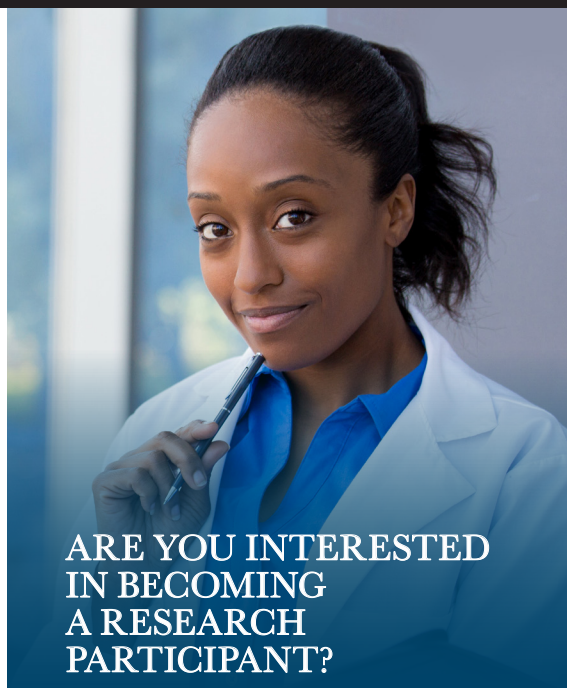
> "DR. MCKENNA IS THE REASON THE CENTER FOR RESEARCH AND INNOVATION EXISTS AT MCLAREN. HE WAS A STRONG ADVOCATE FOR THE VALUE OF RESEARCH IN ATTRACTING SKILLED PHYSICIANS TO OUR SYSTEM AND IN ENHANCING OVERALL QUALITY OF CARE."
>
> *– Chandan Gupte*

He underscored the impact of a strong and comprehensive research division in maintaining a thriving Graduate Medical Education program and collaborative relationships with McLaren's medical school partners.

Dr. McKenna was also a huge fan of the McLaren Research Newsletter and its role in communicating the opportunities, achievements, and results gained through McLaren's research initiatives.

"Each quarter, when a new issue of the newsletter was distributed, he would read through it and say to me 'This is the best issue yet!" Gupte reminisced.

In summing up his impact, Gupte noted he was the "voice of clinical reason", addressing every issue with thoughtful consideration and respect. He was truly a wealth of knowledge and highly respected across the system. "I know I speak for our entire research team in saying it was an honor to be able to work with him and create this growing research enterprise at McLaren."



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

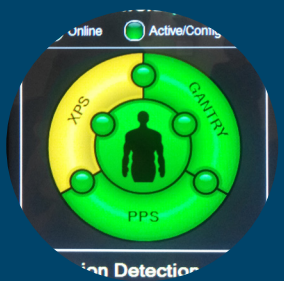
For information on enrolling in a clinical trial please visit our website at www.mclaren.org/main/clinical-research-trials. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

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

- **Diabetes**
- **Orthopedic Surgery**
- **COVID-19**
- **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



INVESTIGATOR SPOTLIGHT:

HESHAM GAYAR, MD

Dr. Hesham Gayar is a Radiation Oncologist at McLaren Flint, that many of us may know because of his compassionate and empathetic bedside manner, his passionate involvement in the Flint community and his expertise as Medical Director of the McLaren Proton Therapy Center. However, some might not know about his commitment to excellence in clinical research. While Dr. Gayar serves as a principal investigator for many Karmanos Cancer Institute clinical trials, he also is strongly involved in non-oncology research at McLaren. Dr. Gayar chairs multiple committees including McLaren Center for Research and Innovation's Protocol Review Committee and the multi-disciplinary McLaren Research Advisory Board. Dr. Gayar's insight as a seasoned investigator is highly valued in both oncology and non-oncology research activity at McLaren Health Care. By participating in such high-level committees Dr. Gayar shines as an example and mentor for other investigators. In fact, he leads the way in Cerner for properly coding his research patients with the z00.6 research patient code more often than any other investigator! According to Barb Rauschendorfer, Director of Research Funding, "Dr. Gayar consistently adds patient participation in a clinical trial to his documentation. This is amazing and ensures McLaren Health Care remains compliant with the complexities of research billing."

> McLAREN CENTER FOR RESEARCH AND INNOVATION WOULD LIKE THAT THANK DR. GAYAR FOR HIS CONSISTENT COMMITMENT TO EXCELLENCE IN CLINICAL RESEARCH AND HIS DEDICATION TO ALL RESEARCH AT McLAREN.

MCRI SITE SPOTLIGHT:

McLAREN BAY REGION

McLaren Bay Region has been a dynamic and successful clinical research site with McLaren Center for Research and Innovation for over 12 years. Their primary focus during this time has been cardiovascular research, with a strong lean toward interventional device trials. Dr. Daniel Lee, Interventional Cardiologist, has been the Principal Investigator on a large majority of trials at McLaren Bay Region. "Clinical trials are an important option for our patients, it gives them a choice in the course of their treatment, and options they might not have elsewhere," said Dr. Lee. "I like being a part of new technology and cutting-edge treatment options, being on the forefront of medicine."

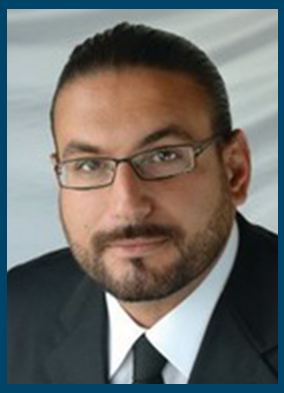
"With a solid history of high-enrollment, McLaren Bay Region is an important site to MCRI", explains Director, Pamela Wills-Mertz, "the investigators have a great reputation with sponsors and the site is known for consistently high performance."

Dr. Nicolas Mouawad, Vascular Surgeon and Principal Investigator, has been enthusiastically building his research portfolio over the last few years, and is one of the only McLaren employed Vascular Surgeons to be conducting clinical trials. "Research collaboration with sponsor companies and peers is vital to being a strong patient advocate and a well-rounded surgeon. Out-of-the-box thinking is what facilitates advancements in medicine, and research allows us all to be a part of that progress while giving patients access to a wider variety of treatment options," expressed Dr. Mouawad.

MCRI is excited to welcome a new Clinical Research Nurse to McLaren Bay Region, Stephanie Bruma, RN. Stephanie was a Research Nurse at our MCRI Flint location and has moved permanently to McLaren Bay Region. We have many new studies for this McLaren Bay, as well as a robust pipeline.

Research Administration is carefully seeking to fill an opening for an second experienced clinical research professional at the McLaren Bay Region location. "We have more study opportunities than we can take on," says Ms. Wills-Mertz, "this is not a bad problem to have, but we do need more coordinator support." Anyone with interest in the position or a referral should contact the MCRI administration office by emailing **MCRI@mclaren.org**, or refer candidates to the McLaren Health Care website to apply.

Daniel Lee, MD



Nicolas Mouawad, MD

RESEARCH AROUND McLAREN

GRADUATE STUDENTS SHOWCASE CANCER RESEARCH PROJECTS AT 11TH ANNUAL RESEARCH SYMPOSIUM

Barbara Ann Karmanos Cancer Institute and the Wayne State University (WSU) School of Medicine's Cancer Biology Graduate Program presented its 11th annual Research Symposium virtually on April 1.

This year's Leonard N. Simons Award for Exemplary Research and Scholarly Achievement went to Carly Martin, a senior student who defended her dissertation, "Characterizing the post-translational modifications of the pro-oncogenic type II transmembrane serine protease TMPRSS13," on March 3.

The Simons Award is awarded at the annual event to a Cancer Biology student who has distinguished him or herself in scholarship and leadership. In 2016, the award was established in the Cancer Biology Graduate Program at Karmanos and WSU. Simons served as the first chair of the board of Michigan Cancer Foundation (now the Karmanos Cancer Institute). Throughout his life, he was a passionate supporter of Detroit's efforts in the fight against cancer. The award pays tribute to Simons and his dedication to excellence in science and education. The Leonard N. Simons Cancer Research Endowment provides funding for the Leonard N. Simons Award for Exemplary Research and Scholarly Achievement.

IZABELA PODGORSKI, PhD AWARDED 2022 CHARLES H. GERSHENSON DISTINGUISHED FACULTY FELLOWSHIP

Izabela Podgorski, PhD, professor of Pharmacology at Wayne State University (WSU) and co-leader of the Prostate Cancer Research Team at Barbara Ann Karmanos Cancer Institute, is awarded this year's Charles H. Gershenson Distinguished Faculty Fellowship.

The honor distinguishes faculty members whose work is nationally recognized. Dr. Podgorski's area of research interest and expertise is in the role of bone microenvironment in the progression of bone-trophic cancers, specifically metastatic prostate and kidney tumors. Her work has been instrumental in establishing the link between bone marrow adiposity, tumor growth and aggressiveness in bone. Dr. Podgorski and her team are investigating how fat cells, which are abundantly present in bone marrow, drive metabolic adaptation and chemoresistance. This two-year fellowship will provide additional support for Dr. Podgorski's ongoing research objectives focused on understanding the biology of metastatic prostate cancer and exploring new targets for therapy to improve outcomes for men with metastatic disease.

The Charles H. Gershenson Distinguished Faculty Fellowship was started by the WSU Board of Governors in 1985. Charles H. Gershenson was a former member of the Board of Governors. Since 1985, 91 Charles H. Gershenson Fellowships and 94 Board of Governors Fellowships have been awarded.

Izabela Podgorski, PhD

DO YOU HAVE A RESEARCH PROJECT THAT NEEDS FUNDING?

McLaren Health Care has formed a corporate level Research Funding Committee. This committee has been created to establish a system-wide strategic plan and process for awarding research funding to investigators. One goal of this committee is to support and strengthen investigator-initiated research within the corporation. Awards of up to $5,000 will be awarded to individuals involved in Graduate Medical Education Research (Residents and Fellows). Awards of up to $20,000 will be awarded to non-GME individuals interested in pursuing Investigator-Initiated research. Non-GME awards are open to all McLaren employees or affiliated providers. These funds are to be used for the conduct of the observational or interventional research study and will be awarded on a quarterly basis. Due dates for application submissions are January 1st, April 1st, July 1st, and October 1st of each year. The application is accessible **www.McLaren.org/FundingApplication**. Required information for the application includes a detailed description of the research project, as well as a proposed budget.

RESEARCH AROUND McLAREN

Introduction to the Phantom Patient
- Orientation Overview
- Introduction to Clinical Trials
- The Research Team
- Oncology 101 and Assessment of the Patient
- Self-Study: Moving Toward Better Cancer Treatment – Getting Involved with Clinical Trials

Phantom Patient Module #1
- The Research Protocol and Review of Eligibility
- Regulatory "Human Research Protection and Review of the Regulatory Coordinator"
- Informed Consent
- Oncore Review

Phantom Patient Module #2
- RECIST 1.1
- Shadow Charts and Source Documents
- CTCAE Toxicities
- Serious Adverse Events and Deviations
- Overview of NCI Studies

Phantom Patient Module #3
- Self-Study: Introduction to Vestigo
- Central Data Management and The Network
- Quality Assurance and the DSMP
- 90 Day Activation
- Pre and Post Awards
- Monitoring Visits
- End of Orientation Wrap Up

IMPLEMENTATION OF PHANTOM PATIENT MODULES FOR STUDY COORDINATOR TRAINING

Three Karmanos Clinical Trials Office authors will have their abstract published in an Association of American Cancer Institutes (AACI) booklet. Elizabeth Cunningham, MS, CCRP; Leah Dunham, MPH, CCRC and Bradley Olsen, BS, CCRP submitted their abstract, "Comprehensive application of supplemental phantom educational resources (CASPER): A friendly phantom patient to guide the way for new study coordinators." CASPER is a new training feature of the enhanced formal orientation program implemented in 2016 for new study coordinators.

After feedback from coordinators who had been through the original program, this new element of orientation includes three interactive Phantom Patient Modules (PPM) for study coordinators to become familiar with processes. PPM were implemented into the program in February 2022. The table (at left) outlines the orientation modules, which shows the phantom patient sessions that review and give more hands-on experience to what was learned in the orientation modules.

Future observation and modifications are planned for the PPM portion of the training to ensure study coordinators continue to become familiar with their roles through this orientation and the program remains relevant to their position requirements.

KARMANOS CANCER INSTITUTE AT THE TOLEDO CLINIC CANCER CENTER NOW OPEN

The Barbara Ann Karmanos Cancer Institute, headquartered in Detroit, has completed its expansion into Ohio with the opening of the new Karmanos Cancer Institute at The Toledo Clinic Cancer Center, located in Maumee. Karmanos and The Toledo Clinic held a ribbon cutting on Thursday, April 14, 2022. This is the first time the world-renown cancer center has provided its level of National Cancer Institute (NCI)-designated care outside of Michigan and the first time Karmanos has formed a partnership of its kind.

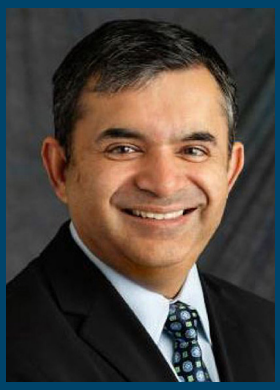
Karmanos began seeing their first patients at the new facility on Wednesday, April 13. Under the agreement, Karmanos operates the clinic's radiation oncology program, encompassing seven of the 22 exam rooms, including two procedure rooms. The Toledo Clinic will provide medical oncology services.

This growth across state lines brings advanced cancer care to the patients of Northwest Ohio, which includes increased access to clinical trials and the expertise and experience of the Karmanos Cancer Network of oncologists and other cancer specialists. The brand-new facility offers many advanced oncology therapies, including the new TrueBeam® radiotherapy system, from Varian Medical Systems. This state-of-the-art image-guided radiation therapy technology includes both HyperArc™ and RapidArc™ capabilities.

"I am thrilled to be able to offer advanced radiation therapy to patients in Maumee," said Faheem Ahmad, M.D., radiation oncologist at Karmanos. "The possibilities that we have in treating patients at this new facility in collaboration with the greater Karmanos network is something this region has not seen before. This partnership will bring a lot of hope to the area. Patients were driving hours to reach a comprehensive cancer center. Now, they have this convenient option in Maumee."

In addition to Karmanos bringing its physical presence to Northwest Ohio, the medical oncologists at The Toledo Clinic will benefit from the extensive experience and clinical knowledge of Karmanos clinicians by participating in the 15 multidisciplinary tumor boards – weekly meetings of Karmanos cancer experts collaboratively sharing patients' details and treatment options to make recommendations that reflect the latest thinking from the specialists.

The new cancer center also offers infusion and laboratory services, diagnostic imaging and an on-site pharmacy.



Faheem Ahmad, MD

RESEARCH AROUND McLAREN

Jijo Paul, PhD

MEDICAL PHYSICIST OUTLINES KEY ROLE OF MP LEADERSHIP IN RADIATION ONCOLOGY AND HEALTH CARE ORGANIZATIONS

Jijo Paul, PhD, M.Phil, EMBA, MS, medical physicist (MP) at Karmanos Cancer Institute at McLaren Macomb, McLaren Oakland and McLaren Clarkston, investigates the primary role of MP team leaders in radiation oncology (RO) administration and their involvement in essential business functions. His article, "What do medical physicists do? Leadership challenges in administration and various business functions," has been accepted for publication in Advances in Radiation Oncology, the official journal of the American Society for Radiation Oncology.

In his analysis, Dr. Paul illustrates the multiple roles of MP team leaders in RO and the health care system. MPs already play a critical role in clinical practices, research and development, teaching, formulating treatment techniques, implementing advanced imaging and treatment technologies and safely administering cancer therapy. In addition, Dr. Paul outlines that MP leaders play an essential role in business functions such as project management, strategic planning, decision making and more. He recommends that MPs should be offered opportunities for leadership, business skills and training provided by premier institutions across the country, and also suggests that this education and training should be a determining factor when choosing candidates to fill MP leadership roles. Dr. Paul's article will be published on the Advances in Radiation Oncology website.

HOW DO YOU DISCO?

KARMANOS RESEARCHERS DEVELOP MOBILE APP TO EDUCATE ABOUT COST OF CARE

In *Oncology Issues*, a publication of the Association of Community Cancer Centers, Karmanos Cancer Institute and Wayne State University researchers, Lauren M. Hamel, PhD, Susan Eggly, PhD, and research assistant Lorna Mabunda, MSI, explain how both institutions developed a mobile app to educate patients and providers about the importance of cost of care discussions. The application is called the Discussions of Cost (DISCO).

To read their article, go to the News section at **karmanos.org** and search "DISCO."

Lauren Hamel, PhD

Susan Eggly, PhD

Lorna Mabunda, MSI

METHOD TO EXTEND RESEARCH IN TIME MERIT AWARD (R37)

KARMANOS RESEARCHERS RECEIVE MERIT AWARD EXTENSION

Nerissa Viola, PhD, member of the Molecular Imaging Research Program at Karmanos and Heather Gibson, PhD, member of the Tumor Biology and Microenvironment Research Program, were recently granted a two-year extension for the National Cancer Institutes (NCI) Method to Extend Research in Time (MERIT) Award (R37). The extension allows Drs. Viola and Gibson to continue their research on imaging interferon-γ (IFN-γ) to interrogate response to immunotherapy.

Drs. Viola and Gibson are principal investigators on this grant entitled "Delineating Functional Immunity via Image-Guided PET." They started this research after realizing that at least half of cancer patients remained non-responsive to immunotherapy treatments, despite generally positive outcomes in the clinic. Through their work, they learned that there is a need for imaging biomarkers to guide immunotherapy and identify genetic markers to predict a patient's susceptibility to the treatment. Positive findings from their research can support predicting outcomes in cancer immunotherapy.

Receiving the MERIT Extension Award for this research is a prestigious accomplishment. Congratulations to Drs. Viola and Gibson!

Nerissa Viola, PhD

Heather Gibson, PhD

RESEARCH AROUND McLAREN

NEW DIGITAL RESOURCE AND SEMINARS TO HELP CANCER PATIENTS NAVIGATE FINANCIAL BARRIERS

THANKS TO MHEF GRANT

The Michigan Health Endowment Fund (MHEF) has awarded research investigators at the Barbara Ann Karmanos Cancer Institute a $100,000 Community Health Impact grant to support a new program addressing financial toxicity among cancer patients. Michigan Community Outreach to Address Financial Toxicity (MI-COST) will build upon ongoing community outreach and engagement work underway within Karmanos' Office of Cancer Health Equity and Community Engagement (OCHECE).

The objectives of MI-COST include developing a series of educational seminars on topics designed to help people with cancer and their caregivers navigate related financial barriers and creating a website to provide patients and caregivers with financial information and resources. OCHECE has been working closely with 11 Cancer Action Councils (CACs) throughout Michigan to gather thoughts on what cancer patients need. CACs are groups of cancer survivors, caregivers and advocates who apply their knowledge about local cancer issues to improve the lives of cancer patients, survivors and caregivers in their communities. In 2019, financial hardship was a theme that emerged in many of the CAC conversations.

"One of our roles in OCHECE is to connect our communities to our scientists and our scientists to our communities to ensure that there is community input into our cancer center's research agenda," said Hayley Thompson, Ph.D., co-investigator for the MI-COST program, associate center director for community outreach and engagement at Karmanos, and professor in the department of oncology at Wayne State University's School of Medicine.

"One of those strategies for doing that includes having this network of CACs who represent different areas, different regions, different populations and different communities. They help us understand what to prioritize in cancer research based on the needs and the disparities they observe around them in their communities. When we mixed the councils into different subgroups, financial hardship emerged as a leading priority and the area they wanted to tackle as a larger network."

Theresa Hastert, Ph.D., assistant professor in the department of oncology at Wayne State University's School of Medicine and member of the Population Studies and Disparities Research Program at Karmanos, is the principal investigator for MI-COST. Dr. Hastert has been approaching this opportunity from a research perspective, starting from the beginning conversations among the CACs. Instead of a more traditional method of creating a survey for CAC members to answer and the investigators making the determination of what's needed based on the themes, she's flipping the process.

"I have a lot of experience working with data that we've already collected, but data we collect through a survey is only as good as the questions we ask," said Dr. Hastert. "By allowing the CAC members to communicate, we're getting richer information about how finances were an impact when cancer entered their lives and what would have been helpful to them at the time. And we're incorporating this information into what we're doing. It's a valuable and unique opportunity as a researcher to have your work be more impactful for the people you want to ultimately help."

With the $100,000 grant, the investigators have begun developing seminars and a digital resource. A Community Advisory Board, which includes CAC members, cancer survivors, caregivers, providers and community organizations, will help determine topics and features that will be included.

Find more information about Karmanos' Office of Cancer Health Equity and Community Engagement and their outreach in 46 counties throughout Michigan at karmanos.org/officeofcommunity.

RESEARCH AND CONVERSATIONS FROM KARMANOS SPECIALISTS

Stay up to date on research, published articles and recognitions from Karmanos multidisciplinary teams and research program members in the News section at **karmanos.org/healthcareprofessionals**, including:

- **Dr. Isaac Powell explains genes in African American men that may lead to prostate cancer diagnosis** – Isaac Powell, MD, urologic oncologist and member of the Genitourinary Oncology Multidisciplinary Team talks to Angela T. Moore of 910 AM Superstation's *Empowered*, about what he has found in his research, which includes population hereditary genetics.
- **Multidisciplinary Team co-leader, senior author of article looking at the impact of heart failure after breast cancer** – Michael Simon, MD, MPH, co-leader of the Breast Cancer Multidisciplinary Team, is the senior author of "Toward a Better Understanding of the Differential Impact of Heart Failure Phenotypes After Breast Cancer," published in the *Journal of Clinical Oncology*.
- **Karmanos Multiple Myeloma Multidisciplinary Team leader co-investigator on national trial confirming importance of Autologous Stem-cell Transplant as part of initial therapy** – Jeffrey Zonder, MD, leader of the Multiple Myeloma and Amyloidosis Multidisciplinary Team and member of the Hematology Oncology Multidisciplinary Team, co-authored, "Triplet Therapy, Transplantation, and Maintenance Until Progression in Myeloma," published in *The New England Journal of Medicine*.
- **Institutional Perspectives in Cancer – Breast Cancer** – A virtual discussion featuring members of the Breast Cancer Multidisciplinary Team (MDT): Hadeel Assad, MD, medical oncologist (discussion chair); Michael Simon, MD, MPH, co-leader of the Breast Cancer MDT; Lawrence Flaherty, MD, medical oncologist and Jailan Elayoubi, MD, medical oncologist.
- **Ovarian Cancer Education Podcast: Clinical Trials** – Podcast discussion featuring Ira Winer, MD, PhD, FACOG, gynecologic oncologist and member of the Gynecologic Oncology and Phase I Clinical-Pharmacology Multidisciplinary Team and Jennifer Land, RN, clinical trials nurse.

EQuIP CORNER

Patricia Ivery, RN, MSN

Andrea Klaver, MBA, CHRC

LEGAL LIABILITY OF CLINICAL TRIALS

By Patricia Ivery, RN, MSN, CHRC and Andrea Klaver, MBA, CHRC

There is an increasing trend of researchers, institutional review boards (IRBs), and administering hospitals or clinics being sued by research subjects. An ordinary Google search will quickly provide you with a laundry list of law offices and various other injury lawyers who are happy to assist those individuals who feel, rightfully or wrongfully, harmed in a clinical trial to sue for medical malpractice. Using phrases like:

> *"Clinical trials should always be conducted as safely as possible. Unfortunately, **that doesn't always happen**, and sometimes volunteers ... suffer severe complications due to **researchers' negligence**,"*
>
> *"Participating in a clinical trial involves signing **reams of paperwork that absolve the researchers** from many aspects of liability,"*
>
> *"Were you coerced into participating in a clinical trial? Doctors and administering clinics are already well-protected from such claims, and they may seem **untouchable** after you signed paperwork."*

Although these types of statements are incendiary and are a harsh misrepresentation of clinical research as a whole, our history – and even present activities – can lead some to believe that these statements are true.

Our past and present has set the tone for litigation

No one can forget the inhumane atrocities, in the name of research, committed by the Nazi physician on concentration camp prisoners without their consent. Several years ago, due to the investigative efforts of medical journalist Rebecca Skoot, it was brought to the public's attention the unethical saga of Henrietta Lacks. In 1951, her cervical cancer cells (HeLa cells) were harvested by Dr. George O. Gey without her consent and sold across the world.

Thalidomide, a drug manufactured in Europe given to pregnant women for morning sickness caused horrific birth defects and death before the age of

one. Although thalidomide was never licensed in the United States, it was distributed as samples to American doctors to try with their patients. It was common practice at that time for drug companies to pass on experimental drugs to doctors who were then paid to collect data on their patient's results without knowledge or consent of the pregnant patient.

The Tuskegee syphilis study is well remembered extending from 1932-1972. Well-intended competent researchers carried out unethical, deceitful, wrongful research on a trusting population of Negro males. Not only did the researchers know there was a cure for syphilis and withheld this information from the subjects, their actions had far-reaching consequences beyond the research subject. The subject's wives contracted syphilis and their children were born with congenital syphilis. Improper research did stop there; it continued.

In 1991 an 18-year-old research subject name Jesse Gelsinger, died because of participating in a gene transfer experiment conducted at the University of Pennsylvania. Jesse had an x-linked genetic disease of the liver. After his death, it was discovered that Jesse did not meet the eligibility criteria to participate in the study. The investigators failed to report two prior subjects had experienced serious side effects that should have halted the trial. The investigator failed to disclose in the informed consent the deaths of monkeys given similar treatment. Most grievous of all, the investigator did not disclose that he had a financial stake in the gene therapy manufacturer.

More recently, a 2014 case arising at the University of Alabama Birmingham proposed to hold researchers liable for failure of informed consent in a clinical trial in the absence of physical injury. Premature infants were treated with varying levels of oxygen, all within the standard of care, to determine ideal oxygen percentage. While OHRP later determined that the informed consent documents did not meet regulatory standards, a district court found that there was no proof that participation in the study injured the participants. In this case, the court considered whether a lack of informed consent claim requires a plaintiff to prove an injury arising from participation in a study.

We could go on and list more, but the point being is that we all understand that if we fail our responsibilities as researchers, specifically non-compliance with federal regulations, institutional policies, and state and local laws, it can have serious consequences. Not only suspension of study, but termination of the study, federally mandated reporting to the FDA or OHRP, disbarment from research, or worse yet, jail time.

Despite institutional and regulatory agency reprimand, investigators can find themselves being sued by the research subject(s) who believes that he or she has been injured or wronged because of participation in a research study.

Why research participants sue

It is not just the investigator who is target of a lawsuit, but also Sponsors, clinical research organizations, IRBs, medical schools, hospital, and group practices. Attorneys will frequently name every potential litigant.

What reason would a research participant file suit? In theory, the list may include: emotional distress; battery; fraud; violation of federal research

CONTINUED ON PAGE 16

EQuIP CORNER

UPCOMING RESEARCH EDUCATION

SOCRA
31st Annual SOCRA Conference
September 14 - 17, 2022
Virtual Event Only
Early bird registration ends August 22, 2022
For upcoming educational opportunities, please visit www.socra.org/conferences-and-education

MAGI
MAGI's Clinical Research Hybrid Conference – East
October 16 - 19, 2022
Las Vegas, Nevada
Planet Hollywood Las Vegas Resort & Casino
For upcoming educational opportunities, please visit www.magiworld.org

ACRP 2022
For upcoming educational opportunities, please visit www.acrpnet.org/events

BROWN BAG SERIES

Our Brown Bag Series is temporarily on hold. Please watch your email and the EQuIP Education webpage at www.mclaren.org/main/research-education for more details.

For more information, contact Research Integrity at (248) 484-4950 or HRPP@mclaren.org.

LEGAL LIABILITY OF CLINICAL TRIALS

CONTINUED FROM PAGE 15

regulations; conflict of interest; breach of confidentiality; or professional negligence. Each of these reasons may be plausible claims under certain conditions. However, according to legal literature, the most appropriate and viable claim will ordinarily be a variant of professional negligence. In the context of clinical research, it would be described as research malpractice.

In order for the plaintiff to successfully prove negligence, it must be shown, by a "preponderance of evidence" that all of the following elements transpired:

1. The plaintiff had a duty toward the plaintiff;
2. Duty was breached;
3. Plaintiff suffered harm or damage; and
4. The breach was the proximate cause of harm the plaintiff suffered.

How might these four elements appear during a clinical research trial? It starts with duty. From the onset of a clinical trial, the mere participant-researcher relationship creates a duty. The participant trusts that the physician-researcher is knowledgeable, appropriately recommended them for the study, explained the study fully, and will keep them informed of relevant information. Duty is further established through the medical standard of care expected from any physician. Adherence to the study protocol, applicable institutional policies, codes, guidelines, laws, and regulations all further create a basis for duty.

It is beyond the scope of this article to give a classroom course in legal liabilities. However, we would like to share with you that in review of clinical trial litigation suits one common theme among most research lawsuits was the claim of insufficient informed consent. Informed consent is one of the most coveted rights of a research subject. According to the textbook, *The Medical Malpractice Survival Handbook*:

> *"But physician-researchers will also have informed consent responsibilities that exceed the "material information/reasonable person" test frequently applied to ordinary clinical care. Physician-researchers will almost certainly be held to accepted national standards for investigators, including the Common Rule, FDA regulations, and ICH-GCP standards. These regulations and the guidance documents that accompany them will likely provide additional evidence of the type of* ***duty that physician-researchers have in regard to informed consent****."*

What can researchers do?

Foremost, pay careful attention to the informed consent process. Maintain a caring and respectful relationship with subjects. Be open and candid during the consenting process. Carefully conducting the research protocol can reduce the likelihood of lawsuits. Besides proper valid consenting of research subjects, there are other golden rules to mitigate the possiblity of clinical trial lawsuits. See the table on next page.

GOLDEN RULES

1. Accept only studies for which you and your practice have sufficient expertise and resources to understand and conduct.
2. Do not accept studies in which the risk to participants outweighs the potential benefits and scientific value of the study.
3. Adhere scrupulously to the inclusion/exclusion criteria.
4. Know and follow applicable aspects of the Common Rule and FDA regulations, ICH-GCP standards and institutional or group practice policies, the research contract, and FDA Form 1572.
5. Ensure that the study has been approved by an appropriate IRB.
6. Consult attorney or insurance carrier to determine whether current insurance policy covers claims related to clinical trials.
7. Employ qualified and certified clinical trial coordinators to help administer the trials.
8. Ensure that potential participants are fully and properly informed.
9. Ensure that "alternative treatments" section of the informed consent document is clear and complete.
10. Disclose conflict of interests to participants during the consent process.
11. Follow approved protocol scrupulously.
12. Monitor medical literature related to the trial, study drug, or participant's medical condition for significant new findings that might impact the study.
13. Ensure that participants have 24-hour access to someone knowledgeable about the study.
14. Withdraw participants from a clinical trial according to the protocol, or when the participant's continuation in the study represents a greater likelihood or degree of harm than anticipated at the outset of the study

SOURCE: *Table from De Ville, K., Brigham, D. Liability in Clinical Trials Research. In Sanbar S (Ed.),* The Medical Malpractice Survival Handbook. *1st ed. Philadelphia, PA: Mosby Elsevier; 2007; 91-109.*

This article should give you just a quick glimpse into the subject of legal liability in clinical trials. If you have any questions, you may always contact Research Integrity at (248) 484-4950 or HRPP@mclaren.org.

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

Carlos F. Rios-Bedoya, ScD

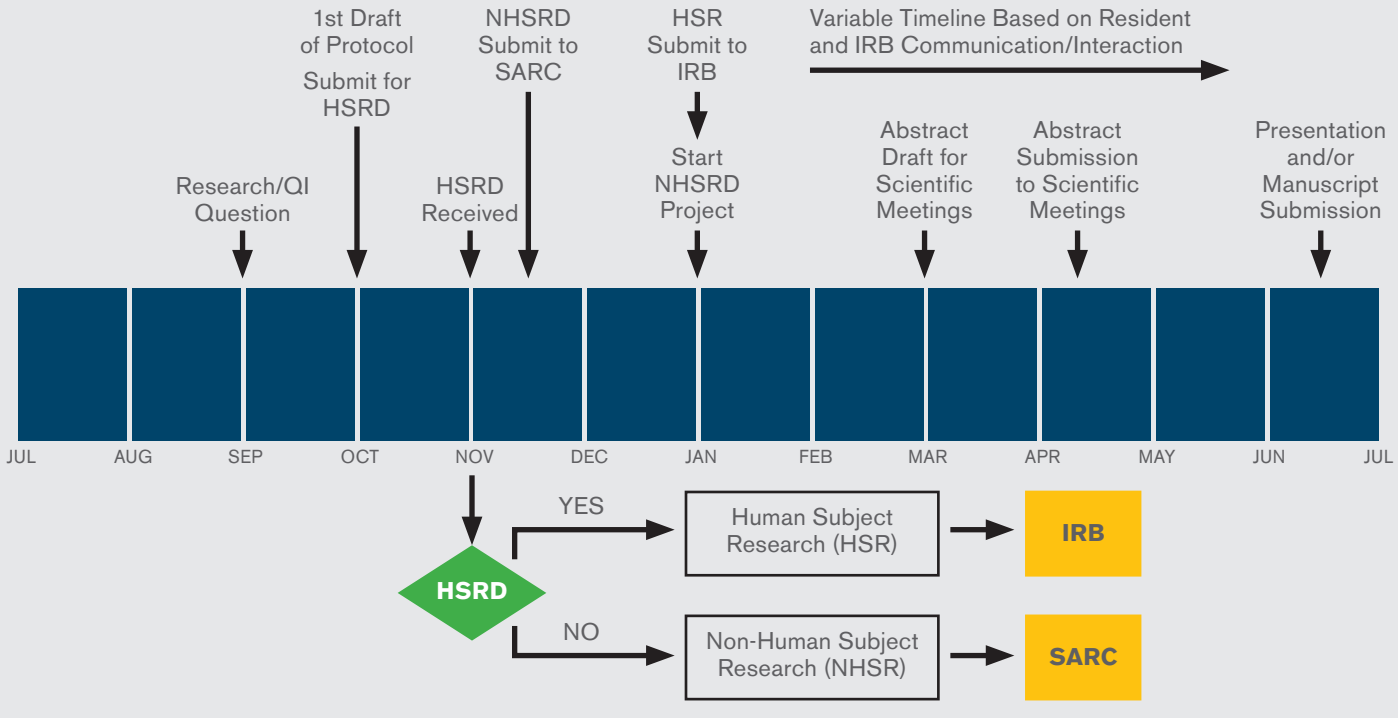
WELCOME TO ACADEMIC YEAR 2022-2023

By Carlos F. Rios-Bedoya, ScD, MPH

I would like to welcome all new and returning residents to McLaren Health Care. Since it is the beginning of a new academic year, I would like to introduce the Division of Scholarly Inquiry (DSI) to our new residents and to remind our returning residents of the recommended timetable to complete their scholarly activity project(s) as required by the Accreditation Council for Graduate Medical Education (ACGME).

Recommended Timetable for Completion of Scholarly Activity Project beginning in Year 2

(Based on a 3-year residency training program)



The DSI is responsible for planning, organizing, implementing, monitoring, and evaluating the scholarly activity curriculum mandatory for all first-year residents. Additional responsibilities include providing support and assistance to all residents in the areas of epidemiology, research design, statistical analysis, dissemination of findings from scholarly activity projects (i.e., poster and oral presentations, manuscript publications) through a cadre of PhDs assigned to McLaren hospitals that sponsor residency training programs and fellowships. This table shows the list of PhDs assigned to those specific McLaren hospitals and residency programs. Furthermore, the DSI also coordinates and leads journal clubs and other graduate medical education trainings and didactics (e.g., Step 3 prep session, biostatistical seminars, and CME granting conferences and trainings).

List of PhDs assigned to McLaren Hospitals and Residency Training Programs

Hospital	PhD	Program *(subject to change)*
Bay Region	Dr. Robert Flora *(temp.)* Dr. Carlos F. Ríos-Bedoya *(temp.)*	Family Medicine
Flint	Dr. Theresa Atkinson	Ortho
	Dr. Sunil Upadhyay	Internal Medicine
	Dr. Erin O'Connor	Family Medicine
	Dr. Carlos F. Ríos-Bedoya	Fellowships
Greater Lansing	Dr. Mark Jones	General Surgery
	Dr. Jacek Cholewicki	Cardiology, GI, Oncology, Internal Medicine
	Dr. John Popovich	Ortho, OB/GYN, Anesthesia, Family Medicine
Macomb	Dr. Grace Brannan Dr. Carlos F. Ríos-Bedoya	Cardiology, Emergency Medicine, Family Medicine, General Surgery, Internal Medicine, OB/GYN, Ortho, Podiatry, Urology
Oakland	Dr. Olga J. Santiago-Rivera	Anesthesia, Emergency Medicine, Family Medicine, Internal Medicine, Ortho, Otolaryngology, Podiatry, Pulmonary and Critical Care, Radiology
St. Luke's	Dr. Carlos F. Ríos-Bedoya	Family Medicine

Finally, I would also like to congratulate all residents, faculty, PhDs, and other personnel involved in residents' scholarly activity projects at McLaren. This past academic year was one of the most productive in terms of number of scholarly activity projects presented at scientific conferences and meetings. Similarly, the number of awards and recognitions received at these dissemination venues was outstanding. Keep up the good work and strive to do it even better this year.

The Division of Scholarly Inquiry is committed to support and facilitate scholarly activity for McLaren residents, fellows, and faculty. For additional information contact Dr. Carlos F. Ríos-Bedoya at carlos.rios@mclaren.org.

ANNOUNCEMENTS AND WHAT'S NEW

CONGRATULATIONS TO McLAREN HEALTH CARE NURSES

Congratulations to the five McLaren Health Care nurses that have completed the DNP program through Grand Valley State University. Funding of this program was provided by the HRSA Advanced Nursing Education Workforce Grant. These five nurses are eligible to sit for the Adult/Gerontologic Nurse Practitioner examination and will practice in rural and/or underserved primary care shortage areas.

GRAND VALLEY STATE UNIVERSITY

McLaren's graduates are:

Kelsey Crampton - McLaren Port Huron

Cory Mills - McLaren Northern Michigan

Lauren Myers - McLaren Northern Michigan

Alec Tuchowski - McLaren Northern Michigan

Tiffany Hornbeck - McLaren Northern Michigan

Lauren Thomas

The Research Integrity Department is pleased to welcome **Lauren Thomas** as the newest Administrative Assistant at the Auburn Hills Corporate Office. Most recently, Lauren worked at McLaren Medical Laboratories in Flint. Dedicated and driven to rendering high quality service, Lauren brings a wealth of experience and is excited to join a team where she can apply knowledge and expand her skill set.

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