RESEARCH Matters

Winter 2025

IN THIS ISSUE...

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

McLaren

RESEARCH AROUND McLAREN

NEURO RESEARCH PUBLICATIONS

McLaren's Comprehensive Stroke Centers at Flint and Macomb have been active in many landmark clinical trials over the last few years. These trials have generated numerous publications that are making a difference in how neruointerventionalists treat stroke patients. MCRI is proud to be involved in such groundbreaking work with investigators Aniel Majjhoo, MD, Mahmoud Rayes, MD and Barath Naravetla, MD. Thank you to the entire Neuro research team for your support and dedication to this important work. Additionally, special thanks are in order for the hospital staff in the cath lab, neuro intensive care unit, neuro clinic, lab, pharmacy and radiology departments who dedicate extra time and effort for research activities. Our hospitals commitment to excellence in research is evident in this library of medical research. It is truly a pleasure to bring cutting edge treatment options to our patients knowing we are doing what's best for stroke care and recovery.

EMBOLISE – NEJM November 2024, https://pubmed.ncbi.nlm.nih.gov/39565988/

TESLA – JAMA September 2024, https://pubmed.ncbi.nlm.nih.gov/39374319/

ASSIST – J Neurointerv Surg January 2024, https://pubmed.ncbi.nlm.nih.gov/38195248/

ASSIST – AM J Neuroradiol December 2024, https://pubmed.ncbi.nlm.nih.gov/39627006/

ASSIST – Clin Neuroradiol August 2024, https://pubmed.ncbi.nlm.nih.gov/39179880/

ASSIST – J Neurointerv Surg January 2025, https://pubmed.ncbi.nlm.nih.gov/39778929/

ASSIST – J Neurointerv Surg June 2024, https://pubmed.ncbi.nlm.nih.gov/38906685/

MOST – NEJM September 2024, https://pubmed.ncbi.nlm.nih.gov/39231343/

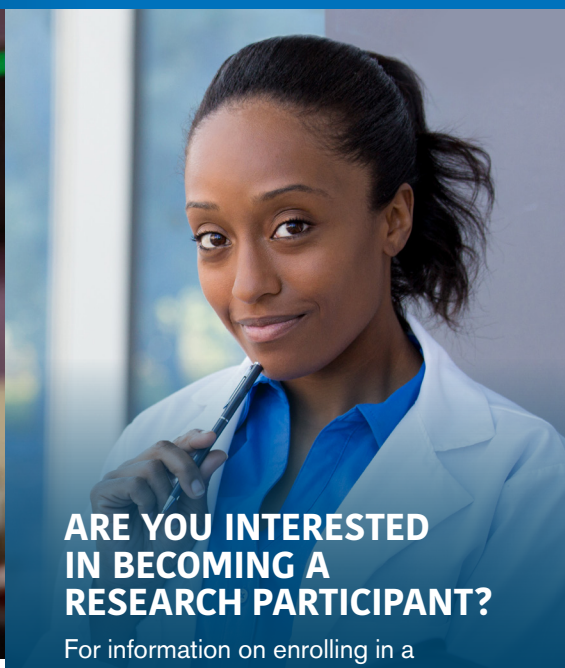
ARCADIA – JAMA February 2024, https://pubmed.ncbi.nlm.nih.gov/38324415/

TIMELESS – NEJM February 2024, https://pubmed.ncbi.nlm.nih.gov/38329148/

DR. MOUAWAD SETS ENROLLMENT RECORD

Contego Medical, sponsor of the Performance III Trial at McLaren Bay Region, recognized Dr. Nicolas Mouawad and the Bay MCRI research team for setting a national study-wide record in October 2024 for enrolling the most patients in a single day! Dr. Mouawad and his team did an unprecedented four research cases in a single day. Performance III is a study utilizing an investigational device called the Neuroguard IEP Direct 3-in-1 delivery system utilized in carotid artery stenting to protect against emboli during the procedure. McLaren Bay Region is currently the second highest enrolling site in the country for the Performance III study! Very special thanks to the whole MCRI research team, and for the consistent partnership of staff in supply chain, OR, ultrasound, Bay Heart and Vascular and all the other McLaren staff who have given extra time and effort to make this achievement possible.

Dr. Mouawad and his team did an unprecedented four research cases in a single day.



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

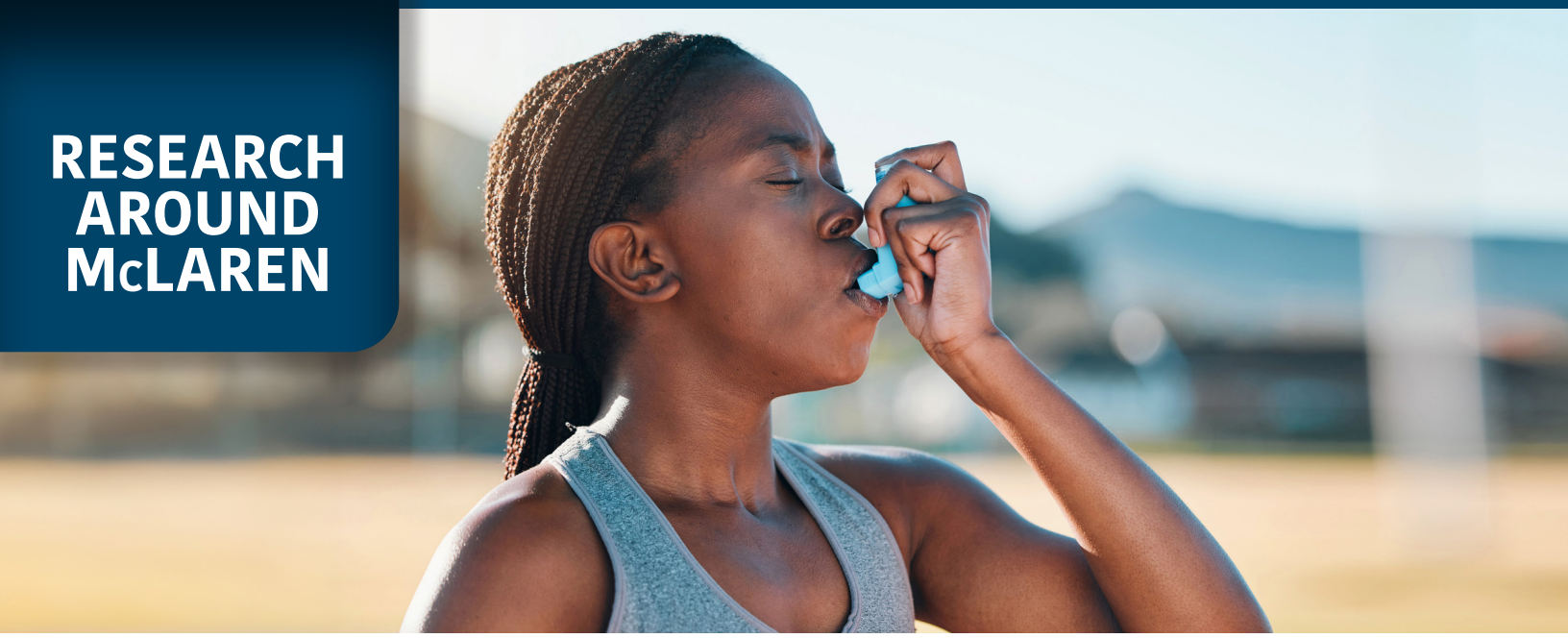
For information on enrolling in a clinical trial please visit **mclaren.org/main/clinical-research-trials**. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

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

IRB Consultations
https://www.mclaren.org/main/irb-consultations

RESEARCH AROUND McLAREN

ADVANCING BREAST CANCER WITH INNOVATIVE, PATIENT-CENTERED THERAPIES

Groundbreaking advancements are reshaping cancer care at the Barbara Ann Karmanos Cancer Institute and Wayne State University School of Medicine. Researchers are pioneering bold, patient-centered therapies designed to battle breast cancer more effectively, ease patients' journeys, reduce side effects, and enhance quality of life.

Approximately one in eight women are projected to develop invasive breast cancer in their lifetime. Through research and innovation, Karmanos oncology experts are working to improve survival rates and quality of life for patients across various stages of the disease.

Michael Simon, MD, MPH, retired medical oncologist, former co-leader of the Breast Cancer Multidisciplinary Team (MDT), and former medical director of the Karmanos Cancer Genetic Counseling Service, and professor of internal medicine and oncology, is encouraged by the latest therapeutic breakthroughs.

Michael Simon, MD, MPH

"There are a number of new treatments targeting specific types of breast cancer, allowing us to both prevent recurrence and treat advanced cases with more tolerable, life-saving medications," he said.

This tailored treatment offers hope for more effective outcomes with fewer adverse effects, which has been a long-standing goal in breast cancer care. Through continuous advancements in targeted therapies, breast cancer care is moving closer to a future where treatments are not only more effective but easier on the body.

Hadeel Assad, MD

One groundbreaking area of research focuses on cellular therapies that use a patient's immune system to combat cancer from within. Hadeel Assad, MD, medical oncologist, co-leader of the Breast Cancer MDT, member of the Phase I Clinical Trials MDT, and associate professor in the Department of Oncology, underscored the potential of these new treatment approaches.

"Cellular therapy could be transformative," she said. "By enhancing the patient's own immune t-cells in the lab to fight their cancer, we could achieve a one-time infusion that potentially keeps cancer at bay for years."

Black women are often diagnosed at more advanced stages and face higher mortality rates. Karmanos and Wayne State are also committed to addressing this critical health disparity through research that is expanding access to early detection and targeted treatments to reach at-risk populations, including a focus on medical care and the social factors that

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CLINICAL RESEARCH NAVIGATOR

The McLaren Center for Research and Innovation (MCRI) would like to remind the research community about the addition of the Clinical Research Navigator to our team. The creation of this role in early 2024, was prompted by the increasing interest across the McLaren system from non-oncology investigators in conducting their own research. From projects that do not involve human subjects, to chart reviews, to full blown multi-site clinical trials, the Clinical Research Navigator will be the first point of contact for those investigators interested in pursuing any non-industry sponsored research, and help guide the investigator through the life of the study.

MCRI's vision for this role is to have a single person assigned to work with an investigator from start to finish, guiding them through the research process and connecting them with relevant resources and colleagues to make their project successful at McLaren. This process will start with an initial consult to identify what the investigator's idea or project consists of and to develop and execute an action plan. Using a "concierge-style" service, the clinical research navigator with work with the investigator to identify the tools, resources and services needed to make their idea come to fruition. The navigator will be available to the investigators from start to finish, guiding them through each step of the research process.

"What we were finding was the whole research process was overwhelming for those that had not participated in writing their own research before," Chandan Gupte, VP of Clinical Excellence and Research, reports. "The concept of the clinical research navigator is to identify one person wo can help navigate the entire process of investigator-initiated research at McLaren."

As any investigator on a sponsored clinical trial knows, there are numerous extra responsibilities and requirements that add to an already busy workload. The idea of initiating a study from conception can seem even more daunting and challenging, and most have no idea where to begin. This new role provides investigators with that starting point and a guide to take them through the complexities of the research process.

"When looking at the steps required to develop and implement a clinical research study, it can seem burdensome. The clinical research navigator will break down the steps and assist with each, thereby making the process much simpler for our investigators," states Pam Wills-Mertz, Director of Corporate Research Administration.

A "start to finish" approach can look different for each project, but may consist of things like, guidance on FDA regulations, protocol development support, funding procurement, drug or device procurement, project feasibility and scientific review, grant and contract management, investigator education and training, consent and source document development, IRB submission, recruitment and enrollment support, audit and QA support, and promotion of institutional policies and best practices.

As we continue to develop this position and support service, we look forward to connecting with investigators and working together to forge new pathways for the conduct of research at McLaren. If you are a non-oncology investigator with a potential project you'd like to discuss, please email MCRI@mclaren.org with "IIT" in the subject line, and we will be in touch to start your action plan. Please note, this service is not applicable to Graduate Medical Education researchers, if you would like to conduct GME related projects, please reach out to your GME leaders.

ADVANCING BREAST CANCER WITH INNOVATIVE, PATIENT-CENTERED THERAPIES

CONTINUED FROM PAGE 6

influence health outcomes. Genetic counseling is another key tool, allowing clinicians to identify individuals at higher genetic risk and provide an increased chance of early detection.

"We will continue to be involved in national studies looking at new treatment options for women at every stage of the disease trajectory from screening, prevention, and treatment of early and advanced breast cancer," said Simon.

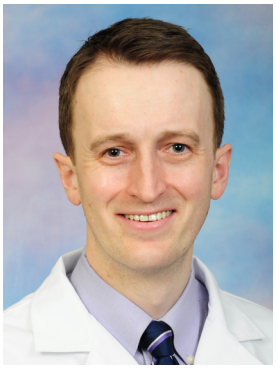
Originally published at Today@Wayne.

RESEARCH AROUND McLAREN

NEW STUDY LINKS AIR POLLUTION WITH HIGHER RATES OF HEAD AND NECK CANCER

A recent study published in *Scientific Reports* correlates higher levels of pollutant particulate matter to higher occurrences of head and neck aerodigestive cancer.

The article "Air Pollution Exposure and Head and Neck Cancer Incidence" is the work of a multi-institutional collaboration with researchers from Karmanos Cancer Institute, Wayne State University, Johns Hopkins University and Mass General Brigham.



John Cramer, MD

The study was led by John Cramer, MD, otolaryngologist, member of the Head and Neck Oncology Multidisciplinary Team at Karmanos, and associate professor of Otolaryngology, and John Peleman, MD, a medical resident in the Department of Otolaryngology at the Wayne State University School of Medicine. They collaborated with Mass General Brigham, an integrated academic health care system.

"There has been previous research on air pollution, but the effects mostly were connected to cancers within the lower respiratory system," Dr. Cramer said. "Head and neck cancer is a harder link to show, and it has a much lower occurrence than lung cancers, but since they also occur as a result of smoking, similar to lung cancers, we wanted to explore any connections. Presumably, the link to head and neck cancer comes from what we breathe to that material affecting the lining in the head and neck. We see a lot of occurrences of where carcinogens touch or pool in the body to where cancers can occur."

"While there has been substantial research investigating the effects of air pollutants on lung disease, few studies have focused on air pollution exposure as a risk factor for the upper airway, including the development of head and neck cancer," said senior author Stella Lee, MD, of the Center for Surgery and Public Health and Division of Otolaryngology-Head & Neck Surgery at Brigham and Women's Hospital, a founding member of the Mass General Brigham health care system. "These findings shed light on the significant role of environmental pollution in cancers of the upper aerodigestive tract, highlighting the need for further awareness, research and mitigation efforts."

Their research used data from the U.S. Surveillance Epidemiology and End Results national cancer database from 2002-12. Dr. Cramer observed the highest association between this type of pollution exposure and head and neck cancer after a five-year lag period. They focused on PM2.5, a particulate matter measuring less than 2.5 microns, and its effect on head and neck aerodigestive cancer incidence.

"We are looking at a certain size of air pollution particulates," Dr. Cramer said. "The size of the particles

is relevant because the classic model for studying the upper airways is that the nose and throat act as filters before it gets into the lungs. Larger particles are being filtered out, but we are conceptualizing that different types of pollution hit different parts of the airways."

Dr. Cramer hopes to expand the research by considering other data sets. He hopes that showing this research to the public could help guide policy and treatment.

"Environmental health and personal health are inextricably linked," said co-author Amanda Dilger, MD of CSPH and Massachusetts Eye and Ear, a member of the Mass General Brigham health care system. "Our study highlights the need to improve air quality standards in order to decrease the risk of developing cancer, including head and neck cancer."

Originally published at Today@Wayne.

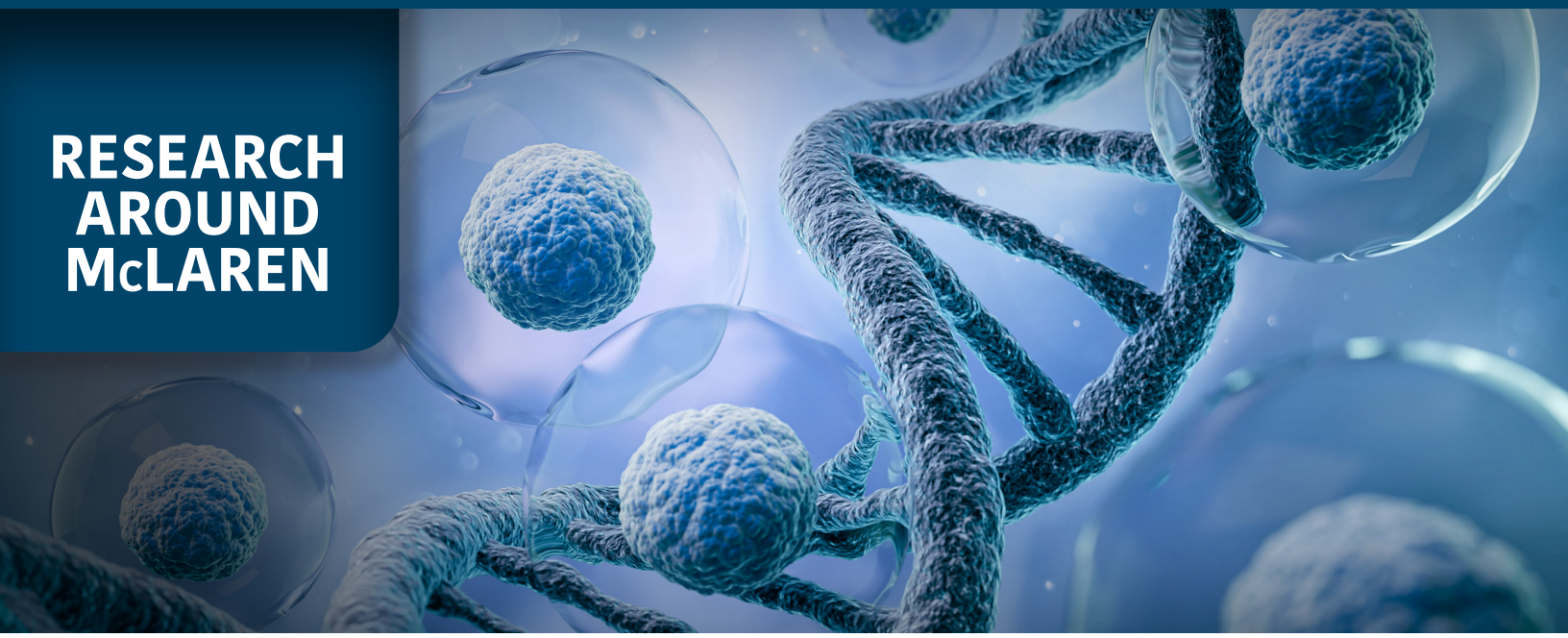
"Head and neck cancer is a harder link to show, and it has a much lower occurrence than lung cancers, but since they also occur as a result of smoking, similar to lung cancers, we wanted to explore any connections."

– John Cramer, MD

KARMANOS PHASE I LEADER PARTICIPATES IN CANCER DISPARITIES PANEL

Wasif Saif, MD, MBBS, medical oncologist, leader of the Phase I Clinical Trials Multidisciplinary Team (MDT), and co-leader of the Gastrointestinal and Neuroendocrine Oncology MDT, took part in a panel discussion about solving cancer disparities in education and clinical research at the 2024 Florida Society of Clinical Oncology (FLASCO) Cancer Disparities and Health Equity Summit in November. He was joined by experts from Cleveland Clinic Florida and Memorial Cancer Institute.

RESEARCH AROUND McLAREN



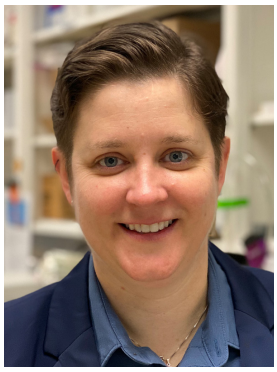
NIH FUNDS PROJECT TO INVESTIGATE GENETIC VARIANTS RELATED TO RACIAL DIFFERENCES IN HER2+ BREAST CANCER THERAPIES

Two Barbara Ann Karmanos Cancer Institute and Wayne State University (WSU) School of Medicine researchers will co-lead a new grant from the National Cancer Institute of the National Institutes of Health to identify mechanisms that contribute to cancer disparities in Detroit.

Kristen Purrington, PhD

Kristen Purrington, PhD, member of the Population Studies and Disparities Research Program and associate professor of Oncology, and Heather Gibson, PhD, member of the Tumor Biology and Microenvironment Research Program and assistant professor of Oncology, are the principal investigators on "Disparities in Immuno-oncology Outcomes in Detroit (DIODE)."

The two-year, $704,282 award will support collaborative interactions and new project development between health disparities and immuno-oncology researchers across Karmanos and WSU. The grant has two parts, with Drs. Gibson and Purrington leading the research project. Dr. Gibson, along with Ann Schwartz, PhD, MPH, vice president and deputy director of Research and Academic Affairs at Karmanos, professor and associate chair of Oncology at the WSU School of Medicine, are co-principal investigators on the administrative core, which will oversee the research and planning components, centralizing and leveraging the existing administrative infrastructure of Karmanos.



Heather Gibson, PhD

"Black women with HER2+ breast cancer experience worse outcomes than White women after receiving the gold standard therapeutic antibody trastuzumab," Dr. Gibson said. "Our hypothesis is that genetic ancestry influences whether the patient induces an anti-tumor immune response after trastuzumab, which then affects therapeutic efficacy."

The project will extend studies in an animal model to evaluate if genetics in specific genome regions impact therapeutic outcomes with trastuzumab.

"The identification of genes and related biological pathways that regulate response to therapy may lead to novel co-therapeutic agents or biomarkers to inform clinical

Ann Schwartz, PhD, MPH

strategy and improve health equity. Additionally, funding from this mechanism will further develop our infrastructure to support future cancer disparities studies here at Wayne State and Karmanos," Dr. Gibson said.

The research team will utilize HER2+ breast cancer samples from a diverse cohort of patients treated at Karmanos to conduct spatial biology analysis.

"These cutting-edge technologies allow us to look at the complex interactions between cancer cells and immune cells. Genetic analysis will be used to look for association between host genetics and the response to trastuzumab and the immune composition within the tumor," Dr. Gibson said.

The project number for this National Cancer Institute of the National Institutes of Health P20 award is CA290450.

Originally published at Today@Wayne.

"Our hypothesis is that genetic ancestry influences whether the patient induces an anti-tumor immune response after trastuzumab, which then affects therapeutic efficacy."

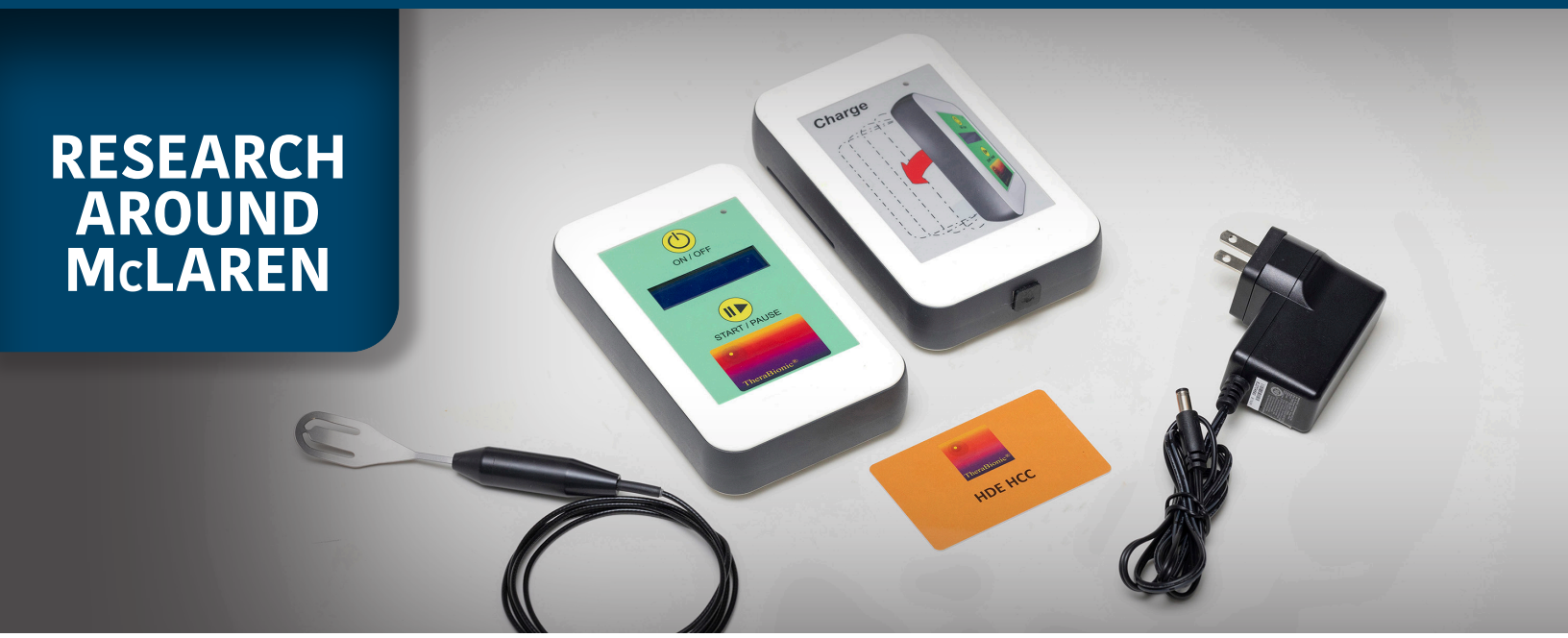
– Heather Gibson, PhD

KARMANOS PSYCHOLOGIST PRESENTS IN THAILAND

MUSIC REDUCING STRESS DURING CHEMOTHERAPY

Felicity Harper, PhD, clinical psychologist, member of the Supportive Oncology Multidisciplinary Team, associate center director of Population Sciences, member of the Population Studies and Disparities Research (PSDR) Program at Karmanos and associate professor of Oncology at Wayne State University School of Medicine, presented at the 2nd World Conference on Cancer and Breast Cancer in Bangkok, Thailand in November 2024. Dr. Harper's presentation was regarding the music medicine study published in JCO Oncology Practice in 2023, titled "Using Music as a Tool for Distress Reduction During Cancer Chemotherapy Treatment," of which she is the lead author. The study found that patients who listened to music while undergoing chemotherapy experienced significant benefits to their mood and level of distress during treatment.

RESEARCH AROUND McLAREN



IN TREATMENT OF ADVANCED LIVER CANCER

KARMANOS CANCER INSTITUTE PHYSICIANS BEGIN PRESCRIBING NEW FDA-APPROVED RADIOFREQUENCY ELECTROMAGNETIC DEVICE

Karmanos is the first in the world with access to this innovative treatment that uses radiofrequencies to target and shrink cancerous tumors

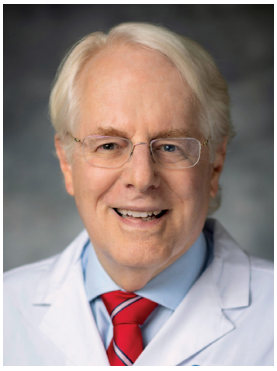
The new TheraBionic P1 device, an FDA-approved, at-home treatment, is now available to treat advanced liver cancer. Karmanos Cancer Center is the first institution worldwide to prescribe this treatment.

The TheraBionic P1 device is a novel, handheld, portable device that produces low levels of 27.12 MHz radiofrequency electromagnetic fields, which are amplitude-modulated at tumor-specific frequencies. The device is coupled with a spoon-shaped antenna placed on the patient's tongue during treatment administered in three one-hour sessions daily, delivering low levels of radiofrequency electromagnetic fields throughout the patient's body. The electromagnetic fields block the growth of tumor cells without affecting healthy tissue.

The P1 device was FDA-approved in September 2023 for the treatment of advanced hepatocellular carcinoma (HCC), the most common type of liver cancer. Patients 18 years of age or older who have failed first- and second-line therapy are eligible for this treatment. The TheraBionic P1 device is the first FDA-approved systemic therapy using radiofrequency electromagnetic fields to treat cancer.

"This new treatment offers additional hope, extended life, and minimal side effects to patients with incurable cancer," said Boris Pasche, MD, PhD, FACP, president and CEO of Karmanos, chair of the Department of Oncology at Wayne State University, and co-inventor of the TheraBionic P1 device. "Having this treatment finally come to market makes a meaningful difference in how we treat this disease and help our patients continue their lives."

Boris Pasche, MD, PhD, FACP



Anthony Shields, MD, PhD

Dr. Pasche is a renowned medical oncologist specializing in treating gastrointestinal malignancies and hereditary cancer. His research focuses on cancer susceptibility and new therapies.

With the TheraBionic P1 device, liver cancer frequencies are recognized by receptors on the liver cancer cells, transforming these frequency signals into growth arrest, making them solely effective in treating liver cancer. However, these same frequencies would not

work for breast cancer tumors, and the reverse is also true. The radiofrequency levels delivered during treatment are lower than those generated by cellular phones when held close to the body.

HCC accounts for approximately 90% of all liver cancers, with average survival rates between 6 and 20 months. Patients with advanced hepatocellular carcinoma who fail first- and second-line therapies often have severely impaired liver function, with many patients needing to enter hospice care, so additional treatment options were previously limited or nonexistent. Multiple studies over two decades have shown using the TheraBionic P1 device resulted in tumor shrinkage, blocked new cancer cell growth, and increased overall survival rates. According to TheraBionic, Inc., patients undergoing treatment in these studies did not experience debilitating side effects associated with other cancer-fighting therapies, including loss of appetite, diarrhea, and irritation of the palms and soles.

A Patient and Caregiver's Experience

Robert Perrier's case highlights the benefits of TheraBionic P1 therapy in treating HCC. Diagnosed in January 2011, he experienced recurrence after surgery and subsequent failed treatments. Perrier began using the P1 device in September 2011 alongside oral chemotherapy, which his physician discontinued two years later due to side effects. From then until he died in 2017, he only received treatments from the P1 device, living nearly six years post-diagnosis. He passed away from kidney failure after declining dialysis following complications from a hip fracture.

His wife attributes her husband's additional years to using the device. "…the TheraBionic device has provided my husband several additional years of life," said Eveline Perrier. "I hope that other patients will be able to benefit from the device in the future."

"I often think about my patients in the past who would have benefited in having more time with their loved ones if this device was available, which is why I am excited we can prescribe it to patients," said Anthony Shields, MD, PhD, medical oncologist and member of the Gastrointestinal and Neuroendocrine Oncology Multidisciplinary Team (MDT), and associate center director for Clinical Science and Community Oncology at Karmanos. "As oncologists who treat gastrointestinal cancers, we often face some of the most incurable diseases. Our team is excited to be able to offer our patients another option in the fight, which is why patients come to Karmanos."

Wasif Saif, MD, MBBS

Najeeb Al Hallak, MD, MS

Along with Dr. Shields, additional prescribing physicians are medical oncologists and co-leaders of the Gastrointestinal and Neuroendocrine Oncology MDT, Wasif Saif, MD, MBBS, and Najeeb Al Hallak, MD, MS.

Additional information on the TheraBionic P1 device can be found at **karmanos.org/therabionic**.

EQuIP CORNER

DOES MY PROJECT REQUIRE AN IRB REVIEW?

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

The Institutional Review Board (IRB) serves an important role in the protection of the rights and welfare of human research subjects. Federal regulations require that the IRB review and monitor research projects involving human subjects. The corporate McLaren IRB is the only entity in the McLaren Health Care system that serves to oversee human subject research.

Susmita Jain, MS

Before undertaking a research project, the question researchers must be certain of "Is my project human subject research or a quality improvement project?". Making this determination can be straightforward if the project involves investigational drugs or devices not yet approved by the FDA. However, if not the determination can be confusing because human subjects research and quality projects share similar characteristics.

It is mandated by the McLaren Human Subject Research Protection Policy MHC_RP0104 "that investigators or researchers cannot make the determination if their research activity is not human subject research. Only the MHC IRB can make this determination". To obtain this determination, the researcher must complete and submit to the MHC IRB the "Request for Determination of Non-Human Subject Research" application in the IRB electronic system, called iRIS.

Why is it important for the IRB to make the determination?

To determine if a project is human subject research, the project must separately meet both the federal definition of "human subject" and "research." The MHC IRB adheres strictly to the federal definitions in determining if a project is "human subject research" or "not human subject research."

Note: Projects that involve activities covered under Food and Drug Administration (FDA) regulations involving human subjects require submission to the IRB.

Regulatory overview in defining human subject research:

1. **Step One: Is it Research?**

   The Federal Policy for the Protection of Human Subjects (Common Rule) defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..."

   What is systematic investigation?

   A Systematic Investigation follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

   - Collection of quantitative or qualitative data.
   - Collection of data using surveys, testing or

evaluation procedures, or interviews.
- Collection of data using experimental designs such as clinical trials.
- Observation of individual or group behavior.

What is generalizable knowledge?

Contribution to generalizable knowledge means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of the following:

- Data presentation at conferences, meetings, or seminars etc.
- Knowledge contributes to an already established body of knowledge.
- Other investigators, scholars and practitioners may benefit from this knowledge.
- Publications including journals, papers, dissertations etc.

2. Step Two: Does it involve human subjects?

The Federal Policy for the Protection of Human Subjects (Common Rule) defines human subjects as "…a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Data about living individuals through intervention or interaction:

"About whom" is key: Consider if the project focuses on the person or policies, practices, or procedures about which the person is knowledgeable. Projects that collect information about policies, practices, or procedures – even if the person who provided that information is identified – do not constitute human subject research.

Intervention includes both physical procedures through which information or biospecimens are collected (e.g., venipuncture) and manipulations of the subject or the subject's environment (e.g., exercise, noise levels).

Interaction includes communication or interpersonal contact between the investigator (or research team) and the living individual. Examples include interviews, questionnaires, or surveys.

Identifiable private information about living individuals:

Identifiable means 1) the identity of the individual from whom the information or biospecimens was obtained may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information or biospecimens was obtained may be readily associated with the data or specimen.

Private Information is information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be

CONTINUED ON PAGE 16

It is mandated by the McLaren Human Subject Research Protection Policy MHC_RP0104 "that investigators or researchers cannot make the determination if their research activity is not human subject research. Only the MHC IRB can make this determination".

EQuIP CORNER

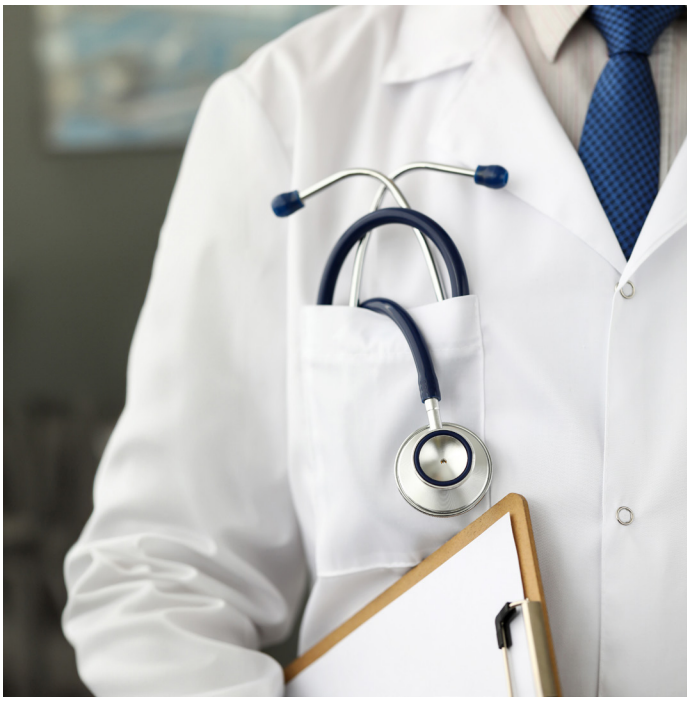
DOES MY PROJECT REQUIRE AN IRB REVIEW

CONTINUED FROM PAGE 15

made public (e.g., medical record, employee, or student records).

Examples of identifiable, private information include the subject's name, address, phone number, social security number, medical record number, student, or employee identification number, or in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age and gender may not individually identify a subject, but when combined, could in certain cases, identify a specific individual.

What is NOT considered identifiable, private information: If the information cannot be linked to a living individual or is considered public (e.g. census data) or is given with the expectation that it will be made public and that it will be linked to the individual (e.g. biography or news story), then it would not be considered private identifiable information. For example, use of a publicly available data set that does not contain identifiers or codes linked to individuals does not involve human subject's research. However, use of a publicly available data set that does contain identifiers or codes linked to individuals does involve human subject research.



Examples of Projects That Are Not Human Subjects Research:

1. The 2018 revision to the Common Rule clarified that the following categories are not human subject's research:
   - Public health surveillance activities
   - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
   - Authorized operational activities (as determined by each federal agency) in support of intelligence, homeland security, defense, or other national security missions.
   - Scholarly and journalistic activities – such as biography, oral history, journalism, and historical scholarship
2. Course-related activities including instruction in research methodologies and techniques for educational or teaching purposes but not intended for use outside the classroom do not require review.
3. Service surveys issued or completed by College personnel for the intent and purposes of improving College services/programs or for developing new services or programs for students, employees, or alumni, may not meet the definition of human subject research as long as the privacy of the subjects is protected, the confidentiality of individual responses is maintained, and survey participation is voluntary.
4. Information-gathering interviews with questions that focus on things, products, or policies rather than people or their thoughts about themselves may not meet the definition of human subject's research.
5. Research involving publicly available data such as census data or labor statistics
6. Secondary use of coded private information or biological specimens that were not collected for the currently proposed project provided the investigator cannot link the coded data/specimens back to individual subjects.
7. Research involving cadavers, autopsy material or biospecimens from now deceased individuals.
8. Quality improvement/quality assurance projects designed to improve the performance of any practice

in relation to an established standard or to determine if aspects of any practice are in line with established standards.

9. Case history or case studies which are published and/or presented at conferences are not considered research if the case is limited to a description of clinical features and/or outcomes of few subjects that do not contribute to generalizable knowledge.

Still unsure?

Please contact us at **hrpp@mclaren.org**.

REFERENCES:

1. *MHC_RP0104 Determination of Human Subject Research*
2. *https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1*

HUMANITARIAN USE DEVICE (HUD) TRAINING REQUIREMENTS

Effective February 28, 2025, physicians and designated personnel listed on Humanitarian Use Device (HUD) IRB applications must complete the HUD Training Course within CITI Program.

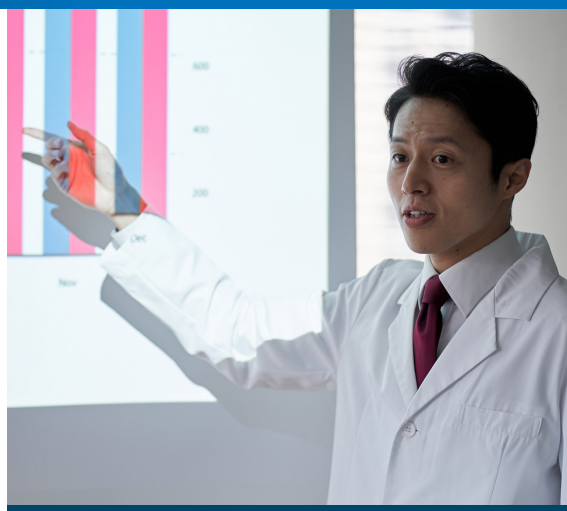
Physicians who are listed as personnel on a HUD application, but are not engaged in any research studies must complete the stand-alone HUD course within CITI. HUD training certification is valid for 3 years and renewal is required.

Below are instructions on how access HUD training in CITI. If you have any questions, please email us at hrpp@mclaren.org.

How to add the Humanitarian Use Device course to your CITI course list at citiprogram.org

1. Under the Courses Page, select the Add a Course in the learner tools section to add a course or change your current selection.
2. After selecting Add a Course, you will be redirected to answer course enrollment questions.
3. Check the box Humanitarian Use Devices (HUD).
4. Scroll down past Question 4 and click on Submit.
5. You are now enrolled in the HUD course(s) you selected.
6. Under the Courses Page, scroll down to the section titled, “Courses Ready to Begin.”

Find the HUD course and click Start Now.



UPCOMING RESEARCH EDUCATION

MHC Research Integrity Brown Bag session
Cultural Humility and its Utilization in Clinical Research
March 06, 2025
12:00 pm - 1:00 pm

Speaker:
Jessica Fritter, DHSc, MACPR, ACRP-CP and **Bashar Shihabuddin, MD, MS**

To register, contact:
susmita.jain@mclaren.org

2025 ACRP – GEAUX Beyond
Hyatt Regency. New Orleans
April 24 - 27, 2025

To register follow the link:
https://acrpnet.org/event/acrp-2025

2025 AAHRPP Annual Conference
HRPP Dedication, Dialogue, and Discovery in Denver
Grand Hyatt. Denver
May 20 - 22, 2025

To register follow the link:
https://www.aahrpp.org/education-news-and-events/annual-conference

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

MULTIPLE RESIDENTS IN SCHOLARLY ACTIVITY PROJECTS

By Carlos F. Rios-Bedoya, ScD, MPH

Carlos F. Rios-Bedoya, ScD

The MHC GME resident's graduation requirements include the completion of at least one research or quality improvement (QI) project. Scholarly activity, whether research or QI, should be a multidisciplinary endeavor that promotes collaboration and participation from different disciplines. However, the underlying principle for this type of approach is one where every participant significantly contributes to one or more areas of the scholarly activity project. These areas usually include the conception of the idea, the design of the study, the project approval processes (e.g., IRB or SARC approval), the data collection process, the analysis, and the manuscript preparation, just to mention a few. The effort of each resident in the projects should be similar, avoiding that just one resident takes the burden of the project while others do not contribute significantly. To prevent this unacceptable, unfair, and unprofessional behavior in our residency training programs, we are developing clear and specific guidelines for the approval of scholarly activity projects where multiple residents participate. We want to guarantee equal effort from each group member, exposure to all the steps of a project, and a comprehensive learning experience.

The guidelines will include a set of criteria and a justification for the need to include multiple residents in a single scholarly activity project will be required. The specific contribution of each resident participating should be stated, and a mechanism to determine the magnitude of the contribution from each resident should also be established and described. We will request feedback from program directors, residents, assistant DIOs, and research advisors (i.e., PhDs) before approving and implementing the guidelines.

We like to promote and create an environment where scholarly activity projects are a positive and valuable residency training experience for everyone. For most residents, this might be the first and probably only hands-on scholarly activity involvement. It should be one that provides them with a real-life example of how much planning, collaboration, and effort is required. Thus, when reading and appraising the medical literature, they will have a good understanding of everything that needs to happen before publishing a manuscript. 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**.

SAVE THE DATE

2ND ANNUAL

McLAREN SCHOLARLY INQUIRY FORUM

April 23, 2025

Somerset Inn | 2601 W. Big Beaver Road | Troy, MI 48084

Join us for an event highlighting research conducted within McLaren Health Care.

Agenda to include a keynote speaker, oral presentations, poster viewing, and award ceremony. Additional information to follow.

McLaren

ANNOUNCEMENTS AND WHAT'S NEW

The McLaren Center for Research and Innovation (MCRI) is pleased to announce Sara Vernon, Clinical Research Coordinator has joined the team at McLaren Bay Region. Sara has 13 years of healthcare experience starting as a phlebotomist in 2011 and completing her Medical Assistant Certificate from Career Quest in 2020. Sara is also working towards her bachelor's degree from U of M Flint. She is excited for the new role and is looking forward to working with the team.

Sara Vernon

Office of Clinical Excellence

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