RESEARCH *Matters*

Summer 2024

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

McLaren

RESEARCH AROUND McLAREN

McLAREN BAY REGION MCRI

EXCELLENCE IN ENROLLMENT

The MCRI team at McLaren Bay Region has shown nothing short of excellence in enrollment in 2024. The team has been steadily leading MCRI into a strong position with overall enrollment for the year. With over 40 enrollments since January, the team is impressing not just McLaren, but the industry partners who sponsor the research. The DEFIANCE study team at Inari Medical featured Dr. Mouawad and the MCRI team in their May 2024 newsletter stating they have been a top enroller since their activation in July 2023, currently sitting at number 3 out of 87 active sites. The same team is currently the third highest enroller in Silk Road Medical's study ROADSTER 3, called by the sponsor, a "North Star Site" in their June 2024 newsletter.

Dr. Daniel Lee and the MCRI team received a certificate of recognition for outstanding recruitment and contribution to the DAPA ACT-HF-TIMI 68 trial with TIMI Study Group and AstraZeneca, earning a Bronze Status for the site.

(Left to Right): Carolyn Harrison, CRC, Marci Roberts, CRC, Nicolas Mouawad, MD, Kiona Graham, CRC

Clinical trial activity is front and center with the cardiovascular group at McLaren Bay Region and we look forward to seeing what future achievements and recognitions they earn in the months to come. Congratulations to all our active investigators and research staff on a job well done!

CONGRATULATIONS, DR. MOUAWAD!

Nicolas Mouawad, MD

Dr. Nicolas Mouawad has been recognized for his exceptional care, earning inclusion on Newsweek's America's Best Vascular Surgeons 2024 list. He is an active investigator with the MCRI team demonstrating this exceptional care with his research patients, as well as his clinical patients. Dr. Mouawad is an excellent example of an engaged investigator and works hard to increase the McLaren footprint in vascular clinical trials.

DR. JUSTIN KLAMERUS AND DR. GEORGE YOO

NAMED IN BECKER'S 2024 CHIEF MEDICAL OFFICERS TO KNOW

Justin Klamerus, MD, MMM, executive vice president and chief clinical officer at McLaren Health Care, and George Yoo, MD, FACS, chief medical officer (CMO) at Karmanos Cancer Hospital, are both listed on Becker's Hospital Review's 2024 Chief Medical Officers to Know.

Justin Klamerus, MD, MMM

The list features CMOs from across the country who "champion patient safety, uphold rigorous quality standards, act as liaisons between leadership teams and medical staff, manage risk," and more. CMOs listed are viewed as leaders who are continually driven for improvement, leading to multiple quality and safety accolades for their organizations.

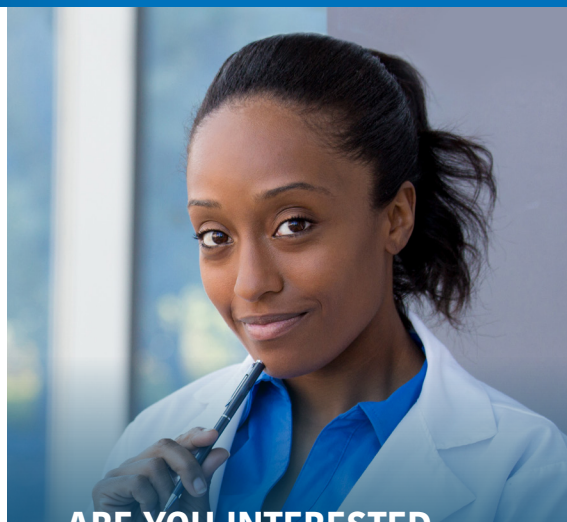
This is Dr. Klamerus' second consecutive year being named on the list. Becker's wrote:

"Dr. Klamerus serves as chief clinical officer for 13 hospitals systemwide, a role that requires him to lead clinical care with a single standard of quality and care across hospitals. He oversaw the expansion of the Karmanos Cancer Network and the opening of the system's first out-of-state location in Ohio. Under his leadership, the system has been recognized for clinical quality and safety, including two CMS 5-star rated hospitals. Dr. Klamerus has been with the system since 2009, when he joined as a practicing oncologist."

Becker's wrote the following about Dr. Yoo:

George Yoo, MD, FACS

"Dr. Yoo has served as CMO at Karmanos Cancer Center since 2008. He manages the group's annual budget, oversees Karmanos' comprehensive medical operations and spearheads strategic initiatives. As CMO, Dr. Yoo is a pivotal senior executive team member, managing medical directors, multidisciplinary teams of specialists and the entire medical staff. He is also active in numerous Karmanos Cancer Hospital and Wayne State University committees, many of which he holds board positions. Dr. Yoo contributes to academia at the WSU School of Medicine, as well as clinical research. He also helps with securing investigational funds for cancer care development. He joined the faculty at WSU in 1996. He has significantly contributed to the WSU Department of Oncology through his teaching and mentoring. As a clinical scientist, Dr. Yoo managed a National Institute of Health-funded laboratory, securing $2 million in grant support, which resulted in the publication of over 70 peer-reviewed articles."



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

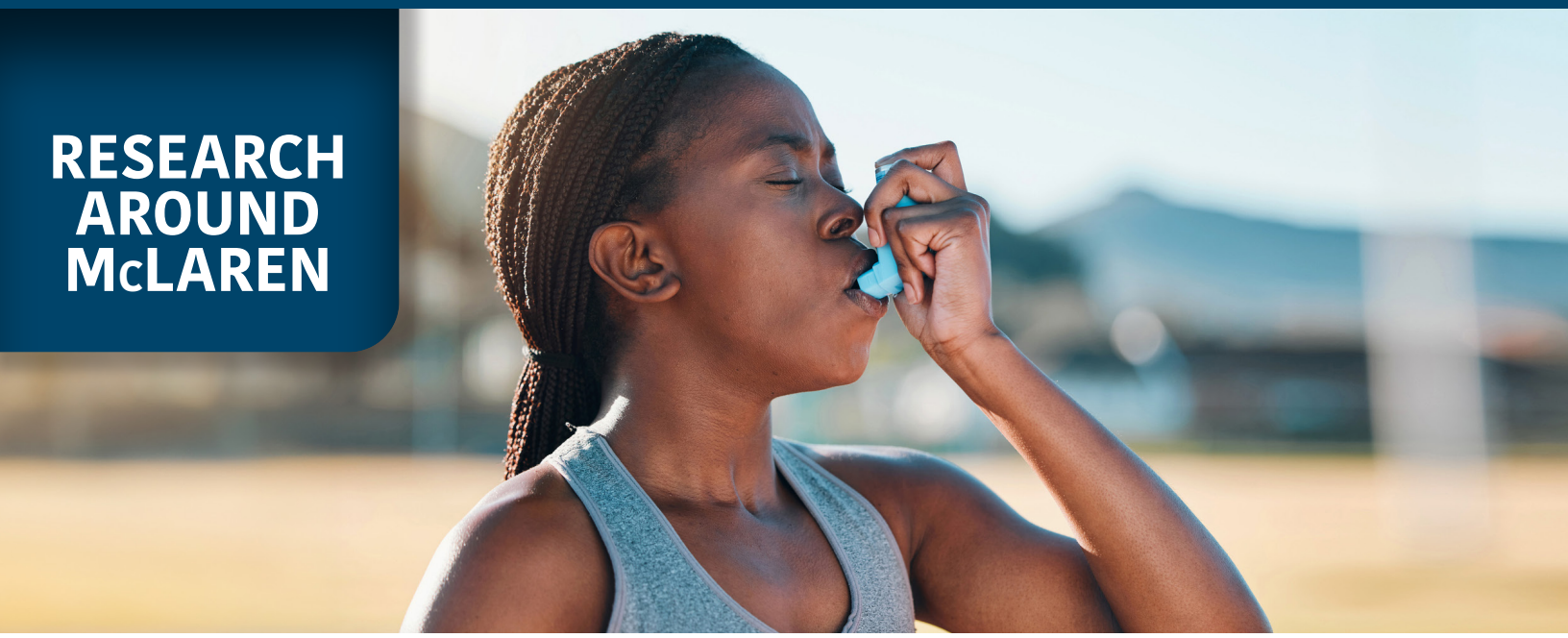
For information on enrolling in a clinical trial please visit **mclaren.org/main/clinical-research-trials**. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

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



ANCHOR ASTHMA CLINICAL TRIAL

INFORMATION FOR PROVIDERS

STUDY REVIEW

Primary Objective: Describe and compare asthma exacerbation rates in the 12 months pre-period to the 12 months post-period among participants switching from SABA only rescue inhaler (e.g., albuterol or levalbuterol) to AIRSUPRA. The patient will receive an RxStudy card that allows them to fill their AIRSUPRA at no cost during the 12-month participation period. The ANCHOR Study team will reach out to the patient every 3 months to gather study-related information.

AIRSUPRA Overview

AIRSUPRA is a combination of albuterol, a beta-2 adrenergic agonist, and budesonide, an inhaled corticosteroid, indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.

In a phase III randomized, double-blind study of patients with moderate to severe asthma comparing AIRSUPRA with Albuterol, AIRSUPRA achieved a statistically significant 28% reduction in the risk of severe asthma exacerbations among adult patients ($p<0.001$).[1]

In another phase III, randomized, double-blind, active-comparator and placebo-controlled lung function study of patients with mild to moderate asthma. The onset of bronchodilation with AIRSUPRA was as fast as albuterol.[2]

Eligible patients should be referred to the study team at **(248) 748-9971** or **ANCHOR@mclaren.org**

Referring Provider Role

- Screen patients for eligibility
- Prescribe AIRSUPRA and send electronic script to the patient's preferred pharmacy
- Report any adverse events and serious adverse events
- All other study contact and consenting will be handled by the ANCHOR team

Inclusion Criteria

- 18 years of age or older
- At least 1 visit with primary or secondary diagnosis of asthma within 12 months before or on enrollment date
- At least 1 filled prescription of SABA only rescue inhaler e.g. albuterol or levalbuterol within 12 months before enrollment date
- At least 1 asthma exacerbation within 12 months before enrollment date
- Had both medical and pharmacy insurance coverage (e.g., Medicare, Medicaid, commercial) for at least 12 months before enrollment date and without foreseeable plans to change or discontinue

Exclusion Criteria

- Patients with major respiratory diagnoses including chronic obstructive pulmonary disease (COPD), cystic fibrosis,bronchiectasis, respiratory tract and/or lung cancer,interstitial lung disease (including pulmonary fibrosis, bronchopulmonary dysplasia and sarcoidosis), pulmonary hypertension and tuberculosis within 12 months before enrollment date
- Inpatient admission, emergency department or urgent care visit due to asthma within 10 days before enrollment date,or self-reported use of systemic corticosteroid for the treatment of asthma within 10 days before enrollment date
- Chronic use of oral corticosteroids (for any condition) within3 months before enrollment date
- History of AIRSUPRA use within 12 months before enrollment date.
- Any history of malignancy (except malignant neoplasm of skin) within 12 months before enrollment date
- For women only: Pregnant, breastfeeding or lactating women at the time of enrollment or planning to become pregnant in the year following the enrollment date

1. *AIRSUPRA® (albuterol/budesonide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023.*
2. *Chipps BE, Israel E, Beasley R, et al. Albuterol-budesonide pressurized metered dose inhaler in patients with mild-to-moderate asthma: results of the DENALI double-blind randomized controlled trial. Chest. 2023;164(3):585-595. doi:10.1016/j.chest.2023.03.035.*

DO YOU HAVE A RESEARCH PROJECT THAT NEEDS FUNDING?

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

INVESTIGATOR RESOURCES

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

CITI Training, Biomedical, GCP
citiprogram.org

SOCRA
socra.org

ACRP
acrp.org

Health and Human Services
hhs.gov/programs/research

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

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

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

Code of Federal Regulations
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
clinicaltrials.gov

RESEARCH AROUND McLAREN

DEPARTMENT OF DEFENSE GRANT ASSISTS KARMANOS RESEARCHERS

STUDYING NEW TREATMENTS FOR OVARIAN CANCER

Gen Sheng Wu, PhD, member of the Molecular Therapeutics Research Program at the Barbara Ann Karmanos Cancer Institute and professor of Oncology at the Wayne State University School of Medicine, recently received a grant from the Department of Defense's Congressionally Directed Medical Research Programs.

Gen Sheng Wu, PhD

The four-year, $924,000 grant will benefit Wu's study, "Targeting Dual-Specificity Phosphatase 1 in Platinum Resistance in Ovarian Cancer," which aims to discover improved treatments for ovarian cancer.

"Ovarian cancer is one of the deadliest diseases," Dr. Wu said. "It's difficult to diagnose early and most cases are only found in the late stages. The late-stage survival rate is approximately 30%. After surgery, chemotherapy is the other primary treatment; however, patients develop a resistance to this treatment very quickly. It's a major problem with ovarian cancer and it's our major challenge in the field."

This research will address the challenge of eliminating drug-resistant ovarian cancer cells using new treatment regimens. Specifically, Dr. Wu and his research team have identified a resistance mechanism involving a protein called dual-specificity phosphatase 1.

Dr. Wu believes this could be an important step in addressing ovarian cancer because it has the potential to improve the efficacy of platinum-based therapies. Platinum-based therapies are the standard first-line chemotherapy for most patients with ovarian cancer. However, almost all patients receiving platinum eventually relapse and die from metastatic disease, mainly due to primary and acquired resistance to the treatment.

"With this grant, we will follow up with findings that phosphatases that can remove the phosphate group to, and thus shut down, MAPK signaling to promote cancer cell survival," Dr. Wu said. "Based on this mechanism, we are studying how this reaction works and how implementing it may increase survival and remission rates."

The award number for this Department of Defense Ovarian Cancer Research Program grant is HT9425-24-1-0694.

Originally published at Today@Wayne.

This research will address the challenge of eliminating drug-resistant ovarian cancer cells using new treatment regimens. Specifically, Dr. Wu and his research team have identified a resistance mechanism involving a protein called dual-specificity phosphatase 1.

CANCER BIOLOGY GRADUATE STUDENT

ADVOCATING IN DC FOR CONTINUED CANCER RESEARCH SUPPORT

A fourth-year doctoral student in the Cancer Biology Graduate Program at the Wayne State University School of Medicine and the Barbara Ann Karmanos Cancer Institute was selected for a second year by the American Association for Cancer Research (AACR) to attend the organization's Early Career Hill Day.

Natalie Snider knows first-hand the importance of advocating for continued funding of the National Institutes of Health (NIH) and the National Cancer Institute (NCI). That's why she traveled as part of a team to Washington, D.C., on Feb. 26 to represent WSU and the states of Michigan and Illinois as an advocate with AACR.

Snider's participation is a prime example of WSU's Prosperity Agenda, in which students are given opportunities to "learn by doing," in turn cultivating the competencies that prepare students like Snider and other future graduates for successful careers. The Grosse Ile native is mentored by Kristen Purrington, PhD, MPH, member of the Population Studies and Disparities Research Program at Karmanos and associate professor of Oncology, whose research focuses on the impact of tumor biology and microenvironment on racial disparities in clinical outcomes for African Americans with cancer.

"It is an honor to represent Wayne State (and Karmanos) at the national level. I am extremely proud to highlight the scientific achievements of the university, many of which have been supported through NIH funding," Snider said. "By showing Congress members how NIH funding directly supports WSU's research advancements as well as comprehensive training for the next generation of scientists like me, we can garner their support for these critically important NIH budget increases."

The annual event brings early-career scientists, including doctoral candidates, post-doctoral researchers, medical residents, medical fellows,

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RESEARCH AROUND McLAREN

TWO KARMANOS LEADERS NAMED HEALTH CARE HEROES

The 2024 list of Crain's Detroit Business Health Care Heroes contains two Karmanos Cancer Institute leaders: Boris C. Pasche, MD, PhD, FACP, and Michael Dominello, DO.

Advancements in Care Hero

Dr. Pasche, president and CEO of the Barbara Ann Karmanos Cancer Institute, was named an Advancements in Care Hero for his co-invention of the Therabionic P1 device. He and his co-inventor, Alexandre Barbault, started studying the use of low-level radiofrequency electromagnetic fields to treat cancer in the early 2000s.

Boris Pasche, MD, PhD, FACP

"This is a systemic targeted therapy; it only targets the cancer cells," Dr. Pasche told Crain's. "There are no side effects. There's no drop in blood counts, which is especially important for cancers like liver cancer. We think we've got something really special here."

The P1 device was FDA-approved in September 2023 to treat advanced hepatocellular carcinoma (HCC), the most common type of liver cancer. By the end of the year, it will be available for patients at Karmanos. In addition, Karmanos researchers and scientists are studying the use of radiofrequency electromagnetic fields to treat other solid tumor cancers.

Dr. Pasche is a medical oncologist who specializes in gastrointestinal malignancies and hereditary cancer. In addition to his position as president and CEO, he is also Karmanos' principal investigator of the National Cancer Institute's Comprehensive Cancer Center Core Grant, chair of the Department of Oncology at Wayne State University (WSU) School of Medicine, and a scientific member of the Molecular Therapeutics Research Program.

Physician Hero

Dr. Dominello, radiation oncologist, medical director of Gamma Knife Radiosurgery, leader of the Neuro-Oncology Multidisciplinary Team (MDT) and member of the Breast Cancer MDT at Karmanos, was named a Physician Hero. He has been focused on incorporating and publishing novel treatments and techniques to improve patients' outcomes, specifically for breast and brain cancer.

Michael Dominello, DO

One such manuscript that Dr. Dominello authored details an innovative radiation delivery method developed by his team at Karmanos to minimize incidental dose to the heart when treating left-sided breast cancers. This technique is now considered standard practice to keep the radiation dose to the heart at near-zero levels (PMID: 34902636). Also, in the

last three years, he has enrolled 25 patients in interventional clinical trials and 193 patients in prospective observational studies with patient-reported outcomes to learn how care teams can better care for patients.

He's laser-focused on streamlining the patient experience and building a thriving radiosurgery program that puts patients' comfort first. Dr. Dominello was integral in bringing the only out-patient Gamma Knife radiosurgery system to the Karmanos Cancer Institute at Weisberg Cancer Center in Farmington Hills and designing the space for the machine. This machine treats brain tumors and neurological disorders. He and his team continue to study how to improve patient experience and outcomes with this non-invasive procedure, utilizing the most precise stereotactic radiosurgery system.

"The brain is very important real estate, and so selecting the optimal tool to treat that spot, that lesion, that tumor … that is a true advantage in cancer medicine," Dr. Dominello told Crain's.

In addition to his above-mentioned positions, Dr. Dominello is a scientific member of the Molecular Imaging Research Program and an associate professor at WSU School of Medicine.

ADVOCATING IN DC

CONTINUED FROM PAGE 7

and some early-stage assistant professors, to Washington to advocate for robust, sustained, and predictable funding for cancer research and biomedical science on behalf of early-career cancer researchers.

In meetings with the offices of U.S. Sens. Gary Peters, Debbie Stabenow and U.S. Rep. Debbie Dingell of Michigan, and U.S. Sens. Richard Durbin, Tammy Duckworth and U.S. Rep. Mike Quigley of Illinois, Snider and the team advocated for the highest possible increase to the NIH base budget for the upcoming fiscal year.

"We asked for $51 billion for the NIH and $9.988 billion for the NCI. These amounts are calculated using the Biomedical Research and Development Price Index, which accounts for how much NIH expenditures need to increase each year to maintain NIH-funded research activity at the previous year's level," Snider said.

Participants stress the importance of investing in the future of cancer research and provide their perspectives as the investigators whose careers may be most impacted by the support of this essential funding. Participants receive support from AACR staff and are accompanied by one or more established investigators with significant advocacy experience.

"While this is not directly related to the content of my thesis work, NIH funding affects nearly all graduate students and their ability to conduct their thesis work by supporting their research and training. Support from the NIH is what helps us to complete our doctoral studies and become independent scientists," Snider added.

Originally published at Today@Wayne.

"It is an honor to represent Wayne State (and Karmanos) at the national level. I am extremely proud to highlight the scientific achievements of the university, many of which have been supported through NIH funding."

– Natalie Snider

RESEARCH AROUND McLAREN

KARMANOS WELCOMES WASIF SAIF, MD, TO LEAD PHASE I CLINICAL TRIALS

INTERNATIONALLY KNOWN CLINICAL AND TRANSLATIONAL RESEARCHER ALSO CO-LEADS THE GI ONCOLOGY TEAM

Karmanos Cancer Institute welcomes Wasif Saif, MD, MBBS, as the new leader of the Phase I Clinical Trials Multidisciplinary Team and co-leader of the Gastrointestinal (GI) and Neuroendocrine Oncology Multidisciplinary Team (MDT). Dr. Saif is a world-renowned hematologist and oncologist specializing in GI cancers, experimental therapeutics and pharmacogenetics. He joined Karmanos in March 2024.

Wasif Saif, MD, MBBS

"Karmanos Cancer Institute is a trailblazer in cancer research and has been a major contributor to significant strides in new drug and therapy development," said Dr. Saif. "I am most excited about continuing translational research at this NCI-Designated Comprehensive Cancer Center with access to a diverse cancer population. This cancer center's rich data from clinical trials, studies, and investigations largely shapes the understanding of cancer and treatment for multiple populations. The avenues the physicians, scientists, and researchers have open to them are endless, and I am honored to be part of this significant work in Detroit."

Dr. Saif has an extensive background in translational research and developing and managing clinical trials. As the Phase I Clinical Trials MDT leader, he will lead a team of physician co-investigators, non-physician providers, clinical personnel, and Clinical Trials Office staff to oversee Phase I solid tumor investigations. Karmanos' Phase I team oversees over 70 clinical trials at various stages of the protocol lifecycle. Members of this MDT include medical oncologists specializing in many different cancers, who research, study, and develop therapies, bringing them from lab to bedside. Having a Phase I team in Detroit gives cancer patients access to promising new treatments not offered elsewhere.

Dr. Saif will also work alongside Najeeb Al Hallak, MD, MS, medical oncologist, in leading the GI and Neuroendocrine Oncology MDT, a team made up of cardiothoracic surgeons, endocrinologists, gastroenterologists, hematologists, medical oncologists, pathologists, radiologists, radiation oncologists, and surgical oncologists that dedicate their research and treatment to GI and neuroendocrine cancers. Dr. Saif specializes in treating anal, biliary, colon, carcinoid, esophagus, GIST, liver, pancreas, rectum, and stomach cancers. His research interests include anticancer drug development with an emphasis on analysis of pharmacokinetics and pharmacodynamics, biomarker discovery, pharmacogenetics, epidemiology

and disparity studies in GI cancers, and developing complementary and alternative medicines to treat cancer.

"Dr. Saif's philosophy and leadership in novel therapeutics fits our vision of continuing to grow our Phase I Clinical Trials Program at Karmanos. His research interests in GI cancers will complement our GI team. I am confident we will see more breakthrough discoveries from these MDTs with Dr. Saif's leadership and vision," said Boris Pasche, MD, PhD, FACP, president and CEO at Karmanos.

In addition to his leadership roles, Dr. Saif sees patients at Karmanos Cancer Center in Detroit. He is also a professor in the Department of Oncology at Wayne State University School of Medicine.

"Karmanos Cancer Institute is a trailblazer in cancer research and has been a major contributor to significant strides in new drug and therapy development."

– Wasif Saif, MD, MBBS

Before joining Karmanos, Dr. Saif served on the faculty at the University of Alabama at Birmingham, Yale University School of Medicine in New Haven, Connecticut, Columbia University in New York City, and Tufts University School of Medicine in Boston, Massachusetts. He has served as the leader of the GI oncology division at Yale, Columbia, and Tufts and as the program leader in experimental therapeutics at Tufts. He has also served in executive roles at Northwell Health in New Hyde Park, New York and Orlando Health. Dr. Saif is a member of the American Society of Clinical Oncology (ASCO), American Association for Cancer Research (AACR), European Society of Medical Oncology (ESMO), Carcinoid Foundation, and American Society of Pharmacology and Experimental Therapeutics (ASPET). He has served as the principal investigator on over 75 clinical trials and has published over 650 scientific papers in addition to textbook chapters, abstracts, and proceedings of meetings.

Dr. Saif earned his medical degree from King Edward Medical College in Lahore, Pakistan, and completed his internal medicine residency at the University of Connecticut School of Medicine in Farmington, Connecticut. He completed medical oncology and hematology fellowships at the National Cancer Institute, National Heart, Lung and Blood Institute, National Institutes of Health, and National Naval Medical Center in Bethesda, Maryland.

RESEARCH AROUND McLAREN

AN UNPARALLELED MENTOR

RETIRED KARMANOS PHYSICIAN-SCIENTIST TO RECEIVE 2024 ASH HONORIFIC AWARD

The American Society of Hematology (ASH) has announced that Charles A. Schiffer, MD, will be presented with one of two ASH Mentor Awards. Dr. Schiffer will receive his award during the 66th ASH Annual Meeting and Exposition in December in San Diego, California.

Charles A. Schiffer, MD

Dr. Schiffer retired as a hematologist and medical oncologist at the Barbara Ann Karmanos Cancer Institute in 2020. He was the leader of the Hematology Oncology Multidisciplinary Team (MDT) and is still very active with the team, often participating in panel discussions and more. He directed the Hematology and Medical Oncology Fellowship program for approximately 15 years. He is now a professor emeritus in the Department of Oncology at Wayne State University School of Medicine. Dr. Schiffer's research focused on platelet and granulocyte transfusion therapy and the treatment of adult leukemias.

Mentoring the next generation of hematologists came naturally for Dr. Schiffer. He leads by example and challenges trainees to remain curious, seize opportunities, and think creatively. His mentees have described him as a one-of-a-kind generational teacher and characterize him as a "mentor of mentors." Dr. Schiffer is widely known for his open-door approach and fine-tuned ability to provide clinical care with rigor, bright humor, and compassion. He has trained many successful clinical investigators whose contributions have substantially influenced leukemia and cancer research and improved patient outcomes.

When he retired, Dr. Schiffer's team members had this to say:

"Dr. Schiffer is truly a legend in hematology, one that you read about in textbooks and journals. Due to his natural teaching ability and uncanny insight, he was an unparalleled teacher and mentor for countless trainees and colleagues alike. He will be impossible to replace. We will all dearly miss his leadership, words of wisdom, sense of humor, and friendship," said Jay Yang, MD, hematologist, medical oncologist and Hematology Oncology MDT leader, stepping into the position after Dr. Schiffer retired.

Throughout his career, Dr. Schiffer has authored and co-authored more than 360 articles and 80 book chapters on topics concerning the treatment of leukemia in adults, platelet transfusion and granulocyte transfusion therapy, among others. He has served on numerous editorial boards, and many professional committees including Chairman of the Leukemia Committee of the Cancer and Leukemia Group B, Chairman of the Food and Drug Administration

Oncologic Drug Advisory Committee and member of the American Board of Internal Medicine – Medical Oncology Board. He has been honored with prestigious awards including the Dr. John J. Kenney Award from the Leukemia and Lymphoma Society of America, the Celgene Award for Career Achievement in Hematology, and is an elected member of the Academy of Scholars of Wayne State University, serving as President this past academic year.

"Dr. Schiffer is truly a legend in hematology, one that you read about in textbooks and journals. Due to his natural teaching ability and uncanny insight, he was an unparalleled teacher and mentor for countless trainees and colleagues alike. He will be impossible to replace."

– Jay Yang, MD

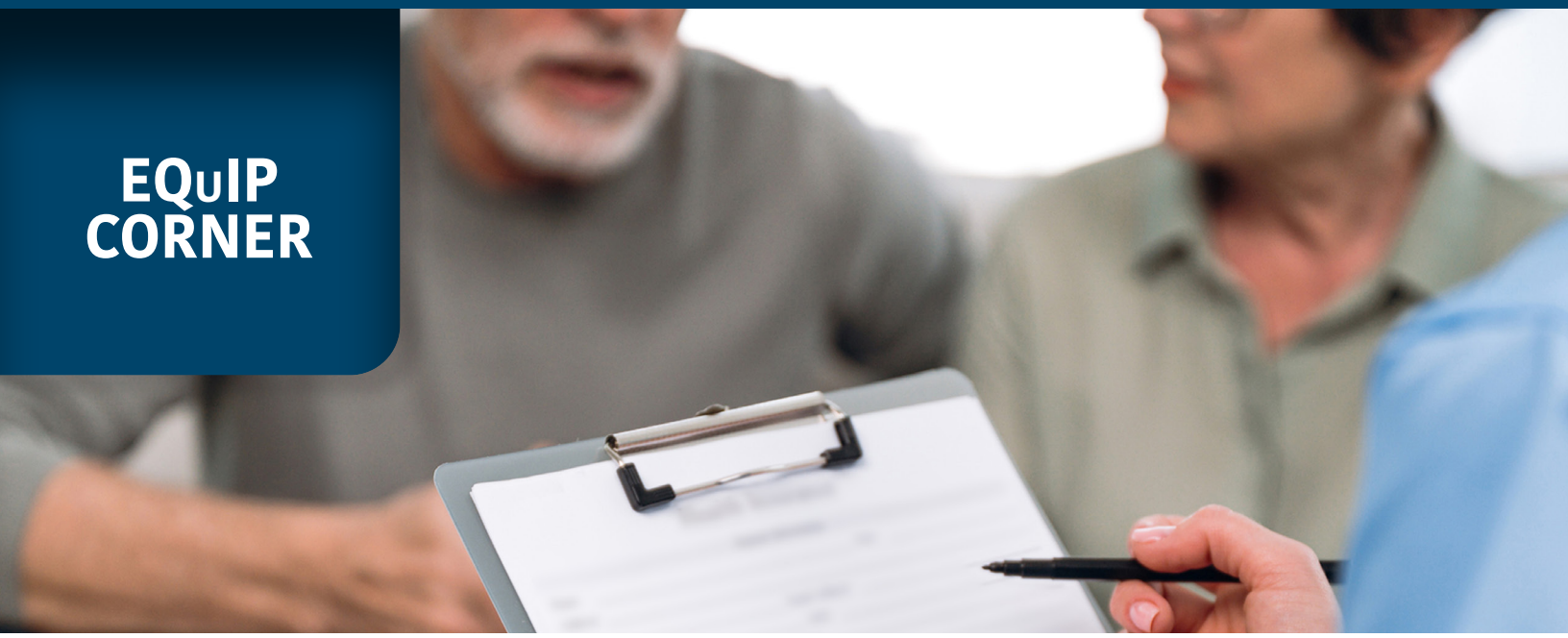
In addition, Dr. Schiffer was instrumental in developing the Joseph Dresner Family Clinic for Hematologic Malignancies & Stem Cell Transplantation at Karmanos. In May 2012, the Dresner Family Clinic opened after a generous donation from The Dresner Foundation, whose namesake founder was treated by Dr. Schiffer. In 2015, Dr. Schiffer was named the first endowed Joseph Dresner Chair for Hematologic Malignancies.

The ASH Honorific Award Recipients are exemplary hematologists who have made significant contributions to the field. This year's recipients are a group of pioneering scientists, innovative clinicians, and selfless mentors who have advanced hematology through vital contributions – from revolutionary achievements in cord blood transplants, hematopoietic stem cell research, and microbiome research to supporting medical students underrepresented in medicine.

"ASH is honored to recognize these outstanding hematologists, whose groundbreaking research, mentorship, and dedication have profoundly advanced the field," said 2024 ASH President Mohandas Narla, DSc, distinguished scientist at New York Blood Center Enterprises. "These visionary leaders have left an indelible mark on hematology and made a lasting impact on the lives of those living with blood disorders."

ASH is the world's largest professional society of hematologists dedicated to furthering the understanding, diagnosis, treatment, and prevention of disorders affecting the blood. Since 1958, the Society has led the development of hematology as a discipline by promoting research, patient care, education, training, and advocacy in hematology.

EQuIP CORNER



INTERNAL IRB AND EXTERNAL IRB
GATEKEEPERS WORKING TOGETHER

By Susmita Jain, MS, Research QI and Education Specialist, McLaren Health Care

The McLaren Human Research Protection Program (HRPP) and the IRB are committed to ensuring the safety of and protecting the rights of human subjects participating in research. There are situations when the local MHC IRB must rely on an external IRB to conduct the protocol review. Although the protocol review is ceded to another IRB, HRPP oversight of the study remains under the purview of the McLaren HRPP.

Susmita Jain, MS

Why McLaren IRB may cede to an external IRB

In the last 20 years, there has been substantial growth in the number of multicenter clinical trials, size of clinical trials, and complexity of the clinical trials. These changes have burdened IRBs, sponsors, and clinical investigators seeking IRB review for multicenter trials. Burdens such as multiple reviews by multiple IRBs can result in unnecessary duplication of effort, inconsistency in reviewing the same study protocol, delays, and increased expenses in conducting multicenter clinical trials. To overcome these challenges, regulatory agencies have proposed and implemented a central approach for IRB review. Under this central IRB approach; policies, regulations, and processes must be followed to ensure compliance and protection of human research subject participants.

Historical review of regulatory requirements on using a single IRB or centralized IRB

March 2006 - FDA guidance document
The FDA issued a guidance document titled "Using a Centralized IRB Review Process in Multicenter Clinical Trials" This guidance document assisted sponsors, IRBs, and clinical investigators involved in multicenter clinical research in meeting the requirements of 21 CFR part 56 by facilitating the use of a centralized IRB review process, especially in situations where centralized review could improve the efficiency of IRB review.

January 2018 – National Health Institute (NIH) Policy
Effective January 25, 2018, the NIH required the use of a single IRB (sIRB) for the review of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. This policy applies to sites in the United States only.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/using-centralized-irb-review-process-multicenter-clinical-trials

January 2020 - Revised Common Rule
Under the revised Common Rule, most U.S.

government-funded cooperative studies that meet the criteria for non-exempt human subject research and involve more than one site, will require sIRB review.

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.114

September 2022 - FDA proposed rule
Food and Drug Administration (FDA) proposed (not in effect) a rule that would require U.S. institutions to use a single institutional review board (IRB) for FDA-regulated cooperative research conducted in the United States. The goals are to reduce administrative and coordination costs, minimize duplicative reviews, and harmonize the requirements for cooperative research with the Federal Policy for the Protection of Human Subjects (revised Common Rule).

https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/institutional-review-boards-cooperative-research-proposed-rule-regulatory-impact-analysis

Process for Ceding to an External IRB

Reliance Agreement
For a single IRB to be the designated IRB of Record a reliance agreement must established between the IRBs. An IRB reliance or ceded IRB review is the act of transferring IRB review from one IRB to another. The IRB ceding review is called the Relying IRB. The IRB of Record who is performing the IRB review on behalf of one or more institutions is called the Reviewing IRB (also referred to as the single IRB or central IRB).

Once the agreement is executed, it can lessen the administrative burden and regulatory oversight of multiple institutions' IRBs and avoid duplicate IRB initial reviews.

When an institution and an institution's IRB rely on review by a central IRB, both IRBs must have written procedures in place to implement the centralized IRB review process (21 CFR 56.108, 56.114). For example, procedures must address the following:

- How the institution's IRB determines that the central IRB is qualified to review research conducted at the institution.
- How the central IRB intends to communicate with relevant institutions, the institutions' IRBs, and investigators regarding its review.
- How the central IRB ensures that it provides meaningful consideration of relevant local factors for communities from which research subjects will be drawn.

The MHC's HRPP policy MHC_RP0128 Relying on an External IRB as an IRB of Record outline under what circumstances the MHC's IRB can participate in a single IRB/ Centralized review process and the role of the MHC IRB in that process.

CONTINUED ON PAGE 18

The McLaren Human Research Protection Program (HRPP) and the IRB are committed to ensuring the safety of and protecting the rights of human subjects participating in research.

EQuIP CORNER

GATEKEEPERS WORKING TOGETHER

CONTINUED FROM PAGE 17

What are McLaren Principal Investigators' obligations when using external IRB?

- Obtaining sign-off from McLaren IRB/HRPP office to use an external IRB.
- Obtaining initial approval as a participating study site from external IRB.
- Communicating information about study progress to the Reviewing IRB via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center).
- Tracking personnel updates, ensuring personnel are qualified and appropriately trained to perform their roles, and providing information about relevant personnel changes to the Reviewing IRB.
- Reporting unanticipated problems, noncompliance, and significant new information to the Reviewing IRB and/or institutional IRB as applicable.
- Complying with the Reviewing IRB's policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints).
- Complying with the determinations of the Reviewing IRB.
- Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents.
- Complying with applicable policies from the local institution (e.g., conflict of interest, training and education, research subject compensation processes, billing compliance).
- Ensuring that the Reviewing IRB approves consent forms, protocol, or recruitment materials before they are implemented.
- Communicating applicable study updates with other relevant local institution committees and/or offices.

McLaren Human Research Protection Program Responsibilities

The institution must know what protocols are being conducted at their site. A point made explicit in the revised Common Rule (45 CFR46.114(a)), was that although IRB review has been ceded, the institution (McLaren Health Care) remains responsible for the conduct of the research at its site and for "safeguarding the rights and welfare of human subjects".

An internal administrative review is also necessary for the relying institution to determine the relevant "local context" information that must be provided to the reviewing IRB. Local context issues can include institutional requirements for informed consent language (e.g., compensation for injury language, HIPAA language), attesting to the adequacy of research team training, qualifications, and resources available to them to conduct the study, and providing any relevant conflict of interest management plans (or, in the case of Federal agencies, assurances that the participation of their research personnel is permissible and consistent with Federal law).

Internal Administrative Review will include:

- All investigators and research personnel must follow McLaren requirements for disclosing Conflicts of Interest (COI) and Financial Conflicts of Interest prior to submitting to the external IRB. Per MHC_RP0203 – Review and Management of Conflict of Interest in Research, certain financial disclosure must be evaluated by the Research COI Committee, a subcommittee of the Corporate COI Committee.
- All investigators and research personnel must meet McLaren's requirements for training and education.
- All research activities at MHC must follow HRPP requirements regarding monitoring and research record retention.
- McLaren, through the MHC HRPP, requires communication and collaboration with all ancillary departments that are included or impacted by research projects, i.e., Protocol Review Committee, Project Impact Statements.
- Administrative review will include review of informed consent form for McLaren required language HIPAA language review will be done the McLaren Privacy Officer.

After the study is approved, PI responsibilities include:

- PI is required to submit a modification for the following:
  - Change in personnel.
  - Change in PI to a new PI must occur before leaving PI leaves the health care system.

  - Change or reporting of COI of PI and research personnel.
  - Change in HIPAA language.
  - Change in research sites.
  - Other local context changes.
- Any reportable unanticipated problems involving risks to subjects or others, or serious or continuing non-compliance that involve McLaren personnel and/or research participants.

Finally, institutions must know and report the volume and nature of the research for which it is responsible. The IRB office, HRPP, and Institutional Official rely on the submissions from their investigators to obtain these data for reporting purposes.

Conclusion

The regulatory requirement is to conduct an internal review of ceded studies by the relying IRB to ensure compliance with their internal policy requirements and that the proposed human participant research can be conducted safely and responsibly at their site. However, this goal is unlikely to be realized without additional work and commitment from the relying institution, research team, and reviewing IRB. McLaren IRB office is the operational arm of the HRPP that is charged with coordinating these activities, ensuring that appropriate internal administrative review has occurred, and assuring that required institutional approvals are in place before the initiation of research.

UPCOMING RESEARCH EDUCATION

MHC Research Integrity Brown Bag Session
Understanding Yourself and Others in the Workplace to Reduce Conflict and Create Productive Relationships
Tuesday, September 10, 2024
12:00 pm - 1:00 pm

Speaker:
Suzanne J. Rose, MS, PhD, CCRC, FACRP
Executive Director of Research, Stamford Health
Assistant Professor in the Department of Medical Sciences, Quinnipiac University

To register email:
Susmita.Jain@mclaren.org

SOCRA
2024 Annual Conference
September 27 - 29, 2024
The Westgate, Las Vegas, NV

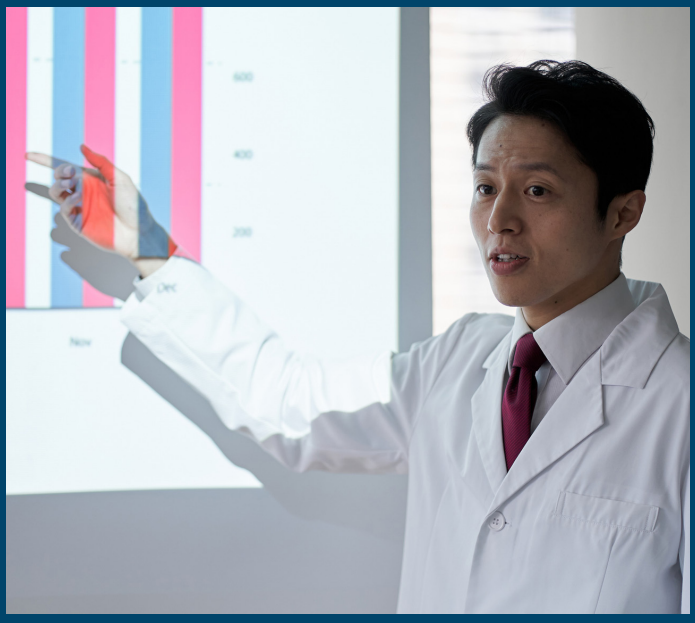
To register follow the link:
https://www.socra.org/annual-conference/2024/2024-annual-conference-information/

ACRP
Who's in Charge When AI is Let Loose on Clinical Research?
September 13, 2024
12:00 pm - 1:00 pm

To register follow the link:
https://acrpnet.org/courses/whos-in-charge-when-ai-is-let-loose-on-clinical-research/

ACRP
Facilitating Understanding in Informed Consent
October 9, 2024
12:00 pm - 1:00 pm

To register follow the link:
https://acrpnet.org/courses/facilitating-understanding-in-informed-consent/



ACRP
Facilitating Understanding in Informed Consent
October 9, 2024
12:00 pm - 1:00 pm

To register follow the link:
https://acrpnet.org/courses/facilitating-understanding-in-informed-consent/

OHRP
Collaboration, Communication, and Connection, a Virtual Research Community Forum
September 9 - 10, 2024

To register follow the link:
https://www.eventbrite.com/e/a-virtual-ohrp-research-community-forum-tickets-902450502747

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

INSTITUTIONAL AFFILIATION

By Carlos F. Rios-Bedoya, ScD, MPH

Carlos F. Rios-Bedoya, ScD

Dissemination of scholarly activity findings usually requires that researchers indicate their institutional affiliation. This might seem obvious for those with an academic background or experience, but their significance and importance might go unrecognized for many people. The institutional affiliation and the format in which it is written have several major implications for the researcher and the institution. In the area of research ethics, an incorrect, outdated, or just false institutional affiliation might be considered scientific misconduct. As such, it could have major negative professional, legal, and ethical repercussions.

Another implication for the institutional affiliation, for a study conducted with human subjects, could be identifying the Institutional Review Board (IRB) that was designated to review and approve the study. An incorrect institutional affiliation could place such responsibility on the wrong IRB. If the journal or conference where the scholarly activity findings are being disseminated requires evidence of IRB approval, as is common, from which IRB should that evidence come? Possible violations of federal regulations could be identified.

Furthermore, some might use or include incorrect affiliations to try to gain an advantage by using prestigious or widely recognized institutions when submitting manuscripts for publication, applying for fellowships, job applications, or other types of professional tasks. Additionally, the wrong institutional affiliation could also have an impact on the "branding" of the institutions.

At McLaren, we have identified a wide variability, not only in how affiliations are written but also in their content. For this reason, we have initiated a project aiming at establishing a standardized institutional affiliation format to use when disseminating scholarly activity findings and for official email communications. Once this template is reviewed and approved, an educational and informational campaign will begin. Through the use of this template, we expect to minimize the possible negative consequences that a wrong institutional affiliation could bring and also to increase the visibility of the McLaren brand.

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

MAY 1, 2004

McLAREN FIRST SCHOLARLY INQUIRY DAY AWARD WINNERS

Oral Presentations – Quality Improvement

1st Place
Elisabeth Arndt, DO
McLaren Greater Lansing, Family Medicine Residency
PROJECT: Simplifying the Depression and Anxiety Screening Process for Patients ≥12 in a Family Medicine Clinic

2nd Place
Ayman Alhadheri, MD
McLaren Oakland, Emergency Medicine Residency
PROJECT: Enhancing Patient Satisfaction in Emergency Medicine: A Quality Improvement Initiative to Improve Press Ganey Scores through Physician Education and Communication Strategies

3rd Place
Sherri Engler, MSN, RN, CNL, CCRN
McLaren Northern Michigan, Trauma
PROJECT: Trauma: Preventing Falls in the Older Population

Poster Exhibit Competition – Quality Improvement

1st Place
Christopher Lesh, DO
McLaren Macomb, General Surgery Residency
PROJECT: Intimate Partner Violence Education: Practice Issues

2nd Place
Yasmeen Basal, DO
McLaren Oakland, Emergency Medicine Residency
PROJECT: Quality initiative to improve emergency department sepsis bundle compliance through resident education and awareness

3rd Place
Brandon Symth, DO
McLaren Macomb, Emergency Medicine Residency
PROJECT: McLaren Macomb Emergency Medicine Website Redesign QI Project

Poster Exhibit Competition – Research

1st Place
Laith Hasan, MD
McLaren Flint, Orthopaedic Surgery Residency
PROJECT: Tibial Aseptic Loosening is Reduced with the Addition of a Tibial Stem Extension for Primary Total Knee Joint Replacement

2nd Place
Rabia Latif, MD
McLaren Flint, Internal Medicine Residency
PROJECT: Association between anxiety and depression with self-reported firearm use in a nationally representative sample of Unites States adults: a cross sectional study

Oral Presentations – Research

1st Place
Dheeraj Alexander, MD
McLaren Flint, Internal Medicine Residency
PROJECT: Impact of Body Mass Index on Delirious Patients Outcomes: A Nation-Wide Analysis

2nd Place
Fahimeh Talaei, MD
McLaren Flint, Internal Medicine Residency
PROJECT: Torsemide versus Furosemide Therapy in Patients with Chronic Heart Failure: An updated Meta-analysis

3rd Place
Mahmoud Ibrahim, MD
McLaren Flint, Internal Medicine Residency
PROJECT: Acetazolamide Therapy in Patients with Heart Failure: A Meta-analysis

ANNOUNCEMENTS AND WHAT'S NEW

Stephanie Gatza

We are pleased to announce **Stephanie Gatza**, Clinical Research Assistant, joined the McLaren Center for Research and Innovation at McLaren Bay Region. She has an Associates of Applied Science from Delta College in Information Technology. Stephanie has 12 years of experience with revenue cycle management within health information management at McLaren Bay Region. She looks forward to bringing her knowledge to MCRI. Welcome, Stephanie!

Leah Kulak

We are pleased to announce **Leah Kulak**, Clinical Research Coordinator II, joined the Karmanos Cancer Institute Clinical Trials Office on May 6, 2024. Leah has a Bachelor of Science in Health Sciences from Saginaw Valley State University and is providing clinical research support at Karmanos Cancer Institute at McLaren Flint and Karmanos Cancer Institute at McLaren Central Michigan. Welcome Leah!

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