RESEARCH Matters

Fall 2022

IN THIS ISSUE...

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

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RESEARCH AROUND McLAREN

BIDDING FAREWELL TO DR. COLFER

After decades of dedication to clinical care and research, Dr. Harry Colfer will be retiring in December of 2022. Dr. Colfer is a well-known interventional cardiologist at McLaren Northern Michigan. In addition to his clinical role, he is a very active researcher with MCRI. In fact, Dr. Colfer created what is now the Northern MCRI site in 1984 under the name of NISUS. He has been the highest enrolling investigator for MCRI for many years running! Dr. Colfer's esteemed dedication to advancing cardiovascular research and clinical outcomes is remarkable and unmatched at McLaren Health Care. He will be greatly missed, and we wish him all the best in his retirement!

INVESTIGATOR INITIATED TRIALS

Also referred to as an Investigator Initiated Study (IIS), Investigator Initiated Trials (IITs) are clinical research trials in which the Principal Investigator conceives of the research question, develops the study protocol and serves as the "sponsor-investigator". The FDA defines a "sponsor-investigator" as an investigator who both initiates and conducts an investigation, and under whose immediate direction the investigational drug or device is administered or dispensed. In such trials, the sponsor-investigator assumes the responsibilities of, and must comply with, FDA regulations applicable to both a sponsor and an investigator. The sponsor-investigator takes on the responsibility of initiating the clinical trial and acting as the coordinating center, and often times takes on a dual role of an investigator conducting the trial as well.

In many aspects, IITs are the same as an industry sponsored trial and need to follow the same pathways for study feasibility, start-up and regulatory approvals as a sponsored clinical trial. As a sponsor, an IIT

investigator's responsibilities include:

- Selection and training of qualified investigators
- Obtaining executed FDA Form 1572 and financial disclosures from each PI
- Assuring the protection and safety of human subjects at all study locations
- Providing the investigators and their study staff with information to conduct the study properly
- Monitoring the progress of the investigation
- Controlling and documenting disposition of the investigational agent

An investigator invited to participate in an IIT, or planning on conducting their own IIT, has the same responsibilities as they would conducting a sponsored clinical trial. Those responsibilities include:

- Ensuring the investigation is conducted according to the investigational plan (protocol)
- Maintaining case histories on each patient
- Providing reports to various vested entities including regulatory entities like the FDA or IRB and the sponsor or funding agency
- Submitting progress reports, safety reports, final reports, and other regulatory documents like financial disclosures and FDA Form 1572
- Protecting the rights and safety of subjects under the investigator's care
- Obtaining and properly documenting informed consent from each patient
- Assuring review by a responsible IRB and complying with its requirements
- Permit FDA inspections of the study records and site

A common question amongst investigators interested in conducting their own IIT is what regulations apply and which rules need to be followed? This is dictated by the funding agency as well as the products employed in the trial. For FDA-regulated products, drugs (FDA 21 CFR 312) or devices (FDA 21 CFR 812) the Code of Federal Regulations (CFR) apply and dictate the conduct of the study. If another federal agency funds the research, Health and Human Services rules may apply (FDA 45 CFR 46). If a study is federally funded by an agency other than HHS, but involves an FDA-regulated product, both sets of rules may apply. There are many FDA guidance documents and HHS guidance documents available online for review prior to initiating an IIT, so an investigator can be aware of what rules might apply give the particular drug or device they wish to study.

Some protocols may require the sponsor-investigator to submit an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application to the FDA. Criteria for this requirement are outlined in the FDA regulations at 21 CFR 312.2(b) or 21 CFR 812. If a sponsor-investigator is unsure what applies to their particular protocol, they should seek counsel from the FDA to be sure they are following all applicable rules and regulations, as well as submitting the proper applications, if required.

All investigators taking part in a sponsored clinical trial or considering an IIT should ensure their knowledge of ethical and scientific standards as well as human subject protection is up to date and documented. Getting started with the basic training requirements is an essential first step. Biomedical Research Training, Conflict of Interest training and Good Clinical Practice

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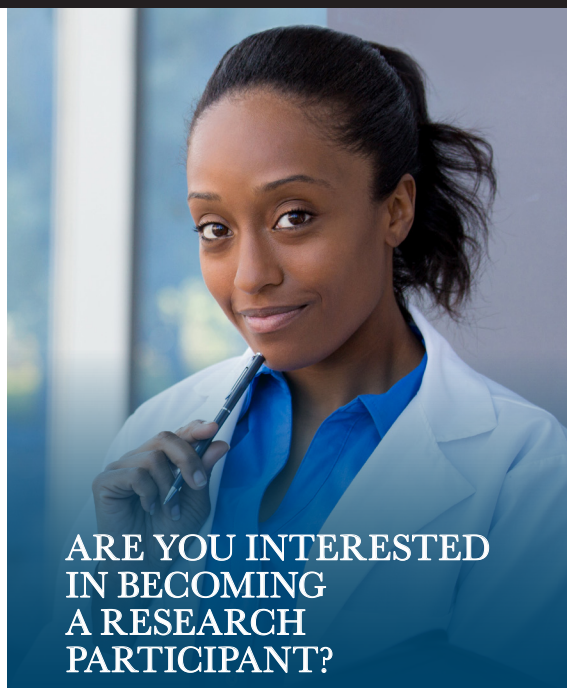

ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

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 RESOURCES

McLaren Research Administration and Research Integrity:
www.mclaren.org/main/research

CITI Training, Biomedical, GCP:
www.citiprogram.org

SOCRA:
www.socra.org

ACRP:
www.acrp.org

Health and Human Services:
www.hhs.gov/programs/research

FDA Guidance for Industry: Investigator Responsibilities:
https://www.fda.gov/media/77765/download

FDA Guidance for Sponsor-Investigators:
https://www.fda.gov/media/92604/download

GCP Regulations:
https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials

Code of Federal Regulations:
www.ecfr.gov/current/title-21

- 21 CFR 312 – Investigational New Drug Application
- 21 CFR 812 – Investigational Device Exemptions
- 45 CFR 46 – Protection of Human Subjects

Clinical Trials.gov:
www.clinicaltrials.gov

INVESTIGATOR INITIATED TRIALS

CONTINUED FROM PAGE 3

training are all made available to McLaren investigators and research staff at **www.citiprogram.org**. You will need to affiliate with McLaren Health Care to access the required courses. To participate in clinical trials or initiate an IIT, these training courses are an institutional requirement.

If you want to increase your knowledge base and take your research education to the next level, consider becoming a member of one of the accredited Clinical Research Associations, SOCRA (Society of Clinical Research Associates) or ACRP (Association of Clinical Research Professionals). Both associations have a wealth of educational opportunities, articles, webinars and courses available to members and non-members. For those who want to certify their knowledge, ACRP offers a Certified Principal Investigator exam to earn the "CPI" credentials. Experienced investigators may also wish to consider attending or speaking at one of the national conferences held yearly by ACRP or SOCRA.

As an investigator at McLaren, if you wish to discuss your ideas for an IIT or becoming an investigator on a clinical trial, your first step is to contact the administrative offices of the McLaren Center for Research and Innovation. The MCRI administrative team can meet with you to discuss the resources available to you for protocol writing assistance or statistical analysis, how to create a budget and apply for funding for your project, data collection tools, coordinator and regulatory support options, and work with you to create a project plan and timeline for initiation of your trial. MCRI can also be your resource for listing your trial on **www.ClinicalTrials.gov**, a federal requirement for qualifying clinical trials.

Investigator initiated trials are important to medical science because they drive translational research, taking data and applying it to day to day, real world practices. IITs demonstrate the commitment of a health care institution to growth and learning, as well as the dedication of a physician to their patients by initiating change in standard practices and innovation in treatment options. They are an important piece of any institution's research portfolio and McLaren strives to support their investigators in such endeavors. Developing and conducting an IIT as a sponsor-investigator is a significant investment of your time and a great deal of effort, but well worth the outcome for you and your patients.

For more information or to start a discussion about your research interests, please contact the administrative offices of MCRI at **MCRI@mclaren.org** or **(248) 484-4960**.

McLAREN HEALTH CARE RESEARCH FUNDS

Since its inception the McLaren Health Care Research Funding committee has awarded $45,500! These awards have been made to eager investigators with their own research ideas and study designs. Support of Investigator-Initiated Research is a strategic goal of McLaren Health Care. If you have a research idea and need funding, we encourage you to apply today.

These funds are to be used for the conduct of the observational or interventional research studies and will be awarded on a quarterly basis.

- 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.

Due dates for application submissions are January 1st, April 1st, July 1st, and October 1st of each year.

Required information for the application includes a detailed description of the research project, as well as a proposed budget. Incomplete applications will be returned to the applicant.

Application link: **www.mclaren.org/FundingApplication**

McLAREN FLINT INTERNAL MEDICINE RESIDENT

PRESENTS TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO)

Dr. Maxwell Aknabi conducted a research study utilizing the SEER (Surveillance, Epidemiology and End-Results) database to evaluate the impact of lung cancer screening recommendations utilizing low-dose CT scanning. The results from his study suggest that the guidelines from the U.S. Preventative Services Task Force led to a more rapid decline in the incidence of advance disease in the United States, especially among minority populations. Dr. Aknabi was asked to present his findings at the 2022 ASCO Annual Meeting. He summarized his study by stating:

"Lung cancer is the leading cause of cancer mortality in the US, and this is because most patients with lung cancer are diagnosed at advanced stages of the disease. Trying to make patients present earlier has been an elusive challenge, until in 2011, when results of the National Lung Cancer Trial were reported. This study showed that low-dose CT scan could improve survival in patients with lung cancer by making earlier diagnosis. Although this has been shown in clinical trials, the government has ruled out lung cancer screening in the general population without also actually knowing whether it is efficacious in the general population.

CONTINUED ON PAGE 7

Maxwell Aknabi, MD

RESEARCH AROUND McLAREN

KARMANOS CANCER INSTITUTE AND WAYNE STATE UNIVERSITY EXPRESS GRATITUDE FOR $100 MILLION FROM STATE FOR NEW MEDICAL EDUCATION-RESEARCH SITE

HUNDREDS OF SCIENTISTS. THOUSANDS OF STUDENTS. UNLIMITED POTENTIAL.

The Barbara Ann Karmanos Cancer Institute and Wayne State University School of Medicine plan to construct a new building complex consisting of two towers that will further their unique academic and research-based partnership. The estimated $450 million capital project is becoming more of a reality with an appropriation of $100 million from the State of Michigan. Karmanos and WSU plan to house collaborative medical education, research and laboratories, health science and community health clinics in the new spaces. The investment will provide employment opportunities for Detroit-area residents, as well as attract and retain new talent.

Planned to be built at a yet-to-be-determined location near the two campuses in Midtown Detroit, the new complex will emerge as a Detroit hub where faculty, students, researchers and scientists work together to ensure greater equity in health outcomes. The medical education facility will educate future generations of physicians and scientists. The research-focused portion of the complex will accommodate state-of-the-art cancer research laboratories to develop breakthrough technologies and treatments.

"Given the scope of the project, I am confident it will have a

> "WAYNE STATE HAS BEEN A TREMENDOUS PARTNER IN THE FIGHT AGAINST CANCER AND DISCOVERING BREAKTHROUGHS IN CANCER TREATMENT."
>
> *– Gerold Bepler, MD, PhD*
> *President and CEO, retired*
> *Barbara Ann Karmanos Cancer Institute*

transformational impact on the state's workforce and talent development pipeline – particularly in health care; contribute to the vitality of Midtown and the city's positive economic development; and close health equity gaps through the deepening of our partnership with Karmanos," said M. Roy Wilson, president of Wayne State. "We are grateful to the state Legislature and governor for recognizing the value of higher education in general, and research universities like Wayne State in particular."

"Wayne State has been a tremendous partner in the fight against cancer and discovering breakthroughs in cancer treatment," said Gerold Bepler, MD, PhD, president and chief executive officer of the Barbara Ann Karmanos Cancer Institute, now retired. "Both institutions rely on philanthropic donors and community investments to continue research, and we are thrilled that our state legislators see the value and need for our partnership. We also extend tremendous appreciation to Peter Karmanos, Jr., for his assistance in bringing our ideas to Lansing. The Karmanos and WSU partnership allows us to provide the best cancer treatments and care to patients across Michigan and northern Ohio. This new site will enhance our collaboration in research, discoveries and education, moving us closer to a world free of cancer."

The 75-year partnership between Wayne State and Karmanos has led to many health care innovations for the region, Michigan and the world.

McLAREN FLINT INTERNAL MEDICINE RESIDENT PRESENTS TO ASCO

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Our study was to evaluate the effectiveness of lung cancer screening in the US general population. You will use the SEER database, we analyzed data of patient diagnosed with lung cancer from 2004 to 2018. Our goal was to see if the incidence of advanced lung cancer reduced over this time. Our results showed that incidence of advanced lung cancer actually decreased in the US population following the rollout of lung cancer screening. This was particularly significant in minority populations. This is encouraging because there have been concerns that lung cancer screening may not be very effective in this population because they had limited access to screening facilities.

So, while this is encouraging, the work is not yet done. Our end goal is to make sure there's reduction in lung cancer mortality. There are still barriers between screening and mortality, so the next stage of our study will be to see whether this reduction in incidence of advanced lung cancer actually translate to reduction in lung cancer mortality".

Congratulations to Dr. Aknabi on your excellent work!

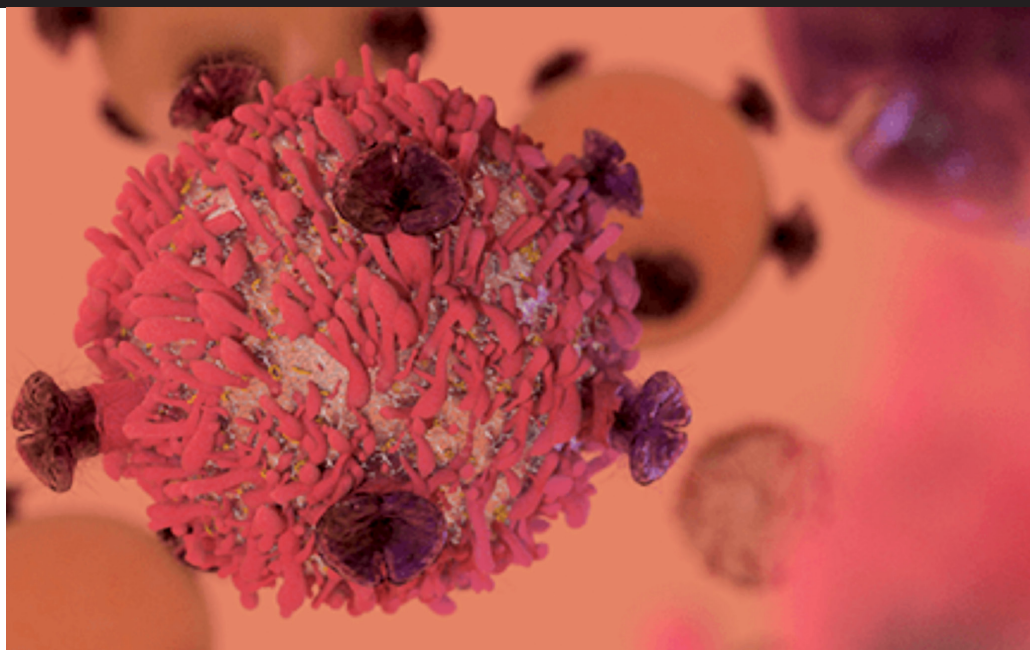
We sincerely regret if we left out any fellow or resident, due to our publication deadline. Nevertheless, our congratulations to all of you that received any recognition for your scholarly activity work. We also would like to recognize faculty, program directors, and all medical education staff for their support and assistance. Without you, none of this would have been possible.

RESEARCH AROUND McLAREN

By Abhinav Deol, MD
Medical Oncologist

Member of the Bone Marrow & Stem Cell Transplant, Hematology Oncology and Multiple Myeloma and Amyloidosis Multidisciplinary Teams at Barbara Ann Karmanos Cancer Institute

Originally published for *OncLive*.



CAR T-CELL THERAPY ESTABLISHES PROMINENT ROLE ACROSS HEMATOLOGIC MALIGNANCIES

In recent years, cellular immune therapies such as chimeric antigen receptor (CAR) T-cell therapy have significantly improved response rates for various hematological malignancies. The Multiple Myeloma and Amyloidosis Multidisciplinary Team (MDT), Bone Marrow and Stem Cell Transplant MDT, and the Hematology Oncology MDT at Barbara Ann Karmanos Cancer Institute in Detroit, Michigan, have helped drive many treatment advancements in cellular immune therapies for cancers

Karmanos offers all approved CAR T-cell therapies for non-Hodgkin lymphoma (NHL), acute lymphoblastic leukemia (ALL), and multiple myeloma (MM). The institute also continues to support research into new treatment indications for which CAR T-cell therapy could be used. CAR T-cell therapy is at the cutting edge of treatments for certain cancers, wherein the patient's T cells, an integral part of the immune system, are genetically modified to recognize and kill the cancer cells.

Cancers Show Promising CAR T Response Rates

The outcomes of CAR T-cell therapies have been remarkable, especially because most patients receiving this immunotherapy have faced difficulties in controlling their disease despite multiple rounds of chemotherapy. The Karmanos team collaborated with leading cancer centers around the country on various pivotal clinical trials leading to the FDA approval of CAR T-cell therapy.

The complete response rates for ALL are approximately 60% to 70%.[1,2] Regarding NHL, the FDA has approved CAR T-cell therapy to treat diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma and transformed lymphoma. Patients with these diseases must meet specific requirements to receive CAR T-cell therapy including that their cancer does not respond to initial chemotherapy and relapses within 1 year or there is relapse after 2 previous lines of chemotherapy.

The long-term complete response rates in patients with DLBCL in the third-line setting are around 40% to 50%.[3-5] For patients with DLBCL whose disease does not respond to initial therapy or relapses within 1 year of completing treatment, CAR T-cell therapy significantly improved the chance of being cured compared with standard salvage chemotherapy.[6,7]

With CAR T-cell therapy, we can also target mantle cell lymphoma. For this disease, we have seen a complete response in two-thirds of patients whose disease had relapsed or not responded to multiple chemotherapy regimens.[8] CAR T-cell therapy also showed very high response rates in patients with follicular lymphoma whose disease had relapsed after 2 prior lines of chemotherapy.[9,10] The response rate for patients with MM whose disease relapsed after 4 or more prior lines of chemotherapy was 80% to 95% after CAR T-cell therapy treatment.[11,12]

Possible Adverse Effects

Some patients may develop unique adverse effects (AEs) that should be monitored closely for the first few weeks after infusion. AEs include cytokine release syndrome (CRS), which may manifest as high fever, low blood pressure, low oxygenation, neurological toxicity, confusion, word-finding difficulty, and rare cases of seizure or coma. The most severe AEs usually occur within the first couple of weeks after infusion of CAR T cells. Patients can also be at risk for low blood counts and a weakened immune system. If this happens, the patient may need antimicrobial treatments to prevent severe infection.

Ongoing CAR T-cell Therapy Research

In the recent years, research has also focused on strategies to reduce the AEs of this unique therapy. Karmanos participated in a clinical trial in which patients with DLBCL received steroids for 3 days at the time of infusion of CAR T-cell therapy, which led to less risk of CRS without compromising efficacy of the treatment.13 This approach is now used for patients at a high risk of developing severe AEs from CAR T-cell therapy.

We have an ongoing clinical trial in which we give an antibody treatment to patients undergoing CAR T-cell therapy, which may help reduce risk of related neurological toxicity. Our team is also participating in clinical trials investigating allogeneic CAR T cells. With this treatment, patients receive genetically modified CAR T cells from a donor. This method may hasten therapy compared with waiting on the patient's manufactured immune cells. We are also collaborating with Karmanos experts specializing in solid tumor oncology for clinical trials with CAR T-cell therapy. These trials involve other cellular treatments for breast, lung, prostate, head and neck, and gynecologic cancers.

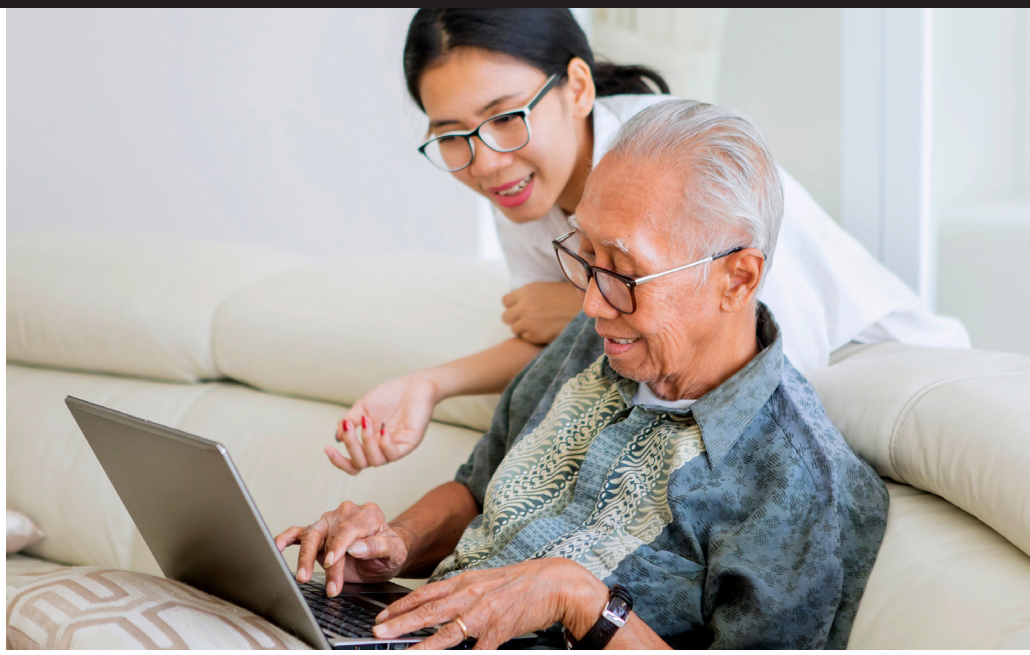
Karmanos specialists have experience in providing commercially approved and investigational cellular therapies. As a National Cancer Institute–designated comprehensive cancer center, we work closely with investigators developing novel strategies to make this therapy safer, develop pathways toward new indications, and ensure more accessibility to CAR T-cell therapy. With our robust clinical trials program and experienced team, we are committed to further improving outcomes for patients who are candidates for these therapies and to overcoming challenges associated with them.

View the list of references in the News section at karmanos.org/healthcareprofessionals. Look for "CAR T-cell therapy establishes prominent role across hematologic malignancies".

RESEARCH AROUND McLAREN

Theresa Hastert, PhD

Hayley Thompson, PhD



THANKS TO MHEF GRANT

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

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, PhD, 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, PhD, 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 make 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.

KARMANOS, WSU RESEARCHERS STUDY DIFFERENCES IN BEHAVIOR DURING CANCER TREATMENT DISCUSSIONS

Karmanos Cancer Institute and Wayne State University (WSU) researchers investigated how synchronized behavior differed between Black and White patients when having cancer treatment discussions with health care specialists. Lauren Hamel, PhD, co-program leader of the Population Studies and Disparities Research (PSDR) Program at Karmanos, associate professor of communication and behavioral oncology at WSU School of Medicine; Susan Eggly, PhD, member of PSDR, professor in the Department of Oncology at WSU; Louis Penner, PhD and Terrance Albrecht, PhD, professor emeriti at WSU and additional research colleagues used a novel software to measure nonverbal synchrony in video recording of patients meeting with their physicians. Their research, titled "Nonverbal Synchrony: An indicator of clinical communication Quality in Racially-Concordant and Racially-Discordant Oncology Interactions," was published in *Cancer Control.*

RESEARCH AROUND McLAREN

Kay-Uwe Wagner, PhD

KAY-UWE WAGNER, PhD RECEIVES 2022 KALES AWARD IN ONCOLOGY

FOR DISCOVERING ROLE OF LUMINAL EPITHELIAL CELLS IN INITIATION AND PROGRESSION OF METASTATIC CLAUDIN-LOW BREAST CANCER

Kay-Uwe Wagner, PhD, leader of the Tumor Biology and Microenvironment Research Program at Barbara Ann Karmanos Cancer Institute and professor of basic science in the Department of Oncology at Wayne State University School of Medicine, was selected as the winner of the 2022 Drs. Anthony and Joyce Danielski Kales Endowed Faculty Award for Innovative Cancer Researcher for his role as the principal investigator of a multi-institutional research team that identified the cellular origin of a specific triple-negative breast cancer subtype called claudin-low.

Dr. Wagner's research, "Highly metastatic claudin-low mammary cancers can originate from luminal epithelial cells," was published in Nature Communications in June 2021. The article was among a collection of publications at Nature.com that was featured during Breast Cancer Awareness Month in October of 2021.

Co-authors of this research include Patrick D. Raedler, Barbara L. Wehde, Aleata A. Triplett, Hridaya Shrestha, Jonathan H. Shepherd, Adam D. Pfefferle, Hallgeir Rui, Robert D. Cardiff and Charles M. Perou.

"On behalf of all my colleagues who contributed to this work, I am very grateful for this honor," Dr. Wagner said. "I see this honor as a recognition of the importance of basic cancer research that several of us scientists conduct here at Karmanos."

Over the last seven years, investigators from several institutions around the country have made important contributions in bioinformatics, histopathology and quantitative imaging to identifying the cellular causes of claudin-low mammary cancer. Dr. Wagner credits colleague Patrick Raedler, PhD, with leading the study and developing new genetic models for forms of triple-negative breast cancer. At the time of this research, Dr. Raedler was a graduate student at WSU and was Dr. Wagner's mentee. He is now a postdoctoral fellow at the University of North Carolina at Chapel Hill.

"The newly developed models provide unique opportunities to investigate further the cellular origins of certain types of breast cancer and how they develop into highly aggressive malignancies. While the findings reported in the research paper are not immediately applicable to the clinic, they provide fundamental information about how cancer develops and how malignant cells can drastically change their appearance over time," explained Dr. Wagner. "We also learned from our models that the malignant development is partially reversible, which heralds the possibility for certain strategies to detect and treat some of these aggressive tumor types."

Dr. Wagner was honored for his research at a special seminar on September 16, part of the Karmanos Cancer Institute Seminar Series. During the seminar, he presented his research specific to the publication on the cellular determinants of claudin-low breast cancer. Additional publications highlighting Dr. Wagner's research were displayed at Elliman Clinical Research Building on the School of Medicine campus and Hudson-Webber Cancer Research Center on the Karmanos campus.

The Kales Award in Oncology was created in 2012 at the WSU School of Medicine to recognize exemplary and innovative cancer research. Drs. Anthony and Joyce Danielski Kales established the award in memory of their brother and brother-in-law, Nicholas Kales, who died from lung cancer. The award is given to a WSU faculty member who is also a researcher at the Barbara Ann Karmanos Cancer Institute. Selection is based on a comprehensive review of published articles within the previous year.

RESEARCH AROUND McLAREN

MULTIPLE KARMANOS RESEARCHERS, WSU FACULTY MEMBERS HONORED FOR THEIR SIGNIFICANT CONTRIBUTIONS TO FURTHER EDUCATION

The Office of Faculty Affairs and Professional Development at Wayne State University's (WSU) School of Medicine annually recognizes faculty who have made outstanding contributions in teaching, mentoring, research and leadership. This year, a number of faculty from Barbara Ann Karmanos Cancer Institute and the Department of Oncology at WSU were recipients of these awards, highlighting their significant contributions in education and more.

School of Medicine Awards

The Research Excellence Awards are given to faculty members who demonstrate excellence and achievement through research. Faculty members are awarded in the categories of basic science, clinical scientist and physician scientist. Those recognized with the Research Excellence Award are:

BASIC SCIENCE

- **James Granneman, PhD**, member of the Tumor Biology and and Microenvironment (TBM) Research Team at Karmanos, professor, Department of Internal Medicine and the Center for Molecular Medicine and Genetics at WSU
- **Renu Kowluru, PhD**, member of the TBM Research Team, professor, Department of Ophthalmology, Visual and Anatomical Sciences
- **Francesca Luca, PhD**, member of the Population Studies and Disparities Research (PSDR) Program, professor (research educator), Department of Obstetrics and Gynecology and the Center for Molecular Medicine and Genetics
- **Xiaohong Zhang, PhD**, mmember of the Molecular Therapeutics (MT) Research Program, associate professor, Department of Oncology

CLINICAL SCIENTIST

- **Hilary Marusak, PhD**, member of the PSDR Program, assistant professor, Department of Psychiatry and Behavioral Neurosciences

PHYSICIAN SCIENTIST

- **Prateek Lohia, MD, MHA**, associate professor (clinical) FTA, Department of Internal Medicine
- **Ira Winer, MD, PhD, FACOG**, surgical oncologist, member of the Gynecologic Oncology Multidisciplinary Team (MDT), Phase 1 Clinical Trials Program, MT Research Program, associate professor, Department of Oncology

There were a number of faculty honored with the **College Teaching Award**, given to those who have shown achievement and excellence through teaching at WSU's School of Medicine. This year's winners include:

- **Aiden Abidov, MD, PhD**, professor (clinical) FTA, Department of Internal Medicine
- **Rouba Ali-Fehmi, MD**, member of the TBM Research Team, professor (clinical), Department of Pathology

- **Siddhesh Aras, PhD, MBBS**, assistant professor (research educator), Center for Molecular Medicine and Genetics
- **Gregory Auner, PhD**, member of the Molecular Imaging (MI) Research Program, professor, Department of Surgery
- **Rafael Fridman, PhD**, member of the TBM Research Team, professor, Department of Pathology
- **Edwin George, MD, PhD**, associate professor (clinical), Department of Neurology
- **David Ledgerwood, PhD**, member of the PSDR Program, professor, Department of Psychiatry and Behaviroal Neurosciences
- **Sabeena Iqbal Malik, MD**, assistant professor (clinical), Department of Neurology
- **Hilary Marusak, PhD**, member of the PSDR Program, assistant professor, Department of Psychiatry and Behavioral Neurosciences
- **Kristen Purrington, PhD, MPH**, member of the PSDR Program, assistant professor, Department of Oncology
- **Shaheena Raheem, DO**, assistant professor (clinical), Department of Internal Medicine
- **Manohar Ratnam, PhD**, member of the MT Research Team, professor, Department of Oncology
- **Julie Samantray, MD, MPH**, associate professor (clinical), Department of Internal Medicine
- **Malathy Shekhar, PhD**, member of the MT Research Team, professor, Department of Oncology
- **Ayman Soubani, MD**, member of the MT Research Team, professor (clinical), Department of Internal Medicine
- **Wael Taha, MD**, assistant professor (clinical), Department of Internal Medicine
- **Kay-Uwe Wagner, PhD**, program leader of the TBM Research Team, professor, Department of Oncology
- **Jay Yang, MD**, medical oncologist, member of the Hematology Oncology MDT and the MT Research Team, associate professor (clinical), Department of Oncology

DEAN'S OFFICE AWARDS

- **Kezhong Zhang, PhD**, member of the TBM Research Team, professor at the Center for Molecular Medicine and Genetics received the **Outstanding Research Achievement Award**. This honor is given to a faculty member in a basic science or clinical department who has made significant and career-long contributions to the advancement of an area of biomedical, behavioral, clinical or medical research.
- **Abhinav Deol, MD**, medical oncologist, member of the Bone Marrow & Stem Cell Transplant (BMT), Hematology Oncology and Multiple Myeloma and Amyloidosis MDTs, member of the TBM Research Team and professor (clinical) in the Department of Oncology, won the **Excellence in Clinical Science Teaching Award**. This recognition is given to a faculty member who has left a mark of excellence and provided learners with a critical understanding of clinical medicine through long and mertirious clinical or behavioral science teaching.

CONTINUED ON PAGE 16

RESEARCH AROUND McLAREN

MULTIPLE KARMANOS RESEARCHERS, WSU FACULTY MEMBERS HONORED

CONTINUED FROM PAGE 15

- **Lauren Hamel, PhD**, co-program leader of the PSDR Program, associate professor (research educator) in the Department of Oncology, won the **Outstanding Diversity, Equity and Inclusion (DEI) Faculty Scholar** award for promoting the advancement of DEI related education, mentorship, service and scholarship.

PROMOTION AND TENURE AWARDS

In addition, many more faculty members were awarded higher academic statuses:

- **Asif Alavi, MD**, now associate professor (clinical), Department of Oncology, medical oncologist, member of the BMT and Hematology Oncology MDTs, TBM program member
- **Abubaker Ali, MD**, now associate professor (clinical), Department of Surgery
- **Fadi Antaki, MD**, now professor (clinical) FTA, Department of Internal Medicine
- **Sudeshna Bandyopadhyay, MBBS**, now professor (clinical) FTA, Department of Pathology
- **Wei Chen, PhD**, now professor (research educator), Department of Oncology, MI program member
- **Sorabh Dhar, MD**, now professor (clinical), Department of Internal Medicine
- **Rodrigo Fernandez-Valdivia, PhD**, now associate professor (research educator) with tenure, Department of Pathology, TBM program member
- **Theresa Hastert, PhD**, now associate professor (research educator) with 50 percent tenure, Department of Oncology, PSDR program member
- **Shakir Hussein, MD**, now associate professor (clinical) FTA, Department of Surgery
- **Prateek Lohia, MD, MHA**, now associate professor (clinical) FTA, Department of Internal Medicine
- **Francesca Luca, PhD**, now professor (research educator), Department of Obstetrics and Gynecology and the Center for Molecular Medicine and Genetics, PSDR program member
- **Rohit Marawar, MD**, now associate professor (clinical), Department of Neurology
- **Tamam Mohamad, MD**, now professor (clinical), Department of Internal Medicine
- **Robert Pique-Regi, PhD**, now professor (research education), Department of Obsterics and Gynecology and the Center for Molecular Medicine and Genetics, PSDR program member
- **Kristen Purrington, PhD, MPH**, now associate professor (research educator) with 50 percent tenure, Department of Oncology
- **Samantha Tarras, MD**, now associate professor (clinical), Department of Surgery
- **Zeng-Quan Yang, PhD**, now professor (research educator), Department of Oncology, MT program member

Congratulations to the faculty members who were awarded higher academic status and to the 2022 Faculty Award winners.

KARMANOS AWARDS OVER $500 THOUSAND TO CANCER RESEARCH PROJECTS

The Barbara Ann Karmanos Cancer Institute has announced the winners of its 2022 Strategic Research Initiative Grants (SRIG). SRIGs are awarded to projects and initial research that exhibits great potential of leading to multi-investigator grants. This year's awards will fund 11 innovative, high-impact proposals that show great potential in leading to peer-reviewed extramural funding and addressing the needs of Karmanos patients in Michigan and Ohio.

A total of $546,923 goes to the following projects, conducted by researchers in Karmanos research programs and professors at Wayne State University:

MOLECULAR IMAGING RESEARCH PROGRAM

- "Ultrasound tomography (UST) guided mild hyperthermia (MHth) for enhanced chemo- and radiation therapy of cancer" – **Nerissa Viola, PhD**, program co-leader, associate professor, Department of Oncology
- "Employing Hypoxia MRI to Improve Immunotherapy Outcomes" – **Matt Allen, PhD**, chair and professor, Department of Chemistry
- "Molecular Imaging of the Human Papillomavirus (HPV)" – **Sheryl Roberts, PhD**, assistant professor, Department of Oncology

MOLECULAR THERAPEUTICS RESEARCH PROGRAM

- "Impact of BRCA mutation on ovarian tumor microenvironment" – **Ayesha Alvero, MD, MSc**, professor, Department of Obstetrics/Gynecology
- "The Metabolic Modulation and Therapeutic Potential of EGFL9 in TNBC" – **Guojun Wu, PhD**, associate professor, Department of Oncology
- "Functional roles and molecular mechanisms of RNA methyltransferase SPOUT1 in tumorigenesis" – **Zeng-Quan Yang, PhD**, professor, Department of Oncology

POPULATION STUDIES AND DISPARITIES RESEARCH PROGRAM

- "DISCO Provider: A multi-level intervention to reduce financial toxicity in patients with cancer through improved treatment cost discussions" – **Lauren Hamel, PhD**, co-program leader, associate professor, Department of Oncology
- "Adaptation and Pilot of a Health Insurance Education Intervention in a Population of Racially Diverse Young Adult Cancer Survivors" – **Theresa Hastert, PhD**, associate professor, Department of Oncology
- "Clinically relevant racial differences in tumor biology among women with hormone receptor positive, HER2-negative breast cancer" – **Kristen Purrington, PhD**, associate professor, Department of Oncology

TUMOR BIOLOGY AND MICROENVIRONMENT RESEARCH PROGRAM

- "ABHD5: a new druggable target for treatment-resistant cancer" – **James Granneman, PhD**, professor, Center for Molecular Medicine and Genetics and the Department of Internal Medicine, and **Jian Wang, PhD**, associate professor, Department of Pathology
- "Mechanisms of Stearoyl-CoA desaturase involvement in metastatic progression in bone" – **Izabela Podgorski, PhD**, professor, Department of Pharmacology

"These studies are just a few examples of the inventive work and dynamic exploration that takes place every day between Karmanos Cancer Institute and Wayne State University School of Medicine," said Ann Schwartz, Ph.D, MPH, Deputy Center Director at Karmanos, professor and associate chair of WSU School of Medicine. "These collaborative projects not only make Karmanos, in partnership with WSU School of Medicine, one of the international leaders in cancer research but also paves the way for new cancer therapies that will bring hope to patients in the future."

The SRIG funding is made available to the awarded projects for a 12-month period so investigators can continue their research. Investigators are required to submit for extramural funding during the 12-month timeframe.

Karmanos has had a 75-year education and research-based partnership with Wayne State University School of Medicine.

EQuIP CORNER

Lauren Thomas

PRIVACY OFFICER INVOLVEMENT IN CLINICAL RESEARCH

By Lauren Thomas, Research Integrity Assistant

Preserving privacy of personal and sensitive health information covets incontrovertible value for ensuring patient autonomy and agency in research. The Health Insurance Portability and Accountability Act (HIPAA) provides the rules of how and when health information may be disclosed. Who can access records for research purposes? What is a valid HIPAA authorization? When would there be a need for a waiver of authorization? How does the research HIPAA Authorization differ from other healthcare HIPAA authorizations? To answer these questions, we must take a closer look into the role and impact Privacy Officers play in adhering to federally mandated privacy rules while ensuring the security of research information is implemented effectively within the McLaren research community.

In the last newsletter, we discussed the legal liability of researchers in clinical trials. In this edition of the EQuIP Corner, we will explore (1) the role Privacy Officers play in the Institutional Review Board (IRB) process, (2) HIPAA regulations in clinical research, including defining the similarities and differences between privacy and confidentiality, and (3) the role of the PI in ensuring compliance throughout the research project.

What is a Privacy Officer?

I want to take time to highlight the integral role our Privacy Officers play in guaranteeing individuals' privacy and security is upheld within the research community. Primarily, the role of Privacy Officers, also referred to as Corporate HIPAA Coordinators, is to provide comprehensive oversight to ensure HIPAA forms are consistent with McLaren Health Care Institutional Review Board (MHC IRB) policies and procedures. Their responsibility extends to monitoring compliance with HIPAA in the process of conducting human subjects research consistent with MHC Policies and Procedures. The Privacy Officer, when reviewing research consents, ensures compliance with 45 CFR 164.501, 164.508, and 164.512(i) (See also 45 CFR 164.514(e), 164.528, 164.532). Privacy Officers promote security and effectiveness through working collaboratively with MHC HIPAA Council, and they help provide a concise analysis of any HIPAA compliance matters under investigation.

Privacy Officers Role in Ensuring HIPAA Compliance

In essence, Privacy Officers are responsible for the consistent implementation of a system-wide HIPAA Privacy and Security program, including the education and reporting of HIPAA activities throughout MHC. Their role centers around working closely with the MHC HIPAA Council and MHC IRB in identifying problems to correct deficiencies and provide solutions through extensive analysis on research facing compliance observations or investigation. In addition to providing education and support, their role includes monitoring subsidiary compliance and implementing corrective action when needed. Their commitment to enforcing adherence of these policies assists in the preservation of patient privacy and prevention of scientific malfeasance within the research community.

Defining Privacy and Confidentiality?

Although the terms confidentiality and privacy share many similarities, they are not interchangeable.

- **Confidentiality:** Data or information not made available or disclosed to unauthorized processes and people.
- **Privacy:** The freedom from unauthorized intrusion an individual's right to control the access of their personal information. In clinical research, this right to privacy disallows a researcher to perform any procedures or access personal information without an individual's consent.

HIPAA in Clinical Research

HIPAA was initially enacted in 1996 with an aim to regulate how personal and sensitive health information is stored and accessed. HIPAA regulations are applied to the use of Protected Health Information and de-identified data in healthcare. The Department of Health and Human Services defines PHI as:

"Individually identifiable health information, including demographic data, that relates to:

- The individual's past, present or future physical or mental health or condition,
- The provision of health care to the individual,
- The past, present, or future payment for the provision of health care to the individual, and
- That identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual."

Please note, there are no federal restrictions barring the use and disclosure of fully de-identified data at this time. In the event the patient's information contains any of the following identifiers or parts of the identifier, it is considered PHI and must follow the criterion put forth in applicable federal regulations *(see sidebar at right)*.

Within research, there are additional requirements for HIPAA authorizations which must be addressed during the process of consent, consistent with the guidelines of the Common Rule (See 21 CFR 50, Subpart A). Consequentially, healthcare providers do not have the ability to access PHI for research without the appropriate HIPAA documentation, including an individual patient authorization or an institutionally approved waiver of authorization, as referenced in the Privacy Rule.

The Privacy Rule

The Privacy Rule is designed to regulate the way covered entities handle PHI and establish the federal protections under which PHI can be used

CONTINUED ON PAGE 20

The 18 Identifiers that make Health Information PHI

- Names
- Dates including birth date (i.e. admission date, discharge date, death date)
- Telephone numbers
- Geographic data smaller than state
- Fax numbers
- Social Security numbers
- Email addresses
- Medical record numbers
- Account numbers
- Health plan beneficiary numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers including license plates
- Web URLs
- Device identifiers and serial numbers
- Internet protocol (IP) addresses
- Full face photos and comparable images
- Biometric identifiers (i.e. retinal scan, fingerprints)
- Any unique identifying number or code

EQuIP CORNER

PRIVACY OFFICER INVOLVEMENT IN CLINICAL RESEARCH

CONTINUED FROM PAGE 19

and disclosed for different purposes, including research. The Privacy Rule included in 45 CFR 160 and 164 was enacted in December 2000 and enforced in 2003 (after the revisions in April of 2002), sets limitations on how applicable entities can access or disclose PHI. The Privacy Rule set the national standard for the protection of health information by health plans, clearinghouses, and providers. However, the Privacy Rule did not replace any additional protections to PHI established by an individual state. In other words, individual states may enact more stringent privacy rules. The more stringent rule will take precedent in the protection of PHI.

A waiver of authorization can exist if the use of PHI involves no more than minimal risk to the privacy of an individual. For the IRB to approve a waiver of authorization under the Privacy Rule, the investigator must satisfy the following criteria:

- An adequate plan to protect identifiers from improper use or disclosure.
- An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research.
- A written assurance that the PHI will not be reused or disclosed to another entity.
- Assurance the research cannot be conducted without access to PHI, and
- Subsequently, the waiver of authorization.

The Security Rule

On the other hand, the HIPAA Security Rule prioritizes the safeguarding of Electronic PHI (ePHI). The Security Rule was published in February of 2003, with enforced compliance in 2005. The Security Rule set national standards for protecting the confidentiality, integrity, and availability of PHI. The Security Rule provides standards for physical safeguards, administrative safeguards, and technical safeguards.

IRB Process

Although Privacy Officers provide oversight throughout the IRB Process in research to ensure compliance with corporate policies and regulations, it is ultimately up to the Principal Investigator (PI) to ensure their research complies with all policies and regulations throughout the entire research process. When conducting research, a PI should ask themselves:

- Do I have an adequate plan to protect identifiers from improper use or disclosure?
- Does my research require a waiver of authorization?
- How long should records be stored? How should they be properly disposed?
- What is the difference between authorization and consent?

Before the research commences, researchers must determine if the use and disclosure of PHI is justified and clinically relevant to the research project. Once it is determined that PHI is justified and clinically relevant to the research, investigators must decide whether to pursue patient authorizations or an institutional approved waiver from the IRB. Research containing PHI that is justified as clinically relevant requires a Research HIPAA Authorization to be submitted to the IRB.

A valid Research HIPAA Authorization must include:

- A clear statement that the PHI will be exclusively used for the research.
- A description of the PHI to be used or disclosed.

- The name of the authorized person to make the requested use or disclosure.
- The purpose clearly stated, in addition to an expiration date (when the privacy protection ends).

In the preparation of research, the investigator can design the study, pre-screen, recruit potential subjects for authorization and assess the feasibility of conducting research.

During the research, to ensure the proper security measures are taken to prevent unauthorized access to PHI or ePHI, the research team shall:

1. Ensure all workstations with the ePHI are password protected and no passwords are shared between research team members.
2. Ensure that all paper records, notes, charts, or other writings with PHI be secured in a locked area that only the research team can access. This can be by locking in private office or in a file cabinet or both. Remember, if persons not engaged in the research project may enter a locked office (e.g. EVS staff), then a locked cabinet should be considered.
3. Ensuring that all ePHI not be stored on the desktop of any laptop or computer and stored in a secure server. Additionally, files storing ePHI or scanned PHI should be password protected.

These certainly are not all the methods for protecting ePHI and PHI. If you have any concerns about how to protect ePHI or PHI, contact one of the Privacy Officers. Please note, no PHI can be removed from the covered entity during the review of research. For example, paper records may not be removed from the covered entity. Additionally, ePHI may not be removed by means of a flash drive or electronic writing device. Finally, "removal" of ePHI is prohibited by emailing any research information unless that email is to a co-researcher, the PI, or research staff. In the event of a breach, please reference policy MHC_CC1109 and immediately contact the Regional Compliance Officer.

After the research ends, PHI must be protected until proper disposal. The PI needs to contact the appropriate Regional Compliance Officer(s) when disposing of PHI. The Regional Compliance Officer must be involved in "monitoring" and/or "supervising" the disposal of PHI used in the research project. Researchers may retain information for the length of time approved by the MHC IRB; However, the information must be maintained in the same manner it was originally approved by the MHC IRB. For more information on retaining research records, please reference policy MHC_RP0114, "IRB Documentation and Research Records". Proper disposal methods of PHI include, but may not be limited to:

- Paper Records – shredding, burning, or pulverizing data so any PHI rendered is indecipherable and cannot be reconstructed.
- Electronic Media – Clearing, the use of software to overwrite data with non-sensitive information; or Purging, the use of exposing the media to a magnetic field in order to disrupt the recorded domains.
- Prescriptions – Keeping labeled bottles in opaque containers until a disposal vendor can properly destroy PHI.

Summary

At McLaren Healthcare, and many other institutions, Privacy Officers play a fundamental role in facilitating adherence in federally mandated HIPAA policies and procedures. These policies are in place to preserve patient's rights to privacy in research settings. We are proud to acknowledge the commitment of our Privacy Officers: Maureen Decker, Kathy Griffin, and Nancy Smith, in ensuring privacy rights compliance throughout the McLaren Research community.

For more information, contact the Research Integrity Department at **(248) 484-4950** or **hrpp@mclaren.org**.

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

Carlos F. Rios-Bedoya, ScD

WHAT SHOULD I DO AFTER THE GRADUATE MEDICAL EDUCATION PRE-DETERMINATION PROCESS HAS BEEN COMPLETED?

By Carlos F. Rios-Bedoya, ScD, MPH

As you might recall, the Division of Scholarly Activity had decided to establish an independent process for the Human Subjects Research Pre-Determination (HSRPD) of scholarly activity projects from residents and fellows. This new HSRPD process was implemented by McLaren Graduate Medical Education on February 1, 2022. All scholarly activity projects, except case reports, case series and systematic literature reviews (without meta-analysis), must follow this new process. As with any implementation of a new process questions emerge and clarifications need to be addressed. One of the most common questions that has been identified is what to do after receiving the pre-determination letter.

The answer to that question depends on which one of the two possible outcomes is included in your pre-determination letter. The first possible outcome included in your letter and identified by a mark in a check box that states the project "DOES NOT qualify as human subject research as outlined in 45 CFR 46.102(d) and (f) or 21 CFR 56.102(c) and (e) and is not subject to oversight by the MHC IRB." The next step would be to consult with your PhD and prepare an application to submit your project to the correct email using the appropriate forms to the Scholarly Activity Review Committee (SARC) for review and approval. To expedite this process, it is imperative that you follow the instructions on the application forms and obtain signatures, initials, or names as specified on those forms. Also, include any additional documentation such as data collection forms, protocols, questionnaires, etc. with your application to allow the SARC a better understanding and review of the project. Remember that the members of the SARC have never read your project; therefore, they depend on what it is sent to them to understand the project and make an adequate review. Once the SARC has received and reviewed all the forms

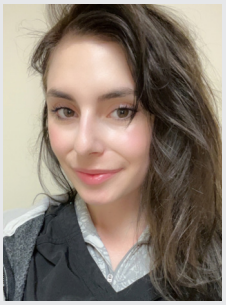
and documentation you will receive a letter stating that either the project has been approved without stipulations or that the SARC is requesting some revisions or modifications. If your project is approved without stipulations, the project can start immediately. If SARC is requesting revisions or modifications, DO NOT begin the project. Make the revisions or modifications requested by the SARC and resubmit. You must wait for the SARC letter stating that the project has been approved without stipulations before moving forward. Including the PhDs in all steps of this process should make it faster and less challenging.

The other possible outcome that could be included in the pre-determination letter and identified by a mark in a check box states that the project "DOES fit the definition of human subjects research requiring MHC IRB approval / oversight (45 CFR 46)." The next step would be to consult with your PhD and prepare an application to submit your project to the McLaren IRB for review and approval. The McLaren IRB has an electronic submission system called iRIS that must be used when submitting a scholarly activity project for review and approval. During this process the IRB will be communicating with the research team through the electronic system requesting clarifications, asking for additional documentation, making comments, etc. It is extremely important to reply to those inquiries as soon as possible. Keeping in constant communication with the IRB is the best approach to facilitate the review and approval process. Otherwise, the IRB can administratively retract the application if they do not receive a response within 30 days.

Once the IRB has successfully completed its review of the application, you will receive an outcome letter stating that either the project has been approved without stipulations or with some stipulations. If the former is included in the letter, the project can start immediately. If the latter is the statement included, DO NOT begin the project, make the revisions or modifications requested by the IRB and resubmit. You must wait for the IRB letter stating that the project has complied with the stipulations and has been approved. Including the PhDs during this process should make it faster and less challenging.

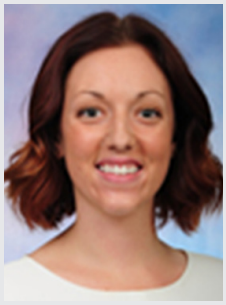
The Division of Scholarly Inquiry is committed to support and facilitate scholarly activity for McLaren residents, fellows, and faculty. For additional information contact Dr. Carlos F. Ríos-Bedoya at carlos.rios@mclaren.org.

ANNOUNCEMENTS AND WHAT'S NEW



Brianna Coderre

The McLaren Center for Research and Innovation (MCRI) is pleased to announce the addition of **Brianna Coderre** to the team! She will be working as a Clinical Research Coordinator at the McLaren Flint location with a strong focus in Neuroscience clinical trials. Brianna has experience as both an Emergency Medicine medical scribe and an Internal Medicine research coordinator. Brianna graduated from Saginaw Valley University with a major in biology and minor in chemistry. She has also obtained a graduate degree from Drexel University with a major in Clinical Research Management and Organization. Brianna found her passion in research at SVSU studying reproductive toxicity in rats, as well as a novel research project in fruit flies.



Paige Dykema

The Karmanos Cancer Institute Clinical Trials Office (CTO) is pleased to announce the addition of **Paige Dykema** as a Regulatory Manager. Paige will directly oversee all CTO regulatory personnel, including the Regulatory Supervisors, and will directly supervise the GU, Thoracic, Breast, BMT and Data Entry Tech Regulatory teams until an additional Regulatory Supervisor is hired. Paige has extensive regulatory knowledge and experience with our Clinical Trials Office policies and procedures. She previously served as a CTO Regulatory Coordinator from May 2016 - December 2020. Her experience also provides the team a more robust understanding of Sponsor/Contract Research Organization (CRO) operations, which is tremendously helpful to our group. We are so grateful Paige had rejoined our Karmanos Cancer Institute CTO team!

Jacki Wilson

Research Integrity is pleased to welcome **Jacki Wilson**, our newest IRB Analyst at the Auburn Hills Corporate office. Jackie brings more than 25 years of Research Management experience to the McLaren IRB. We are glad to have her join our team!

Michael Flores

Research Integrity is pleased to welcome **Michael Flores**, our newest IRB Analyst at the Auburn Hills Corporate Office. Michael brings a background in Project Management and the implementation of IRB compliance solutions software. Michael strives to learn and improve his skills regularly so he can perform to his highest potential!

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