RESEARCH *Matters*

Spring 2025

IN THIS ISSUE...

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

McLaren

RESEARCH AROUND McLAREN

McLAREN EXPANDS RESEARCH TO WOMEN'S HEALTH

McLaren Center for Research and Innovation is pleased to announce a collaboration between Dr. Brian Tesler, Chief Medical Director of Women's Health at McLaren Healthcare, and Dr. Sonia Hassan the founding director of Wayne State University's Office of Women's Health. The Synergy of Scholars for Maternal and Infant Health Equity (SOS MATERNITY) Network, coordinated by the Office of Women's Health (OWH) at Wayne State University, is pioneering the coalition of 14 institutions across Michigan dedicated to improving maternal and infant health outcomes. McLaren is delighted to be one of those collaborating institutions and plans to roll out the program in Flint beginning in Spring of 2025. This research-based project is funded by the Michigan Department of Health and Human Services.

Dr. Tesler is spearheading McLaren's collaboration with The SOS Maternity Network. This program includes 4 key components:

- Medical Interventions: evidence-based practices within clinical settings, such as screening to detect early signs of health conditions impacting women and their babies.
- Structural Interventions: beyond clinical care, it will address social determinants of health through providing complementary transportation to all medical appointments.
- Comprehensive Support: Each site features a Research Coordinator who enrolls the participants, records data, and connects patients to local resources.
- Collaborative Approach: SOS Maternity is partnering closely with regional organizations like McLaren to leverage expertise and community relationships.

The SOS Maternity Network was developed as a response to poor outcomes. In November of 2023, the March of Dimes graded Michigan a D+ for efforts to safeguard the health of pregnant women and babies.

The SOS Maternity Network was developed as a response to poor outcomes. In November of 2023, the March of Dimes graded Michigan a D+ for efforts to safeguard the health of pregnant women and babies. The Michigan preterm birth rate was 10.4% in 2023, significantly higher than any other developed nation. Additionally, the infant mortality rate in Michigan stood at 6.2 per 1,000 live births, also substantially above the national average. The SOS Maternity Network aims to dramatically reduce premature births and help treat or prevent pre-eclampsia and high blood pressure; thereby

Brian Tessler, MD

combating maternal and infant mortality. The vision in participation is for all McLaren Flint pregnant patients to all be enrolled in this program since the Genesee County infant mortality rate is higher than the Michigan rate at 8.5 deaths per 1000 live births.

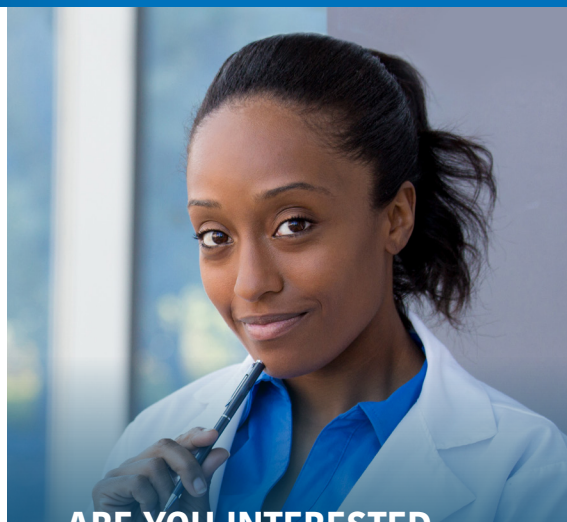
Laura Taylor

"MCRI is particularly excited about this program as Women's Health is a new therapeutic area for research at McLaren. We hope this is a springboard into future Women's Health clinical trial offerings for our patients," says Corporate Director of Research Administration and HRPP, Pamela Wills-Mertz. "Bringing clinical research opportunities to our OB/GYN patients at McLaren is an important and innovative way to grow the service line and provide our patients with exceptional care," Dr. Tesler adds. Corporate Director of Women's Health, Laura Taylor, will serve as an investigator on the SOS Maternity Network program, helping to bridge any gaps between the midwife providers and the new research program.

Please visit The Office of Women's Health - SOS MATERNITY in Michigan for more information on the SOS Maternity Network, or contact the McLaren Center for Research and Innovation at **(248) 484-4960** or email **MCRI@mclaren.org**.

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.



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

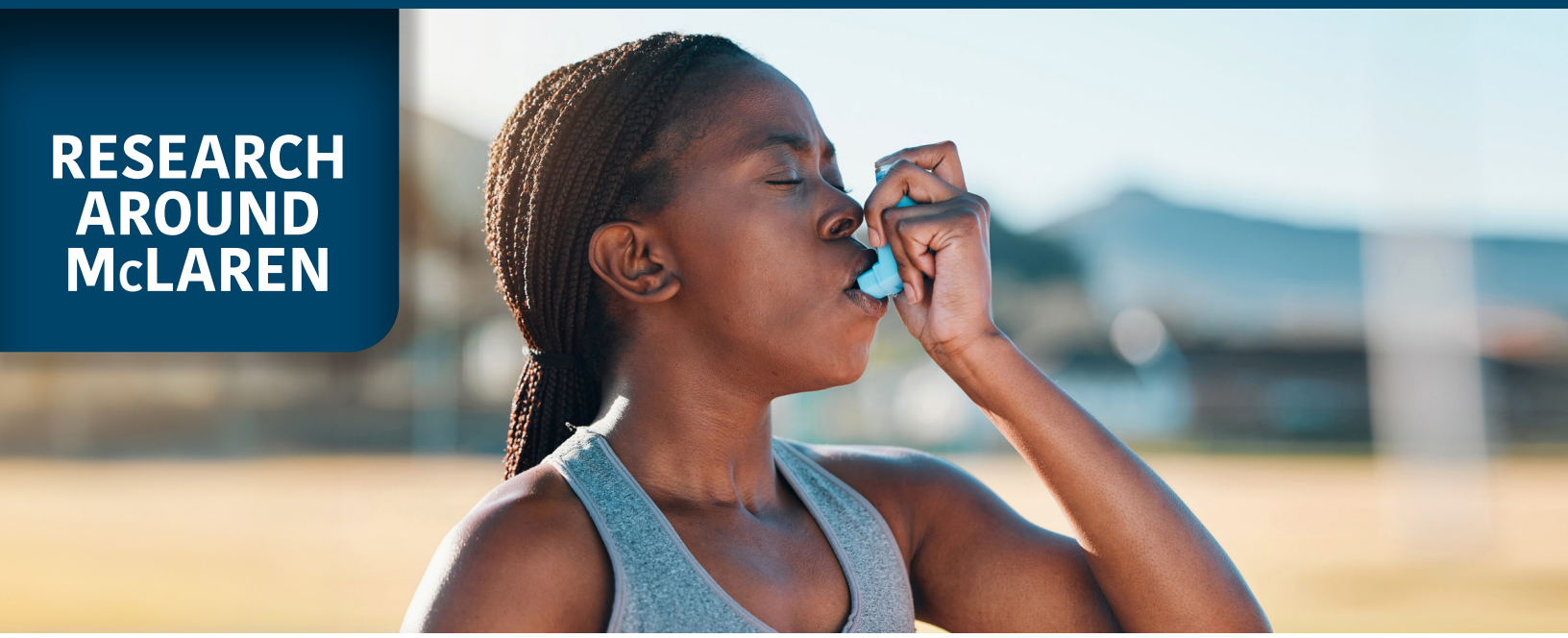
For information on enrolling in a clinical trial please visit **mclaren.org/main/clinical-research-trials**. Here you will find a list of open enrolling studies at McLaren, including which hospital the research is being done at and contact information for each study.

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.*

HAPPY CLINICAL TRIALS DAY

Celebrated internationally on May 20 of each year, Clinical Trials Day is a celebration of clinical research professionals and participants, recognizing their contributions to public health and medicine. Clinical Trials are research studies with human volunteers that are intended to add to overall medical knowledge. Behind every medication and medical intervention are thousands of patients that volunteered to participate in Clinical Trials.

McLaren Health Care would like to take this time to thank our clinical research professionals for their tireless efforts to advance medical science, as well as improving the health and well-being of our patients.

Clinical Trials at McLaren Health Care are conducted by the McLaren Center for Research & Innovation and the Karmanos Cancer Institute.

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

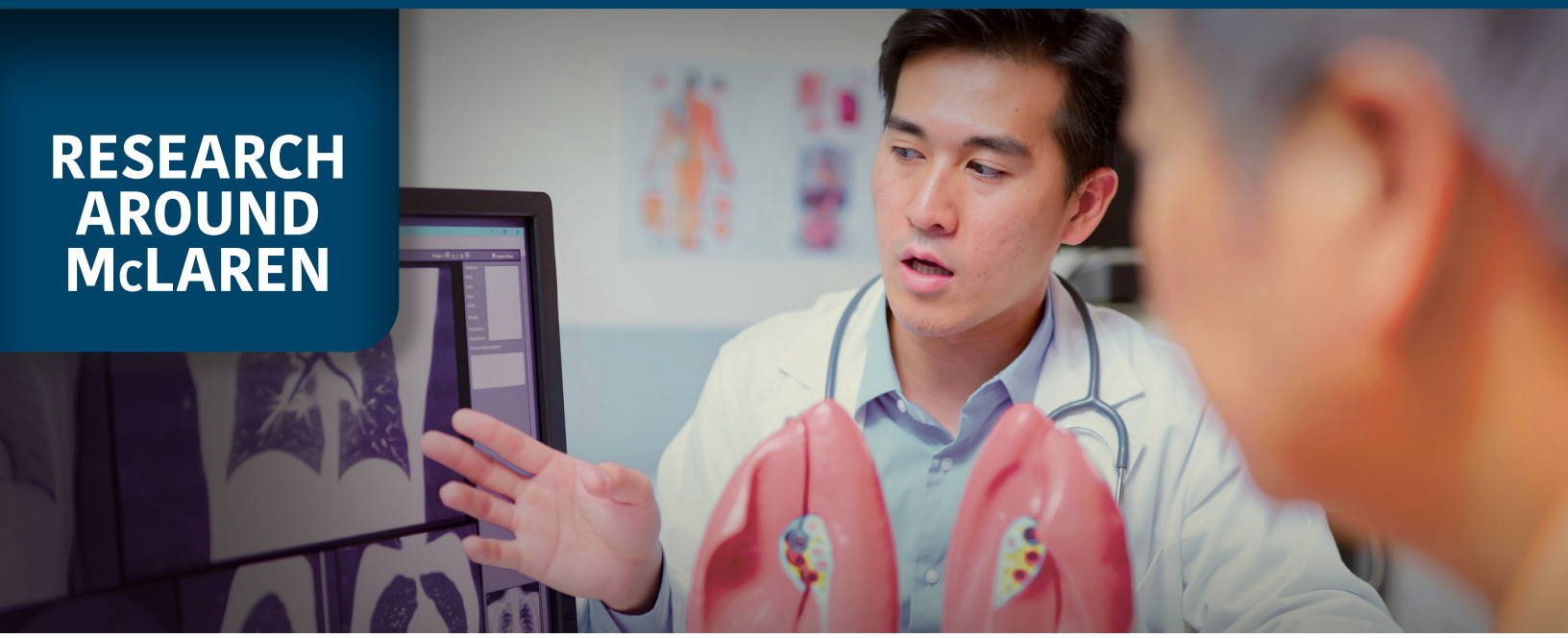
Code of Federal Regulations
ecfr.gov/current/title-21

- 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



NEW EDITORIAL SUPPORTS CONTINUED IMMUNOTHERAPY AFTER SURGERY

IMPROVING OUTCOMES FOR NON-SMALL CELL LUNG CANCER PATIENTS

An editorial argues that patients with resectable non-small cell lung cancer (NSCLC) who achieve a complete pathological response (pCR) after neoadjuvant chemoimmunotherapy should still receive adjuvant immunotherapy to increase their chances of long-term survival. Dipesh Uprety, MD, medical oncologist, member of the Thoracic Oncology and Phase I Clinical Trials Multidisciplinary Teams, and member of the Molecular Therapeutics Research Program at the Barbara Ann Karmanos Cancer Institute, was the lead author on "Adjuvant Immunotherapy Should Be Used in Patients With Non-Small Cell Carcinoma With a Pathologic Complete Response to Neoadjuvant Immunotherapy," which published in the Journal of Thoracic Oncology. The paper was published in the Controversy in Thoracic Oncology section in the January 2025 issue.

Dipesh, Uprety, MD

Dr. Uprety and his co-authors from the Mayo Clinic and Lausanne University Hospital, presented several points to back up their argument including, "recognition that achieving pCR does not necessarily equate to a cure and it is logical to promptly initiate the immunotherapy that was effective in the neoadjuvant setting to enhance the chances of a cure as there are a significant number of patients who achieve pCR that still experience disease recurrence," Dr. Uprety stated.

Evolving Treatment Strategies for NSCLC

Historically, patients with resectable NSCLC were treated with surgery followed by adjuvant chemotherapy. Neoadjuvant chemotherapy was not widely used due to concerns about its effectiveness compared to post-surgical treatment, with the potential for disease progression by delaying definitive surgery. However, recent clinical trials have demonstrated that combining chemotherapy with immunotherapy in the neoadjuvant setting significantly improves survival rates and leads to higher rates of pCR.

"However, the lack of mature data has sparked debate on whether patients who achieve a pathologic complete response should receive adjuvant immunotherapy after surgery," explained Dr. Uprety.

Why Adjuvant Immunotherapy Matters

Analysis of recent research underscores that even in cases where pCR is achieved, microscopic disease may persist undetected, leading to potential relapse. Data from landmark trials, including CheckMate 77T and KEYNOTE-671, show that patients receiving adjuvant immunotherapy after neoadjuvant treatment and surgery significantly reduces the risk of recurrence and improves the five-year overall survival rate.

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CANCER BIOLOGY GRADUATE STUDENT ADVOCATES FOR CONTINUED CANCER RESEARCH FUNDING

A fifth-year doctoral student in the Cancer Biology Graduate Program at the Wayne State University (WSU) School of Medicine and the Barbara Ann Karmanos Cancer Institute went to Washington, D.C., last month for the third time in as many years. Natalie Snider-Hoy advocated for continued funding of the National Institutes of Health (NIH) and the National Cancer Institute (NCI) as part of the American Association for Cancer Research Early-Career Hill Day.

She traveled as part of a team from Feb. 25-26 to represent WSU and the state of Michigan, serving as a group leader in meetings with Michigan members of Congress on behalf of the American Association for Cancer Research (AACR) staff.

The annual event brings early-career scientists, including doctoral candidates, post-doctoral researchers, medical residents, medical fellows, and some early-stage assistant professors, to Washington to advocate for robust, sustained, and predictable funding for cancer research and biomedical science.

In meetings with staff members of U.S. Sen. Elisa Slotkin, U.S. Sen. Gary Peters, U.S. Rep. Shri Thanedar and U.S. Rep. Debbie Dingell of Michigan, and with U.S. Sen. Rick Scott, U.S. Sen. Ashley Moody and U.S. Rep. Laurel Lee of Florida, the team asked for $51.3 billion for the foundational work of the NIH in fiscal year 2025. This includes $7.934 billion for NCI, the highest possible appropriation increase. They also advised the U.S. Congress to complete work on fiscal year 2025's spending bills as quickly as possible to avoid delays and disruptions caused by continuing resolutions.

It is a privilege to highlight the groundbreaking and life-saving research conducted by researchers at Wayne State University and the Karmanos Cancer Center and discuss the cutting-edge training I have received in the city of Detroit.

– Natalie Snider-Hoy
Doctoral Student,
Wayne State University School of Medicine

Snider-Hoy is a T32 trainee, an AACR associate member, and a recipient of additional career development awards from the AACR, including Scholar-in-Training awards to present her research. She is a molecular epidemiologist-in-training, mentored by Kristen Purrington, Ph.D., MPH, member of the Population Studies and Disparities Research Program at Karmanos and associate professor of Oncology. Snider-Hoy plans to pursue a career in science policy and regulatory science upon graduation.

"It is an honor to represent Wayne State at the federal level. Wayne State has been my home for many years, from undergrad to now near the end of my Ph.D., and has shaped me into the scientist I am today," she said. "It is a privilege to highlight the groundbreaking and life-saving research conducted by researchers at Wayne State University and the Karmanos Cancer Center and discuss the cutting-edge training I have received in the city of Detroit. Congress members are always very impressed with the work we do and take great pride in the research institutions in their home state. I feel that by highlighting our progress, this instills in them confidence that funding the NIH and NCI provides both immediate and long-term returns on biomedical

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RESEARCH AROUND McLAREN

KARMANOS, WSU LANDS ON TOP 10 LIST FOR NRG ONCOLOGY TRIALS

NRG Oncology has named the Barbara Ann Karmanos Cancer Institute and Wayne State University among the "Top 10 Accruing Lead Academic Participating Sites" for oncology trials. In January, the organization announced the leading sites at its annual Winter Meeting in Phoenix, Arizona.

Being acknowledged on this list means that Karmanos enrolled a high number of participants in therapeutic clinical trials between Jan. 1 and Dec. 31, 2024. The clinical trials are National Clinical Trial Network (NCTN) and National Cancer Institute Community Oncology Research Program (NCORP) trials credited to NRG Oncology.

Michael Dominello, DO

"Being on the forefront of establishing new ways to treat our patients more safely and effectively through clinical trials has the potential to directly impact quality of life and cancer outcomes," said Michael Dominello, DO, radiation oncologist, leader of the Neuro-Oncology Multidisciplinary Team (MDT), member of the Breast Cancer MDT, and principal investigator at Karmanos as an NRG Lead Academic Participation Site. "Making these trials available at Karmanos gives our patients therapy options not offered at non-NRG participating sites.

> **Being on the forefront of establishing new ways to treat our patients more safely and effectively through clinical trials has the potential to directly impact quality of life and cancer outcomes.**
>
> *– Michael Dominello, DO*
> *Radiation Oncologist*

With the collective data from national and international accrual on these studies, we will better understand how new treatment strategies may provide improvement over current standard-of-care options."

To maintain their status, Lead Academic Participation Sites must meet rigorous requirements, such as providing timely high-quality data on trial performance, meeting enrollment requirements in either NCTN or NRG Oncology foundation trials, and receiving and maintaining data from NRG affiliate members.

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve cancer patients' lives.

CANCER BIOLOGY GRADUATE STUDENT ADVOCATES FOR CONTINUED CANCER RESEARCH FUNDING

CONTINUED FROM PAGE 7

innovations and the next generation of scientists to continue this work."

Although Snider-Hoy has attended the advocacy day in the past, during AACR's 10th annual Early Career Hill Day, she said it was mentioned during training this year's visit is likely the most important one yet.

"The Hill was much busier than my last two trips with AACR in 2023 and 2024. Not only do we have a new president, but we also have plenty of new Congress members settling into their positions," Snider-Hoy explained. "Many groups, not just biomedical research advocates, are visiting the Hill to discuss the issues they feel are important and hoping to make relationships with these new Congress members to help promote their causes and find new allies. The weeks before the budget is set are always very busy and there is a sense of urgency among everyone visiting the Hill. This is the most important time of year to advocate for funding, as items are actively being allocated. We must be persistent to ensure that our funding needs are met for the NIH. While biomedical research funding (especially cancer research funding) always has bipartisan support, Congress members often do not fully understand its impacts and implications. Therefore, we had much to talk about in our congressional meetings."

Originally published at Today@Wayne.

NEW EDITORIAL SUPPORTS CONTINUED IMMUNOTHERAPY AFTER SURGERY

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Furthermore, the comparison between perioperative and neoadjuvant-only strategies has demonstrated a nearly 40% reduction in disease recurrence or death compared to neoadjuvant treatment alone.

Future Implications

This editorial provides compelling evidence for the continued use of immunotherapy in NSCLC patients who achieve a strong response to neoadjuvant treatment. Further research is needed to identify the specific patient populations that will derive the greatest benefit from this approach. According to Dr. Uprety, authors hope that more mature data regarding pCR patients will provide further insight into this topic.

UPCOMING SYMPOSIUMS

Molecular Therapeutics Annual Research Symposium 2025
May 16, 2025
9:00 am - 4:00 pm
For more information and registration:
https://waynestate.az1.qualtrics.com/jfe/form/SV_9o7yLuBqTEbXFSCg

Lymphoma Symposium
August 2, 2025
8:00 am - 2:00 pm
To sign up and receive registration information:
karmanos.org/lymphomasymposium

Lung Cancer Symposium
September 27, 2025
8:00 am - 2:00 pm
To sign up and receive registration information:
karmanos.org/lungsymposium

Gastrointestinal Oncology Symposium
October 18, 2025
8:00 am - 2:00 pm
To sign up and receive registration information:
karmanos.org/gastrointestinalsymposium

Head and Neck Symposium
November 8, 2025
8:00 am - 2:00 pm
To sign up and receive registration information:
karmanos.org/headandnecksymposium

RESEARCH AROUND McLAREN

Dr. Wei, 2024-25 president of TRCCC, raises her gavel to officially begin the conference.

KARMANOS HOSTS THE 2025 MEETING OF THE TRANSLATIONAL RESEARCH CANCER CENTERS CONSORTIUM

Karmanos Cancer Institute had the pleasure of hosting the 2025 meeting of the Translational Research Cancer Centers Consortium (TRCCC) from Feb. 19-21, 2025, at the Seven Springs Ski Resort in Seven Springs, Pennsylvania. The TRCCC annual meeting brought together 13 cancer research institutions, including 10 National Cancer Institute-Designated Comprehensive Cancer Centers, to review and elevate research and clinical achievements in "The New Era of Cancer Immunotherapy." This year's meeting was led by Wei-Zen Wei, PhD, professor at the Wayne State University (WSU) School of Medicine, and Heather Gibson, PhD, assistant professor at the WSU School of Medicine. Drs. Wei and Gibson are also members of the Tumor Biology and Microenvironment Research Program at Karmanos. Boris Pasche, MD, PhD, FACP, president and CEO of the Barbara Ann Karmanos Cancer Institute, also gave a special introduction. Ben Herring, director of Research Administration, Jayne Bissonnette, grant development coordinator, and Lezina Topciu, research assistant from the Research Administration office at Karmanos, were in attendance and provided their support.

Karmanos is not only a leader and innovator in Michigan but also provides leadership well beyond to drive collaborations among cancer centers across the U.S. and Canada.

Originating in 1998, the TRCCC has grown in annual meeting attendance, affiliated cancer centers, and covers a breadth of research topics. Now a 501(c)(3) not-for-profit organization, the primary goal of TRCCC is to disseminate and advance research in tumor immunology and immunotherapy by fostering collaborative efforts and trainee development in a nourishing environment. Participation by cancer advocates is one of the most celebrated portions of the agenda. Over 200 trainees, post-docs, and junior faculty delivered presentations during breakout sessions at this year's meeting to continue the mission of developing new cancer immunology researchers.

Dr. Gibson enjoys the camaraderie with students and colleagues at the conference.

The featured presentations from five prominent tumor immunology researchers were delivered to over 400 in-person attendees. Additional uplifting sessions in wellness, advocate-scientist collaborations, and a pre-meeting symposium on “Cell Therapy for Solid Tumor” rounded out this year’s exciting agenda.

The response from attendees at this year’s meeting has been overwhelming. Thank you notes from the participants continue to pour in. Karmanos is not only a leader and innovator in Michigan but also provides leadership well beyond to drive collaborations among cancer centers across the U.S. and Canada. Plans are underway for next year’s meeting, which the Case Comprehensive Cancer Center will host.

Dr. Pasche welcomes attendees on behalf of Karmanos, the hosting institution for the 2025 TRCCC meeting.

Pictured left to right: Wei-Zen Wei, PhD; Jayne Bissonette, MPH; Heather Gibson, PhD; Lezina Topciu; and Ben Herring, MA

The featured presentations from five prominent tumor immunology researchers were delivered to over 400 in-person attendees. Additional uplifting sessions in wellness, advocate-scientist collaborations, and a pre-meeting symposium on “Cell Therapy for Solid Tumor” rounded out this year’s exciting agenda.

EQuIP CORNER

ABOUT THE RESEARCH COMPLIANCE PROGRAM

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

What is Research Compliance?

Research Compliance is a systematic approach to ensuring research meets predefined standards and regulatory requirements for maintaining research integrity and credibility.

This process:

- Ensures the reliability and credibility of our data and research publications.
- Protects the rights and safety of research participants
- Maintains public trust in the scientific process
- Ensures continued federal and industry funding for clinical research.
- Reduces liability.
- Demonstrates to regulatory agencies (FDA, OHRP, NIH, DOD, etc.) that McLaren Health Care (MHC) takes compliance seriously.

McLaren Health Care has created an Education and Quality Improvement Program (EQuIP). This program:

- Performs routine random QA/QI reviews to assess and monitor research compliance of human subject research regardless of funding sources.
- Conducts for-cause audits (directed) as necessary to ensure the protection of research subjects and integrity of the data.
- Educates the research community about policies, regulations and best practices in clinical research.

During QA/QI reviews, when deficiencies or non-compliances is discovered, it can lead to suspension or even termination of the trial, and/or reporting to federal regulatory agencies. In addition, investigators who are not compliant with regulations and McLaren clinical research policies and procedures may not be able to submit new protocols or renew current projects until all concerns have been addressed.

Susmita Jain, MS

This article will spotlight the most common deficiencies encountered during routine clinical research reviews conducted at MHC.

Most common deficiencies found during QA/QI review:

- Altering an IRB approved process or documents without prior IRB approval.
- Failure to follow the IRB approved study protocol.
- Inadequate documentation, incomplete or inaccurate data and record-keeping.
- Obtaining informed consent from participants using invalid consent forms.
- Lack of PI oversight of activities involving human research subjects.
- Initiating changes to the research protocol without prior IRB approval.

- Failing to have appropriate MHC required CITI training or lapse in training.
- Collecting research subject's PHI data elements without IRB approval.
- Lack of proper training for staff involved in the study.

The following are some of the process improvements to overcome these deficiencies:

- Develop clear, detailed SOPs for all research processes and procedures, which are followed carefully.
- Diligently document every aspect of the research. This includes signing and dating of informed consent forms by participants, capturing complete records of study activities, documenting all communications, noting every decision, and detailing any changes made during the study period.
- Provide justification for any deviations from the initial study plan. Using standardized forms and digital platforms can aid in uniform documentation.
- When changes to the protocol are inevitable, they should be pursued with the necessary regulatory approvals and must be comprehensively documented.
- Ensure that research staff members have been provided comprehensive initial and ongoing training.
- Maintain detailed and up to date training records and competency assessments.
- Foster a compliance culture within your study team or study site.
- Implement version control and regular review of the research documents.
- Understand and adhere to the complex regulatory landscape. This is crucial for effective QA compliance in research. Utilize resources and guidance from sponsors, CROs, and regulatory agencies, staying informed about Good Clinical Practice (GCP), and other relevant standards, through subscriptions from regulatory bodies or joining clinical research forums, can also be helpful.
- Establish clear and regular communication with study team members by holding routine meetings to review study status and progress and ensure accessibility and understanding among all team members.
- Clearly delegate tasks, ensuring that study staff are adequately trained, and their authority is documented.
- A protocol deviation log should be maintained, and the PI should review and sign it regularly, especially if there are major deviations.
- The PI should attend the site initiation visit and be available for monitoring visits.
- The PI should be actively engaged with study subjects and ensure their rights, safety, and welfare are protected.
- The PI should ensure that all staff participating in the conduct of the study, including new staff, have adequate training on the protocol, CITI, GCP, and applicable regulatory requirements.

When non-compliance occurs:

- Notify the study PI.
- Notify the study sponsor, if applicable.

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A research compliance system is a necessary component in conducting successful clinical research. It requires a structured approach, involving clear procedures, well-trained personnel, and continuous monitoring and improvement.

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

WRITING AN ABSTRACT

By Carlos F. Rios-Bedoya, ScD, MPH

Carlos F. Rios-Bedoya, ScD

During the call for abstracts for the 2nd Annual McLaren Scholarly Inquiry Forum and their corresponding review, much variability in abstract format and quality was observed even though detailed instructions were provided. Since the Forum is an intramural event but also a teaching opportunity, it was decided to accept all kinds of abstract submissions regardless of their format and quality. However, this is not the usual or established approach at other scientific conferences and meetings where the submission will be rejected without review just by not following the format specified in the instructions by the scientific conference or meeting.

Given our experience with the Forum and to increase the chances of abstract acceptance we want to provide some suggestions and guidance on how to write an abstract. These suggestions apply not only to conferences/meetings but also to submitting a manuscript for publication. The first and most important recommendation is Read the instructions! Scientific conferences/meetings receive hundreds if not thousands of abstracts for their call for abstracts. The easiest and first step in reviewing an abstract is to determine if it complies with the instructions. This is the first screening and easiest one for the administrative, not even scientific, reviewers to reject an abstract. For example, if the conference asks for a minimum font size of 10 or Times New Roman, that is what you must use. Otherwise, the abstract will be rejected without a scientific review. Similarly, if the instructions state a maximum of 300 words or 3000 characters, if the abstract has even 301 words or 3001 characters it will also be rejected without a scientific review. Please, pay special attention to whether the conference is establishing a maximum number of words or characters. If the latter, also verify whether spaces, commas, and periods count toward the character limit.

Second, conferences usually require a structured abstract format. The sections of an abstract include at least: Purpose/Aim, Methods, Results, and Discussion/Conclusion. The suggestion on how to distribute the limited number of words/characters is as follows: PURPOSE/AIM (10%); one or at most two sentences stating the purpose or objective of your scholarly activity project. METHODS (40%); provide enough details for reviewers to assess the methodological rigor of the project and for other researchers to be able to replicate your study. Include at least the study research design, study population, how the participants were selected (inclusion and exclusion criteria, if applicable), define the main outcome and how it was assessed, any use of instruments and/or surveys/questionnaires, what other variables were measured and how, and the statistical analysis used. RESULTS (40%); provide a summary of the most important results of the study. This section will allow reviewers to determine the impact/significance of

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UPCOMING RESEARCH EDUCATION

MHC Research Integrity Brown Bag session
The Research Roller Coaster Ride!
June 5, 2025
12:00 pm - 1:00 pm

Speaker:
Evonne Lackey, BA, CCRP
Director of Oncology Research, Swedish Center for Research and Innovation

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

SOCRA
FDA Clinical Trial Requirements, Regulations, Compliance and GCP Conference
Embassy Suites by Hilton – Minneapolis Downtown
12 Sixth Street South
Minneapolis, MN 55402
June 25 - 26, 2025

To register:

ACRP
Michigan Chapter
More diverse enrollment means more attention to inclusion/exclusion language
May 21, 2025
12:00 pm - 1:00 pm

Speaker:
Teri I. Crumb MSN, RCN, CCRC
Project Manager, Pediatric Nephrology Research Consortium

To register:

ACRP
New Jersey Chapter
ICH E6(R3) unpacked: leveraging compliance to deliver quality outcomes
May 21, 2025
5:45 pm - 7:45 pm

Speaker:
Leslie Sam

To register:

ACRP
Greater Kansas City Chapter
Real World Applications of A.I. in Clinical Trials
May 22, 2025
5:30 pm - 7:30 pm

Speakers:
Kyle McAllister
Co-founder and CEO of Trially

Jody Ehrhardt
Director of Clinical Research at Iterative Health

To register:

ACRP
Streamlining Excellence
Best Practices for Developing Research Site SOPs
June 11, 2025
12:00 pm - 1:00 pm

Speaker:
Suzanne Rose, MS, PhD, CCRC, FACRP
Executive Director of Research, Stamford Hospital

To register:

ACRP
St. Louis Chapter
(2024 conference replay)
Revolutionizing informed consent through responsible use of artificial intelligence
Jul 9, 2025
6:00 pm - 7:30 pm

Speakers:
Jeri Burr, MS, RN, PED-BC, CCRC, FACRP
Program Director, University of Utah

Ann Johnson, PhD, MPH, IRB & HRP
Director, University of Utah, Institutional Review Board

John VanBuren, PhD
Associate Professor, University of Utah

To register:

ABOUT THE RESEARCH COMPLIANCE PROGRAM

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- Notify the IRB, if applicable, according to MHC IRB policies. Please note deadlines for notification.
- The study team should meet to discuss the non-compliance and any necessary CAPA.
  - Identify the problem and root causes: Investigate the reasons for any non-compliance issues.
  - Implement corrective actions: Address the immediate problems and implement measures to prevent recurrence.
  - Develop preventative actions: Create the preventative action plan and measure its effectiveness. If needed, improve or modify the plan.
  - Document all actions: Maintain detailed records of all corrective and preventive actions taken.

A self-audit in the future is a sure-fire way to assess if the CAPA worked!

CONCLUSION

A research compliance system is a necessary component in conducting successful clinical research. It requires a structured approach, involving clear procedures, well-trained personnel, and continuous monitoring and improvement. This approach ensures data integrity, maintains regulatory compliance, and fosters public trust in research outcomes.

ANNOUNCEMENTS AND WHAT'S NEW

Drita Nuculovic, RN joined Karmanos Cancer Institute Clinical Trials Office in April 2025. Drita is a Clinical Research Nurse providing clinical research support in medical oncology and radiation oncology at Karmanos Cancer Institute at McLaren Lapeer Region. Drita brings over 20 years of patient related experience with the last 4 years dedicated to outpatient radiation and medical oncology as well as clinical research. Drita obtained her Associates of Science in Nursing degree at Schoolcraft College and obtained an Oncology Patient Navigator Certification at George Washington University. Drita is excited to be able to provide clinical research opportunities to our patients and expand her knowledge in clinical research in this new role.

Jaclyn Simmons, CCRC, has joined the McLaren Center for Research and Innovation as a Senior Clinical Research Coordinator. She will support Dr. Brian Tesler's collaboration with Wayne State University on the SOS Maternity Network. Jaclyn brings over 13 years of clinical research experience and has a strong OB/GYN research background. She will be stationed primarily at McLaren Women's Health clinics in the Flint area working with local pregnant women who enroll in the SOS Maternity Network program. Jaclyn is excited to be able to provide clinical research opportunities to our patients.

WRITING AN ABSTRACT

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your study and whether your findings are worth presenting at the conference/meeting. Provide information regarding the number of participants, selected demographic characteristics of the study sample, and the findings that answer the research question/hypothesis presented in the purpose/aim section together with any statistical estimates and their respective 95% CI and/or p-values. CONCLUSION/DISCUSSION (10%); provide one or two sentences about the impact of your findings on your field and how your study helped your field move forward. Include any significant potential contribution that your findings provide to patient care, public health, or quality of health care. The percentages are suggestions and serve as guidance based on how reviewers assessed abstracts and the importance of each section. 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**.

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