RESEARCH *Matters*

SUMMER 2021

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

McLaren | DOING WHAT'S BEST.®

RESEARCH AROUND McLAREN

CARDIOLOGIST ENGAGES IN RESEARCH STUDY INVOLVING NEW CARDIOVASCULAR ROBOTIC SYSTEM

For Harry Colfer, MD, research has been an integral part of his thriving cardiology practice. An interventional cardiologist at McLaren Northern Michigan, Dr. Colfer has been involved in clinical research for the past 40 years.

In citing the benefits of research, he noted there is evidence that patients involved in clinical trials do better than those not participating in clinical trials, even if they are similarly treated.

"Research requires physicians to be more diligent and pay close attention to all aspect of care," he said. "I find that it truly sharpens my practice. For me, personally, research adds a level of motivation and a reason to get up in the morning and be excited about what I do."

Dr. Colfer's latest research project involves a national study which examines the effectiveness of the CorPath Vascular Robotic System compared to standard techniques for managing heart attacks. There are 20 clinical sites across the country enrolled in the study, and Dr. Colfer is the principal investigator at McLaren Northern Michigan. His colleague, Dr. Steve Mattichak, will also be part of the study, which has been approved and will soon be enrolling patients. Dr. Colfer noted the goal is to enroll 20 patients.

In December of 2020, Dr. Colfer made history when he became the first physician in the Midwest to perform back-to-back robotic procedures treating STEMI heart attacks using the CorPath Vascular Robotic System.

A STEMI (ST-elevated myocardial infarction) occurs when a coronary artery becomes completely blocked and a large portion of the muscle stops receiving blood.

"With a STEMI, it is critical to get to the patient as quickly as you can," he said. "The longer it takes, the more heart muscle damage occurs. The robotic system has the ability to be more precise, increasing the ability to get to the blocked vessel more quickly."

Dr. Colfer noted that the expertise of cardiovascular invasive specialists in the cath lab is also crucial in operating the technology involved with the CorPath vascular robotic system. They load the equipment with necessary wires and

Opposite page, left to right: Denise Antonishen, RN, BSN, CCRC; Harry Colfer, MD; and Colleen Shaw, RN, BSN, CCRC.

balloons and work closely with the cardiologist throughout the procedure.

The study has two components: 1) comparing if a heart attack can be treated more effectively at the bedside with the robotic technology compared to conventional manual management by the physician, and 2) if pre-programming the robot enhances the efficiency of getting the wires positioned.

McLaren Northern Michigan is one of only 65 hospitals in the country to offer the CorPath Vascular Robotics System.

Along with benefits to the patients in terms of more precision and accurate placement of lifesaving stents, the CorPath system also offers benefits to the physicians and cath lab staff. It allows for reduced x-ray exposure and less operator fatigue.

"We are in the early stages of robotic surgery," Dr. Colfer said. "As we use these technologies and become involved in research, we are not only doing what is best for our patients today, we are also helping to expand medical practice which will lead to more innovation in the future."

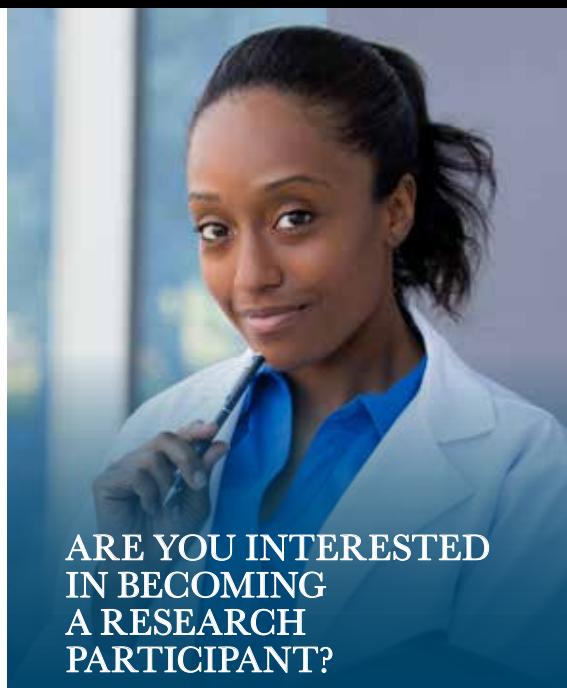
MCRI SITE SPOTLIGHT

McLAREN NORTHERN MICHIGAN

McLaren Center for Research and Innovation at McLaren Northern Michigan is a recognized leader in the conduct of cardiology clinical trials. Previously known as NISUS, the department was originally opened in 1984 and was a premiere site for conducting clinical trials from well known Industry Sponsors in many therapeutic areas. Today, MCRI at Northern Michigan is strongly focused on cardiology, which is only fitting given the subsidiary has been ranked in the top 50 cardiovascular hospitals in the nation for several years. "Our research studies and clinical trials - as both leaders and participants – increase the breadth and depth of treatments, including new medications and emerging interventional protocols", said Heart and Vascular Center President and local Principal Investigator, Harry Colfer, MD.

Dr. Colfer is the Principal Investigator on eight active drug and device trials at McLaren Northern, and has been involved in research at the site since the beginning. Dr. Colfer is currently supported by an outstanding team of clinical research professionals. Denise Antonishen, BSN, RN, CCRC, Colleen Shaw, BSN, RN, CCRC, Peggy Ward, RN, CCRC and Mary Catton, BSN, RN, are all highly experienced research nurses who support the day to day operations of extremely complex clinical trials. The whole team is supported by research assistant, Lisa Rogers.

MCRI has a number of exciting new trials coming through the pipeline and with several studies actively enrolling, McLaren is proud to offer patients in Northern Michigan a wide variety of research opportunities and hope that their involvement in these trials can provide the basis for new directions in accepted treatments, for the benefit of current and future patients.



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**
- **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

McLaren Center for Research and Innovation is actively seeking out Orthopedic clinical trials and any investigators who might have interest in conducting them across the McLaren system. Please contact the McLaren Center for Research and Innovation at (248) 484-4960 or MCRI@mclaren.org if you are interested in adding to our orthopedic clinical trials portfolio.

MCRI OPENS FIRST ORTHOPEDIC CLINICAL TRIAL AT McLAREN GREATER LANSING

McLaren Center for Research and Innovation is pleased to announce the opening of our first orthopedic clinical trial with Dr. Wesley Mesko at McLaren Greater Lansing. "The Orthopedic service line is something we have been looking to add for quite some time," says MCRI Director, Pamela Wills-Mertz. The TRIATHLON study with Stryker is a unique retrospective and prospective registry for patients who have had a Triathlon All-Polyethylene Tibia implant over the last ten years. Dr. Mesko has been using the Stryker implant for many years and looks forward to gathering some useful data on the device.

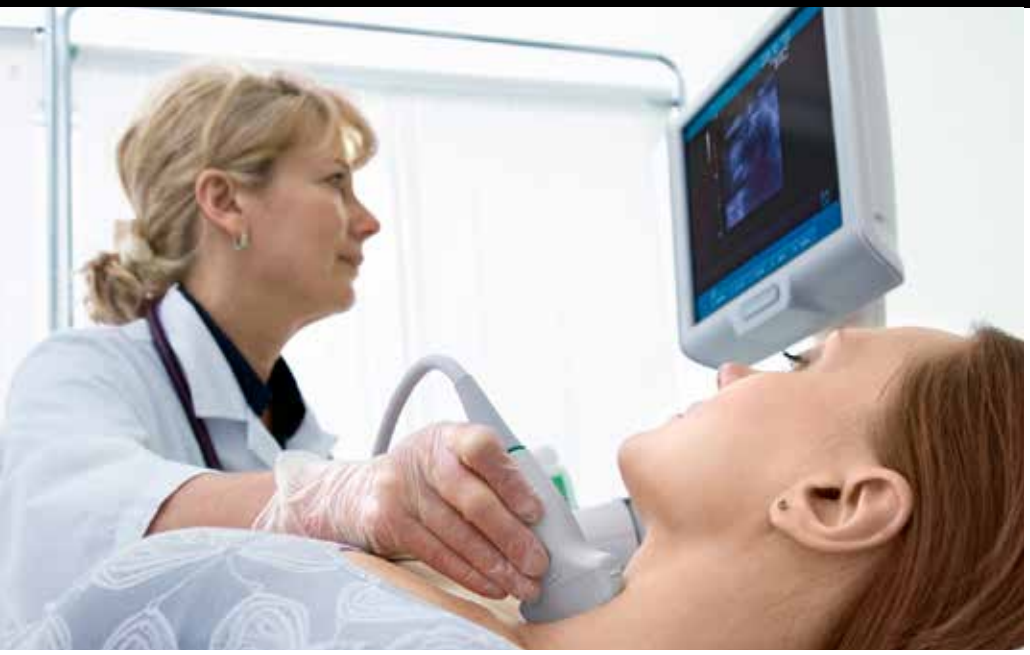
J. Wesley Mesko, MD

Dr. Linda Peterson, Chief Medical Officer of McLaren Greater Lansing, is excited to see the orthopedic service line gaining some traction with clinical trials, "Being able to provide our patients with an individualized, multidisciplinary approach to their care is made possible by high quality research. Medical advancements and emerging technology that comes from clinical research trials are something we are proud to offer McLaren patients. Enhancing the orthopedic service line with clinical trials gives us the opportunity to positively impact the clinical outcomes of our patients and increases the value of their care."

Linda Mercado Peterson, MD

RESEARCH FUNDING FOR INVESTIGATORS

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 November 1st of each year. Submit your application to www.McLaren.org/FundingApplication. Required information for the application includes a detailed description of the research project, as well as a proposed budget. Research Matters will publish awardee information in future issues. Good luck to all applicants!



THROAT CANCER NOW SURPASSES CERVICAL CANCER AS THE MOST COMMON HPV-RELATED CANCER

Karmanos offers five different clinical trials testing customized treatments for this type of cancer

Ammar Sukari, MD

Doctors have long known that the Human Papilloma Virus (HPV) is linked to cervical cancer. However, many members of the general public and even members of the medical community aren't aware of the strong link between HPV and head and neck cancers.

Ammar Sukari, MD, leader of the Head and Neck Multidisciplinary Team at the Barbara Ann Karmanos Cancer Institute and associate professor in the Department of Oncology at Wayne State University School of Medicine, notes that almost 15,500 men and approximately 3,500 women were diagnosed with HPV-related oropharyngeal squamous cell carcinoma (generally considered throat cancer) in 2015. He cites statistics from the Center for Disease Control and Prevention (CDC).

This means that oropharyngeal cancer has surpassed cervical cancer as the most prevalent HPV infection-related cancer.

Oropharyngeal squamous cell carcinoma accounts for about 30 to 40 percent of all head and neck cancers. Oncologists are seeing cases of this cancer due to HPV infection in mostly non-smokers, non-drinkers and younger Caucasian males in higher socioeconomic brackets, according to Dr. Sukari.

HPV is a human-only virus that can infect skin and mucosal membranes (such as those in the mouth or anus). More than 200 subtypes of HPV can infect a human's squamous cells at the basal layer (the deepest layer) through damaged areas in the skin or mucosa.

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RESEARCH AROUND McLAREN

THROAT CANCER NOW SURPASSES CERVICAL CANCER AS THE MOST COMMON HPV-RELATED CANCER

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The majority of HPV subtypes exclusively infect human skin, and specific HPV subtypes infect only the mucosa. These mucosal HPV viruses are sexually transmitted and affect tens of millions of Americans every year. HPV infections are so prevalent that the CDC states that nearly every sexually active man and woman will be diagnosed with HPV sometime in their lives.

Many times, HPV infections are asymptomatic. Nine out of 10 cases of mucosal HPV are eliminated by the human immune system. However, in 10% of HPV infections – specifically 20 to 40 subtype infections -- some of the infected cells survive and serve as the spark leading to different types of cancers.

This is dependent on the primary location of the infection. For example, an HPV infection at the base of the tongue could lead to tongue cancer 20 to 30 years after the initial infection.

"Some people will have changes in their DNA where the virus DNA will be embedded in those infected cells' DNA," Dr. Sukari said.

HPV-related cancers include oropharyngeal cancer, cervical cancer and anal cancer. Additionally, some cancers of the vulva, vagina and penis are caused by HPV infections.

Symptoms of HPV-related throat cancer (oropharyngeal) may include swollen lymph nodes in the neck, a lump or ulcer in the throat, difficulty swallowing and/or pain with swallowing.

If caught early, HPV-related oropharyngeal cancer (HPV+ OPC) is highly curable. Treatment varies depending on cancer stage, presentation, patient's comorbidities (health conditions that the patient already has), and the medical team's expertise level in managing head and neck cancers.

As a general rule, treating most OPC requires more than one type of treatment modality and may include surgery, radiation and chemotherapy.

In the cases of locally-advanced cancer, oncologists might use a combination of chemotherapy, radiation and surgery, although chemotherapy and radiation are often adequate to cure up to 95% of this type of cancer, even when it has spread to less than three lymph nodes, according to Dr. Sukari.

The CDC notes that throat cancers linked to HPV have increased significantly over the last 15 years in the United States. Dr. Sukari accredits this increase to changes in sexual practices and greater awareness among doctors regarding the link between HPV and oropharyngeal cancer.

"The World Health Organization added HPV as a risk factor for oropharyngeal cancer approximately 15 years ago," Dr. Sukari said. "Before that, doctors weren't checking their head and neck cancer patients for HPV biomarkers." Biomarkers are substances or processes that are indicative of the presence of cancer in the body.

Although many doctors are more aware of the link, Dr. Sukari says there's much more work needed to raise awareness. He said the field is changing so quickly, there's a likelihood that individuals teaching today's medical students aren't yet fully aware of the scope of what he calls the HPV infection and head and neck cancer health crisis.

"Everyone knows about cervical cancer and Pap tests," he said. "The incidence of cervical cancer has been on the decline for a long time. The same needs to be done to raise awareness about HPV and its link to oropharyngeal cancer. It's very common, and it's on the rise. The red light is flashing on this disease."

Dr. Sukari also strongly advocates for the HPV vaccine, also known as Gardasil®, which was first approved by the U.S. Food and Drug Administration (FDA) in 2006 to prevent cervical cancer linked to HPV. In 2018, the FDA approved a supplemental application for Gardasil 9, expanding the vaccine's approved use to include women and men aged 27 through 45 years. Gardasil 9 prevents certain cancers and diseases caused by the nine HPV types covered by the vaccine.

Because of the lack of awareness of the link between HPV and oropharyngeal cancer among the public, Dr. Sukari emphasized that more people need to be aware of the benefits of receiving the HPV vaccine in preventing the incidence of many cancers in the future.

"There is some stigma around the vaccine," he said. "All those sexually transmitted diseases have a stigma around them too. Some doctors may not be comfortable discussing this with their patients or parents, in the case of pediatric practices. There is an urgent need to have a lot of work done on the part of schools, universities and public health professionals in educating the public about the HPV vaccine. The vaccine can prevent cancer nearly 100 percent of the time, both cervical cancer and oropharyngeal cancer."

Karmanos currently offers five different clinical trials for those diagnosed with HPV-related oropharyngeal cancer to test treatments created explicitly for HPV-related throat cancers. These trials have two goals in mind, the first being to increase the cure rate of these cancers and the second to minimize long-term organ damage that may occur due to different treatment modalities needed to cure these cancers.

"There are a lot of new studies and clinical trials, so we have the ability to tailor treatments," Dr. Sukari said. "We have trials that require high-level skills and specialized centers to be able to run them. We want to apply the most effective treatments while at the same time the least toxic treatments. We have most of the national clinical trials in HPV-related head and neck cancers."

For more information about HPV-related head and neck cancer treatments, participating in a clinical trial or scheduling an appointment, please call 1-800-527-6266 or visit Karmanos.org.

RESEARCH AROUND McLAREN

KARMANOS CANCER ACTION COUNCIL WORKS TO SUPPORT LGBTQ CAREGIVERS

Being a caregiver to a loved one with cancer is a challenging but essential position for anyone who fills it. There is a robust network of resources available for many caregivers, including support groups, instructional guides and more. Unfortunately, for caregivers in the lesbian, gay, bisexual, transgender and queer (LGBTQ) community who may be supporting partners, friends or chosen family, resources are slim. This is concerning considering that one out of every three LGBTQ adults serves in an unpaid caregiving role. In contrast, only one out of every six adults in the general U.S. population is an unpaid caregiver, according to research compiled by the National LGBT Cancer Network.

The LGBTQ Cancer Action Council (CAC), organized by the Office of Cancer Health Equity and Community Engagement (OCHECE) at Karmanos Cancer Institute, identified the lack of resources for LGBTQ caregivers as a top priority for the group to address. The LGBTQ CAC is a group of community stakeholders that are LGBTQ-identified cancer survivors, cancer caregivers and advocates. This group works with OCHECE researchers to center their voices and experiences in future research projects.

The LGBTQ CAC has spent the last year identifying shared challenges amongst LGBTQ caregivers so they may design an intervention to address the needs of these critical support people. Their review unearthed a variety of issues. For example, they found that support materials tend to be heteronormative and focus on a male/female dyad. Additional troubling findings reflect those reported by the National LGBT Cancer Network, which states:

> *LGBT caregivers have experienced microaggressions such as rendering a partner's role in care decisions as "illegitimate," or hostile remarks and behaviors by medical staff, along with macro-level discrimination such as prohibitions against including same-sex partners on health insurance, designating visiting spaces as "family only," or fining same-sex partners for parking in areas where family members can park for free.*

In response, the LGBTQ CAC has outlined a plan to begin addressing the lack of resources available for LGBTQ caregivers. They started by examining existing interventions to identify sources that can be adapted to be more inclusive. The

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THE DONATION WILL FUND DIFFUSE LARGE B CELL LYMPHOMA RESEARCH

The Barbara Ann Karmanos Cancer Institute has been awarded a $325,372 grant from U CAN-CER VIVE Foundation. The funds will support cancer research focused on diffuse large B cell lymphoma (DLBCL).

“We continue to be amazed by the work the dedicated doctors and researchers at Karmanos have made and are optimistic that this new grant will provide the support they need to continue their lifesaving research,” said Kelley LaFontaine, co-founder, U CAN-CER VIVE. “We take great pride in knowing that each dollar we raise goes directly toward cancer research here in the state of Michigan.”

The U CAN-CER VIVE Foundation grant will fund the study Circulating Tumor DNA as a Predictive Biomarker of Outcomes of Autologous Stem Cell Transplantation in Relapsed Diffuse Large B cell Lymphoma, led by Dipenkumar Modi, MD member of the Hematology Multidisciplinary Team at Karmanos. In this pilot study, Karmanos researchers will measure circulating tumor DNA (ctDNA) to help identify patients who are likely to relapse after autologous stem cell transplantation.

“Diffuse large B cell lymphoma (DLBCL) is the most common subtype of non-Hodgkin’s lymphoma (NHL). Approximately 30 percent of patients with this disease experience a relapse after standard treatment. About half of the patients with disease relapse achieve durable remission when treated with salvage chemoimmunotherapy followed by autologous stem cell transplantation. Currently, the available methods are not highly sensitive enough to identify patients who are likely to relapse following autologous stem cell transplantation. Through this study, we hope to find a biomarker to help identify patients at high risk of relapse and predict transplant outcomes. This will have a significant impact on patient care, and the results of this study will set the foundation for precision medicine-driven treatment strategies in DLBCL,” Dr. Modi said.

About U CAN-CER VIVE

Founded by siblings Ryan and Kelley LaFontaine, it is the ongoing mission of the U CAN-CER VIVE Foundation to provide vital funding and support for local cancer research grants to create a cancer-free world. Upon becoming an official nonprofit foundation in February 2016, U CAN-CER VIVE has raised nearly $3,000,000, providing funds for research grants in the State of Michigan. This passion toward the fight against cancer stems from the heart and soul of LaFontaine’s commitment to give back after experiencing the affliction of cancer firsthand.

Left to right: Todd McKay, grant chair of U CAN-CER VIVE; Gerold Bepler, MD, PhD, president and CEO of Karmanos; Max Muncey, communication chair, U CAN-CER VIVE Foundation; Kelley LaFontaine, co-founder, U CAN-CER VIVE; Dipenkumar Modi, MD, Karmanos physician; Linda Filipczak, fund development officer at Karmanos; Joseph Uberti, MD, PhD, co-leader, Karmanos Bone Marrow & Stem Cell Transplant Multidisciplinary Team; Jim Bennethum, chair, Karmanos Cancer Foundation.

RESEARCH AROUND McLAREN

KARMANOS CANCER INSTITUTE PARTNERS WITH THE TOLEDO CLINIC TO ESTABLISH A NEW CANCER CENTER IN NORTHWEST OHIO

The Barbara Ann Karmanos Cancer Institute is pleased to announce that it has entered into a partnership with The Toledo Clinic to establish a new cancer center in Maumee, Ohio.

Under this partnership, Karmanos will operate the radiation oncology program at a new freestanding cancer center outside of Toledo, Ohio. Together, Karmanos and The Toledo Clinic will provide medical oncology services with multidisciplinary clinics, diagnostic imaging, pharmacy, laboratory, genetic counseling and social work services in 22 exam rooms and 24 infusion bays. These services will give patients increased access to advanced cancer care and clinical trials. The innovative facility is expected to treat its first patients in the spring of 2022.

Collaboration provides convenient access to world-class cancer care in one location.

A bold and ambitious collaboration for cancer treatment

"This partnership represents a bold and ambitious collaboration for cancer treatment and research in Lucas County and northwest Ohio," said Justin Klamerus, MD, president of the Karmanos Cancer Hospital & Network. "Our colleagues at The Toledo Clinic share a common vision with the entire team at Karmanos: use the very latest in treatment modalities combined with access to 'bench-to-bedside' clinical trials and precision medicine to achieve the goal of eradicating cancer."

By working together, Karmanos and The Toledo Clinic are expanding the reach of Karmanos' life-saving resources into Ohio for the first time. Karmanos is one of only 51 National Cancer Institute (NCI)-designated Comprehensive Cancer Centers in the country. Bringing this prestigious designation and the care that follows will empower patients in northern Ohio who need cancer care by consolidating services into one convenient location.

"Having the Karmanos Cancer Institute bring the third NCI designation to Ohio is very important," said Mike D'Eramo, Chief Administrative Officer of The Toledo Clinic. "With that designation comes a significant increase in research protocols and clinical trials, as well as continued efforts to improve the standard of care in cancer treatment."

NCI-designated comprehensive cancer centers are characterized by scientific excellence and the capability to integrate diverse research approaches with a focus on curing cancer. They play a vital role in advancing the goal of reducing morbidity and mortality from cancer.

Karmanos offers one of the most extensive clinical trials programs in America, giving patients access to more than 250 promising new treatments. Many of the latest cancer-fighting medications approved by the Food and Drug Administration were available to Karmanos patients first. Collaboration between Karmanos and The Toledo Clinic means that innovative cancer care will be easily accessible to patients.

The patient experience is the top priority in the partnership and building design. Dr. Klamerus explained, "Not only can patients receive care in their own backyard, they will also be able to get all the services they need under one roof. Our collaboration brings together every element of care from the lab, to the pharmacy, to imaging and the infusion center".

Patients will benefit from the most up-to-date therapies and individualized, evidence-based clinical care plans, which are cornerstones of patient care at Karmanos. The Maumee teams will work collaboratively across the continuum of care to ensure that patients have the expertise of many providers without the burden of multiple appointments. Additionally, telemedicine visits and critical auxiliary services, such as virtual support groups, social services and art therapy, will be accessible through this partnership. Patients treated at the new facility will also be able to obtain a wide variety of educational, spiritual, nutrition and palliative care services to ensure that they and their families have the support needed to ensure positive outcomes. All aspects of treatment are designed to facilitate an atmosphere of healing and empower patients on every level.

"Cancer is a heavy burden. When patients can be treated for cancer close to home, it makes a big difference. Not only are they able to reduce travel time, they can stay connected to their friends and family," said Dr. Klamerus. "Knowing that world-class care is available nearby will have a tremendous impact on those seeking cancer care in Northwest Ohio."

KARMANOS CANCER ACTION COUNCIL WORKS TO SUPPORT LGBTQ CAREGIVERS

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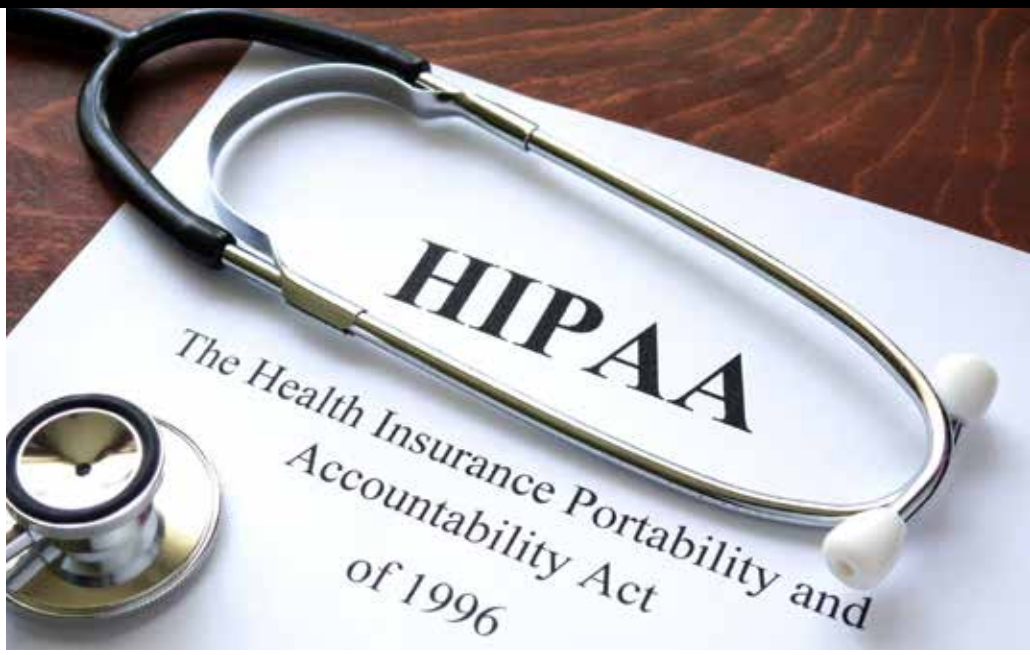
group has also applied for grant funding that will aid them in their work. When complete, they hope to share their work with cancer centers across the nation to ensure that LGBTQ caregivers have the resources they need to support their loved ones. Final offerings may include education in coping skills and symptom management, strategies for addressing homophobic encounters with medical staff, information for social workers and methods to connect with other LGBTQ caregivers.

"We are still early in the process of designing a new intervention, but we are excited about what's to come," said Forrest Hosea, research assistant, Office of Cancer Health Equity & Community Engagement and LGBTQ CAC facilitator. "There is a huge need to fill. LGBTQ CAC members are using their unique perspectives to make a difference in the lives of caregivers."

For more information about Cancer Action Councils and the Office of Cancer Health Equity and Community Engagement, click here.

EQuIP CORNER

Andrea Klaver, MBA, CHRC



HIPAA AND CLINICAL RESEARCH

By Andrea Klaver, MBA, CHRC

The Health Insurance Portability and Accountability Act (HIPAA) was initially enacted in 1996. The Privacy Rules included in CFR 160 and 164 became enforceable in 2003, so HIPAA has been with us for 18 years already. However, even after all this time, the HIPAA Rules can feel very complex, especially when applied to research. In this issue, we explore how HIPAA impacts clinical research from start to finish.

Revised Common Rule and FDA Regulations
First, let's distinguish between the Privacy Rule, the Common Rule, and the FDA's research regulations.

Most research involving human subjects operates under Federal research regulations known as the Common Rule and/or the FDA's human subject protection regulations, which apply to most Federally funded, and some privately funded, research.

The Privacy Rule builds on these protections and creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

HIPAA Privacy Rule 45 CFR Part 160 and Part 164 (Subparts A and E)
The Privacy Rule regulates the way covered entities handle protected health information – commonly known as PHI. The Privacy Rule established the conditions under which covered entities can use or disclose PHI for many purposes, including research.

A covered entity is any health plan, health care clearing house, or provider who transmits health information in an electronic form.

It is important to remember that the Privacy Rule does not replace Federal, State, or other laws that grant individuals even greater privacy protections. Covered entities are free to retain or adopt more protective policies or practices as they see fit.

A Note on the HIPAA Security Rule
The HIPAA Security Rule concentrates on safeguarding PHI by focusing on the confidentiality, integrity, and availability of PHI.

- **Confidentiality** – Data or information is not made available or disclosed to unauthorized persons or processes.

- **Integrity** – Data or information has not been altered or destroyed in an unauthorized manner.
- **Availability** – Data or information is accessible and useable upon demand only by an authorized person.

A Clear Distinction: Privacy vs. Confidentiality

Privacy is the freedom from unauthorized intrusion – the right to be left alone. In many research settings, this translates to the right of a person to control who has access to their information. In clinical research, this usually means that the researcher may not perform any procedures or access any personal information about someone without their consent.

Confidentiality is the ability to keep something secret. In IRB terms, this relates to an investigator's responsibility to prevent the unauthorized disclosure of information without permission of the research subject. A breach of confidentiality will harm the trust relationship between the subject and the researcher and be difficult to mend.

Are confidentiality and privacy issues different in research than they are in clinical practice? Probably not. The major difference is that in clinical practice, any invasion of privacy is done for the best interest of the patient, whereas in research, an invasion of privacy is not for the benefit of the subject but is for the advancement of science. Thus, the subject or patient might more easily accept something that is done for his/her benefit than for the benefit of others.

De-Identified Data vs. Limited Data Set

De-identified data is no longer PHI because it contains no information that could identify a person. There are no restrictions under HIPAA on the use or disclosure of de-identified data.

A limited data set is PHI that excludes certain direct identifiers such as name, address, SSN, MRN, etc. of the individual and there must be a data use agreement between the researcher and the covered entity before use or disclosure of the PHI.

HIPAA regulates how PHI may be obtained and used for research. This is true whether the PHI is completely identifiable or partially de-identified in a limited data set.

HIPAA Authorization and Research Data

A HIPAA research authorization clearly states the PHI will be used for research. A researcher or healthcare provider is not entitled to use PHI in research without the appropriate HIPAA documentation, including individual patient authorization or an institutionally approved waiver.

A valid HIPAA authorization must contain a description of the PHI to be used or disclosed, names of the persons authorized to make the requested use or disclosure, the purpose of the requested use or disclosure, an expiration date – even if it is listed as "none," and it must be signed and dated by the person giving their authorization. An authorization may also be "blended" into the informed consent.

Regarding waivers of authorization, the following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

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THE "HIPAA 18"

1. Names
2. All geographical subdivisions smaller than a State
3. All elements of dates (except year) related to an individual
4. Phone numbers
5. Fax numbers
6. E-mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including fingerprints
17. Full face photographic images
18. Any other unique identifying numbers

EQuIP CORNER

UPCOMING RESEARCH EDUCATION

SOCRA – ONLINE
Virtual 30th Annual Conference
September 22 – 25, 2021
SOCRA CE, CME, and CE: 50 Continuing Education Credits
Early Bird Registration ends August 20th, 2021

For more virtual continuing education and training opportunities, please visit the SOCRA Events Calendar at https://www.socra.org/conferences-and-education/events-calendar/

MAGI – ONLINE
Clinical Research Conference – Fall
October 18 – 21, 2021
and October 25 – 28, 2021

90+ CME, CNE, CLE, CCB, and other contact hours available
Group pricing discounts available

ACRP 2022
Annual Conference
Tentative: Orlando, Florida
April 22 – 25, 2022

Please visit https://acrpnet.org/ for updates

BROWN BAG SERIES

Our next Brown Bag Session is tentatively scheduled for September 2021. Please watch your email for more details as the time approaches. The Research Integrity team hopes you can attend.

For more information, contact Andrea Klaver at (248) 484-4987 or andrea.klaver@mclaren.org.

HIPAA AND CLINICAL RESEARCH

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Before the Research Begins: Data Mining for Potential Subjects
The Principal Investigator (PI) must attest that the use and/or disclosure of PHI is only for activities preparatory to research. No PHI can be removed from the covered entity during the review. This review allows the researcher to determine whether a sufficient number or type of records exists to conduct the research.

The preparatory to research provision of the regulation allows researchers to contact individuals if the researcher works for the covered entity and is contacting the individual for the purpose of seeking authorization.

The Privacy Rule permits a covered entity to use or disclose PHI for research purposes without patient authorization if the IRB has granted a waiver of the authorization requirement. Specific criteria must be met, as mentioned prior.

At the Start of Research: Authorization or Not?
A waiver of authorization can exist if the PHI use or disclosure (1) involves no more than minimal risk to the privacy of individuals based on an adequate plan to protect health information identifiers from improper use and disclosure, (2) has an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research, and (3) includes adequate written assurances that the PHI will not be released or disclosed to any other person or entity – except as required by law, for anticipated oversight of the research study, or for other research permitted under the Privacy Rule.

During the Research: An Information Security Case Study
The Office for Civil Rights (OCR) recently settled potential HIPAA violations with the Feinstein Institute for Medical Research for $3.9 million. This is the second largest settlement amount ever agreed to with the OCR, behind the $4.8 million settlement with New York Presbyterian Hospital and Columbia University in 2014. (However, this is the largest amount paid by a single covered entity.)

The settlement stems from an investigation into a breach of 13,000 research participants' data in 2012. The breach involved the theft of an unencrypted laptop computer from an employee's vehicle, left on the back seat of a car in full view of anyone passing by.

The laptop stored a wealth of data including research participants' full names, addresses, dates of birth, medical data relating to the research study, and Social Security numbers. This example should act as a warning to providers and other HIPAA covered entities to take data privacy and security seriously during the course of research.

How can we prevent breaches from happening in the first place?
McLaren Policy MHC_CC1109 "HIPAA Privacy and Security Breaches, Notifications, and Mitigation" defines a breach as the acquisition, access, use, or disclosure of Protected Health Information (PHI) in a manner not permitted by the Privacy Rule which compromises the security or privacy of the PHI.

The best thing we can do is ensure proper physical security of sensitive electronic and physical data wherever it lives!

- Lock down workstations and laptops as a deterrent.
- Secure your area, files, and portable equipment before leaving them unattended.
- Don't leave papers, computers, or other electronic devices visible in an empty car or house.

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FACULTY, FELLOWS & RESIDENTS
SCHOLARLY ACTIVITY NEWS

CASE REPORTS:

NO IRB NEEDED BUT PRIVACY OFFICER AUTHORIZATION REQUIRED-AN UPDATE

By Carlos F. Rios-Bedoya, ScD

Carlos F. Rios-Bedoya, ScD

The Division of Scholarly Inquiry wants to congratulate those residents that completed their training program and those residents that begin their training at McLaren this year. Case reports (one patient)/Case series (two cases or less; per McLaren IRB regulations) are a very popular type of scholarly activity that most residents like to use as part of their scholarly activity training requirements. They DO NOT need Institutional Review Board (IRB) Determination nor Scholarly Activity Review Committee (SARC) revision. However, this does not mean that there are no authorizations or reviews prior to submit them for presentation or publication.

Some conferences and most peer-reviewed and PubMed indexed journals are currently requiring some type of consent/authorization form for case reports or case series. Most journals provide their own forms if the author's institution does not have one. One journal even requires the patient to review the manuscript and give consent before submitting it to the journal for review. Recognizing these trends/requirements from conferences and peer reviewed journals and to assist residents/fellows/faculty in their scholarly activities, the Division of Scholarly Inquiry in collaboration with the Corporate Compliance Program developed a process and form.

The established process for review and authorization of Case Reports/Case Series requires the patient or his/her legally authorized representative to sign the McLaren Authorization to Release Information Form. The form is available at the Scholarly Inquiry Division website for residents/fellows/faculty to download and could also be requested to the PhDs. In addition, the McLaren Corporate Privacy Officer must review and authorize the Case Report/Case Series before sending it for presentation or publication. Instructions on how to implement this process are also available on the website mentioned above. The signed form and the abstract/manuscript should be emailed at least 48 hours before the submission deadline. Neither the abstract nor the manuscript should be submitted without the Corporate Privacy Officer authorization.

It is highly recommended, that as soon as a resident/fellow/faculty identifies/considers a potential patient for a case study or case report/case series they now **must obtain authorization to release information from the patient**. Please use the McLaren Authorization to Release Information Form while the patient(s) is/are in the hospital rather than wait after discharge and having to chase that/those patient(s) for authorization. Adopting a proactive approach will save time and effort.

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

ANNOUNCEMENTS AND WHAT'S NEW

Jonathon Stearn

McLaren Center for Research and Innovation is excited to announce our newest team member. **Jonathon Stearn** has joined the team at McLaren Flint in the role of Clinical Research Assistant. He is currently enrolled at the University of Michigan-Flint pursing a biology degree, with a goal of attending medical school. Jonathon started his career as a pharmacy technician, and later went on to become a Certified Medical Assistant. Jonathon looks forward to contributing to the current studies and furthering his knowledge of the medical field. MCRI looks forward to all the amazing accomplishments that he will achieve.

HIPAA AND CLINICAL RESEARCH

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- Shred sensitive paper records before disposing of them.
- Don't leave sensitive information lying around unprotected, including on printers, fax machines, copiers, or in storage.

After the Study Closes

Researchers are still responsible for protecting and securing PHI after the study closes. You must treat this information with the same respect and compliance with the regulations as you would insist that your own information is protected.

You may need to retain and store the information for the length of time that was approved by the IRB. It must be maintained in the same manner as originally approved – on secured servers, encrypted USB drives, etc. If information is maintained in paper records, they must be kept under lock and key.

The OCR offers a wealth of examples of proper disposal methods, found on the OCR HIPAA home page (https://www.hhs.gov/hipaa/).

HIPAA: Everyone's Responsibility

It is everyone's responsibility to take the confidentiality of patient information seriously during the course of clinical research. Now, more than ever, patients are both concerned and aware that their private health information might be used or released without their knowledge. To foster trust with our clinical research participants, we must take HIPAA seriously.

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