RESEARCH *Matters*

SPRING 2023

IN THIS ISSUE...

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

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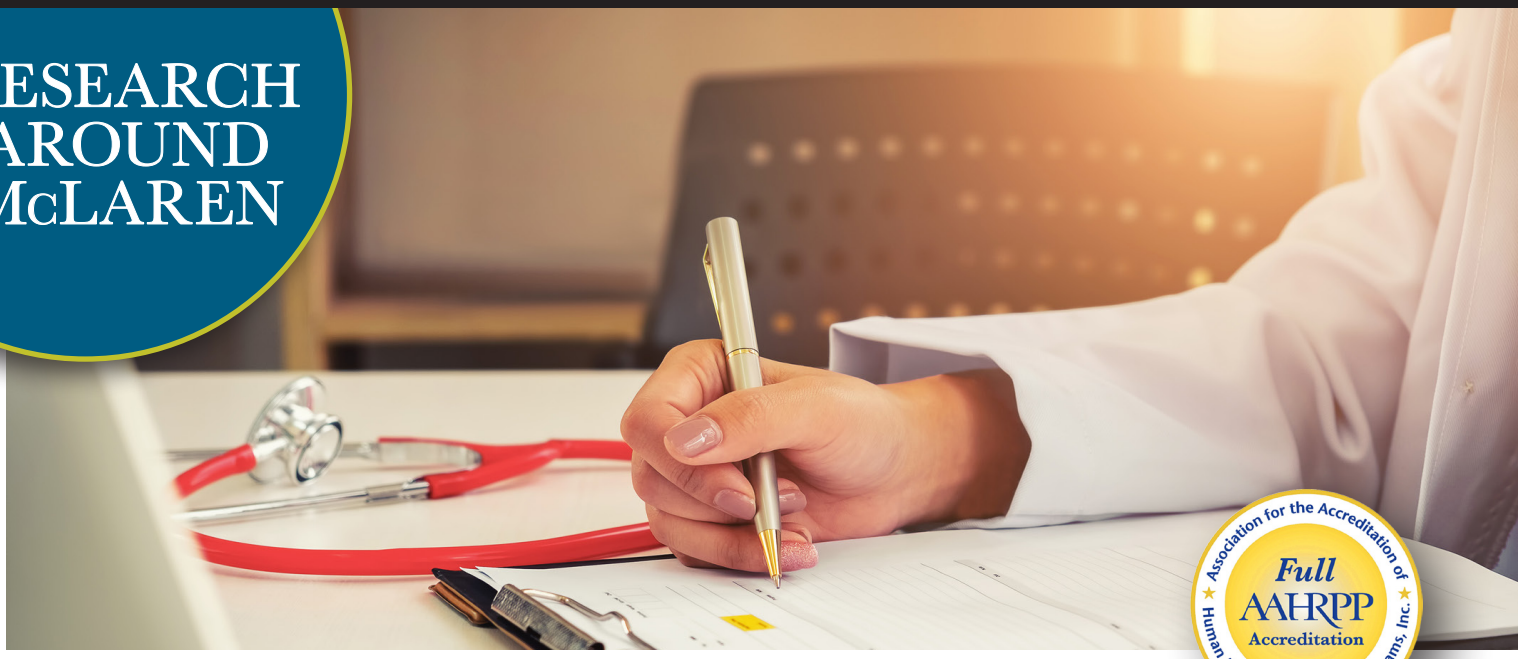
RESEARCH AROUND McLAREN



HUMAN RESEARCH PROTECTIONS PROGRAM UNDERGOES AAHRPP REACCREDITATION VISIT

What is a Human Research Protections Program?

A Human Research Protections Program or HRPP is a system of interdependent groups and individuals interacting to achieve a common aim to protect research participants in the conduct of human research. McLaren Health Care is committed to the highest standards of ethical conduct through our HRPP. The protection of human subjects participating in research is a shared responsibility of researchers and the institution. Our policies and practices ensure that we act responsibly, ethically, and in compliance with federal, state, and local regulations.

A common misconception is that an HRPP is a department, when it is actually a comprehensive program involving *everyone* participating in human research at McLaren.

What is AAHRPP?

AAHRPP (pronounced “ay-harp”), the Association for the Accreditation of Human Research Protections is an organization, founded in 2001 by seven national organizations committed to the ethical conduct of human research, whose mission is to offer a voluntary accreditation program for research institutions responsible for overseeing research involving human subjects. AAHRPP was created in response to the intense scrutiny research programs were experiencing at the time.

McLaren Health Care’s HRPP achieved full accreditation by AAHRP in 2013 and was awarded full reaccreditation in 2016. Accredited Organizations renew their accreditations three years after the initial accreditation and every five years thereafter. The MHC HRPP was due for reaccreditation in 2021, but the COVID-19 pandemic delayed this event to February of 2023.

Why are AAHRPP and their Standards Good for Research?

The accreditation process involves extensive fact-finding and self-assessment, for which AAHRPP offers guidance to promote high-quality HRPP practices. Institutions can therefore improve their practices on the road to accreditation, and through the reaccreditation process.

AAHRPP accreditation benefits research organizations, study participants, and the research process. It requires organizations to take a comprehensive look at their HRPP to identify and address any weaknesses and to build upon their strengths. The result is a more cohesive HRPP, with the systems in place not only to protect study participants but also to develop better research.

Accreditation demonstrates our ongoing commitment to the most comprehensive protections for human research participants and the highest quality and ethically sound research. It is representative of the different areas that collectively help make our HRPP successful.

As the "gold seal," AAHRPP accreditation offers assurances – to research participants, researchers, sponsors, government regulators, and the public – that a HRPP is focused first and foremost on excellence.

What did the reaccreditation process involve?

The reaccreditation process served as an opportunity to comprehensively assess process improvements, benchmarks and best practices through rigorous records review and extensive interviews with the accreditation site visitors. When examining the broad research study portfolio of an organization like McLaren, the AAHRPP site visit team considers several issues, including how the MHC interprets the accreditation standards according to the different types of research being conducted.

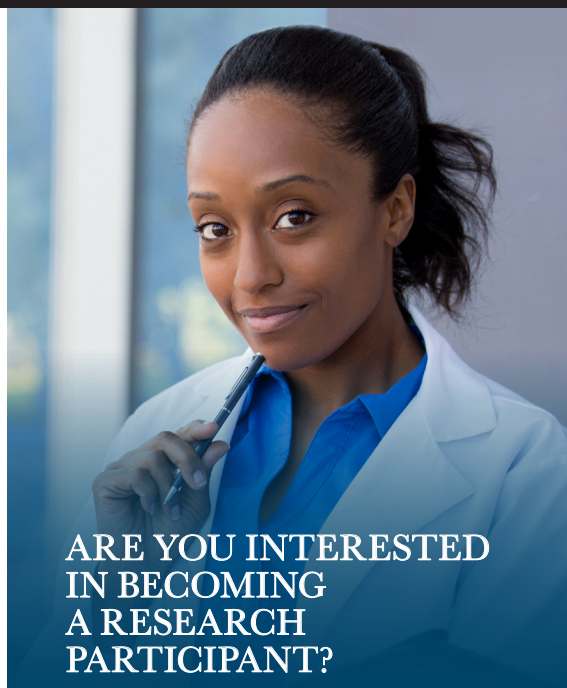
During the virtual site visit that was held February 16 and 17, 2023, representatives from AAHRPP conducted numerous interviews and record reviews to ensure that our policies and procedures had been implemented effectively and are being adhered to throughout McLaren. Investigator and research team members are an integral part of the McLaren HRPP and the reaccreditation review depended largely on interviews of many of these team members.

What was the reaccreditation visit outcome?

After an intensive two-day virtual site visit, the AAHRPP reviewers expressed a very positive view of the MHC HRPP. Teamwork and enthusiasm were common themes in their comments to institutional research leadership. We were given minimal feedback in areas in which we could make improvements. Many, if not all, of their suggestions have already been put into place. The final decision from AAHRPP will be made in June at their council meeting. MHC anticipates a full reaccreditation at that time.

Dr. Justin Klamerus, Executive VP & CMO, who serves as the Institutional Official for research at McLaren expressed his appreciation to the research community, "My sincere congratulations to the entire team for the superb re-accreditation visit with AAHRPP. The reviewers shared their comments with me about their high confidence in the professionalism, dedication, and strong commitment that all team members showed to human subject research integrity. Thank you for your great work! We look forward to their final report and our review at the June meeting of AAHRPP."

Please look for an announcement of the AAHRPP final report in the Summer 2023 *Research Matters* newsletter.



ARE YOU INTERESTED IN BECOMING A RESEARCH PARTICIPANT?

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

We have enrolling studies for the following conditions (not a complete list):

- **Diabetes**
- **Orthopedic Surgery**
- **COVID-19**
- **High Blood Pressure (Hypertension)**
- **Stroke**
- **Heart Attacks / Heart Failure / Heart Disease**
- **Kidney Diseases**
- **Lung Diseases**
- **Peripheral Artery Disease**
- **Carotid Artery Disease**
- **Mastectomy**
- **Various Cancers**
  - **Breast**
  - **Lung**
  - **Prostate**
  - **Multiple Myeloma**
- **Patients who underwent intracranial aneurysm coiling**
- **Drug study for patients with recent acute coronary syndrome**

For a complete list of conditions, please visit our website listed above.

RESEARCH AROUND McLAREN

COLLABORATIVE PARTNERSHIP WILL OFFER McLAREN INVESTIGATORS NEW AND INNOVATIVE OPPORTUNITIES

The McLaren Center for Research and Innovation has recently embarked on a collaborative relationship with Premier's PINC AI™ Applied Sciences (PAS) team. The PAS team is a trusted leader in accelerating healthcare improvement through services, real-world data, real-world evidence and scalable solutions, spanning the continuum of care and enabling sustainable innovation and rigorous research.

The PAS team utilizes standardized and connected data that spans the continuum of care to fuel evidence- and population-based analyses.

In addition, PAS technology-enabled tools and advanced analytics to identify improvement opportunities, consulting services for clinical and operational design, and workflow solutions to hardwire sustainable change.

MCRI and the PAS team are working together to accelerate research at McLaren that can help generate better answers to key questions with greater transparency, equity, operational efficiency and savings. Together the teams will continuously evolve the collaboration and look for ways to align strategically.

McLaren and the PAS team will collaborate in several ways, including:

- Jointly leveraging data, clinical input and other research to evaluate novel, new therapies and interventions for commercial development.
- Conducting prospective research on specific care pathways and other interventions using real-world data and evidence (RWD/RWE).
- Improving the quality and speed of clinical trials or research studies using artificial intelligence (AI) to identify the best possible patient candidates more rapidly.

Since 2000, PAS researchers have produced more than 864 publications which appear in 264 scholarly, peer-reviewed journals, covering a wide variety of topics, and conduct population-based analyses of drugs, devices, treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.

Some projects that McLaren and PAS will focus on include but are not limited to:

- Value-based projects related to equity and disparities.
- Quality and value improvement in primary and specialty care.
- Population health.
- Research around chronic disease

To learn more about the collaboration and clinical projects, please reach out via email to **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.

RESEARCH AROUND McLAREN

Ariel Washington, PhD

WHY AFRICAN AMERICAN PARENTS MAY DELAY OR REFUSE HPV VACCINATION FOR THEIR CHILDREN

The human papillomavirus (HPV) infection is an infection that almost everyone will contract at least once in their lifetime, according to the Centers for Disease Control and Prevention (CDC). HPV is related to many types of cancer, including cervical, vulvar, vaginal, penile, anal, throat, and oropharyngeal (mouth) cancers. With this knowledge of the virus, research has shown that African American parents refuse or delay having their children receive the HPV vaccine.

Approved for people up to age 45 by the U.S. Food and Drug Administration, the FDA currently recommends children and adults ages 9 through 26 receive the HPV vaccine. A recently published article by lead author Ariel Washington, PhD, MSSW, community outreach and engagement scientist with the Office of Cancer Health Equity and Community Engagement (OCHECE) at the Barbara Ann Karmanos Cancer Institute, aimed to explain the perspectives of African American parents in not having their child vaccinated or deferring their vaccination.

Investigators used a focus group of 20 parents who are predominately African American and have children between 11 and 17 years old. The participating parents live in Detroit, Inkster and Flint. The participants have previously decided not to give their child the HPV vaccine or have delayed vaccination for the virus.

Investigators used a model called the Vaccine Hesitancy Determinants Matrix. This model was created by the Strategic Advisory Group of Experts on Immunization (SAGE), a vaccine and immunization advisory group to the World Health Organization.

“The Vaccine Hesitancy Determinants Matrix helped us examine what factors impact vaccine decision-making,” explained Dr. Washington.

"Using deductive content analysis, the team compared what the parents discussed in the group settings with the matrix."

After analyzing qualitative data collected from the focus groups, the parents identified many reasons they delayed or denied the opportunity for their child to receive the HPV vaccine. Reasons included concerns about their child's age, discrimination and mistrust of doctors because of their race and socioeconomic status, and vaccine safety.

"One recurring theme that emerged from the parents was how they often felt unheard and unable to ask questions regarding HPV vaccination. The factors found during this study allow researchers, health practitioners and parents to understand there may be personal and influential life experiences that can play a role in vaccine decision-making," said Dr. Washington. "It is also apparent through this study that comprehensive conversations about HPV vaccination are important to have with parents. Future researchers and healthcare practitioners can use these results to tailor HPV vaccination education initiatives."

The team's study, titled "'Why is it so necessary?': African American Parents' Perspectives on Delaying and Refusing HPV Vaccination," was published in the Journal of Pediatric Health Care in February 2023.

Co-authors of this study include Jasmine Chabaan, Ali Fakih and Yang Kim, research assistants; Maida Herrera, research support manager; and Hayley Thompson, PhD, faculty supervisor of the OCHECE, associate center director for Community Outreach and Engagement at Karmanos, professor of oncology and leader of the Center for Health Equity and Community Knowledge in Urban Populations (CHECK-UP) at Wayne State University. Sabrina Ford, associate professor at Michigan State University, Lisa Rutledge, special projects manager at Western Wayne Family Health Centers, and Jametta Lilly, CEO of Detroit Parent Network, are also co-authors of this study.

RESEARCH AROUND McLAREN

Susan Eggly, PhD

STUDY LED BY KARMANOS RESEARCHER

INTERVENTION TO IMPROVE PATIENT-PHYSICIAN COMMUNICATION MAY IMPROVE BLACK PATIENT PARTICIPATION IN CLINICAL TRIALS

Clinical trials are the pathway to finding new cancer treatments to improve patient outcomes. The National Institutes of Health and other professional organizations require that studies include participants from diverse populations. Historically, Black patients have been underrepresented in clinical trials. This is especially problematic when enrolling Black men in prostate cancer clinical trial studies. Prostate cancer affects more Black men than White men.

A recently published study in Cancer Medicine titled “Addressing multilevel barriers to clinical trial participation among Black and White men with prostate cancer through the PACCT study” looks at some barriers to increasing enrollment of Black men into prostate cancer clinical trials. It also looks at ways to overcome those barriers, including a communication intervention. Susan Eggly, PhD, professor in the department of Oncology at the Wayne State University (WSU) School of Medicine and member of the Population Studies and Disparities Research (PSDR) Program at the Barbara Ann Karmanos Cancer Institute, led the study. Black and White men participated in this four-year study at Karmanos Cancer Institute in Detroit and Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland.

With help from patients who enrolled in the study, researchers examined two possible barriers to enrolling Black patients in clinical trials. The first was eligibility – many clinical trials have rigorous eligibility requirements. At the completion of the study, Dr. Eggly and her team found only a small percentage of patients were eligible for a clinical trial. Researchers also found that patients with higher incomes were more likely to qualify for a

clinical trial than patients with lower incomes.

The second possible barrier was patient-physician communication. There are documented differences in communication between physicians and Black patients versus White patients. The communication intervention used in this study is called a Question Prompt List.

“It is very important for patients to feel empowered to ask questions and get the information they need from their doctors and health care team,” said Dr. Eggly. “This particular question prompt list was designed to help patients prepare for clinic visits by thinking through their questions and concerns about clinical trials.”

At the end of the four-year study, the research team found that patients who received the Question Prompt List had better communication with their doctor and were more likely to receive an invitation to participate in a clinical trial than patients who did not receive the Question Prompt List.

“It is our responsibility in medical institutions to include a diverse patient population in clinical trials, such as the population we serve at Karmanos. We can do that by expanding eligibility requirements to include more patients and creating trusting patient-physician relationships that allow talking about the importance of clinical trials to find better cancer treatments and help more patients,” concluded Dr. Eggly.

In addition to Dr. Eggly, study co-authors affiliated with Karmanos and WSU included Nicole Senft, PhD; Seongho Kim, PhD; Elisabeth Heath, MD, FACP; Hyejeong Jang, MS; Tanina Moore, PhD; Fatmeh Baidoun, MS; Louis Penner, PhD; Terrance Albrecht, PhD; Mark Manning, PhD; and Lauren Hamel, PhD. The authors also included Michael Carducci, MD, and Dina Lansey, MSN, both of Johns Hopkins Sidney Kimmel Comprehensive Cancer Center.

Results and recommendations that come from this study are shared with Karmanos’ 16 locations.

A National Cancer Institute grant supported this study.

RESEARCH AROUND McLAREN

Ann Schwartz, PhD

STUDY BY KARMANOS AND GEORGETOWN RESEARCHERS FIND RELATIONSHIP BETWEEN DISCRIMINATION AND FRAILTY IN BLACK CANCER SURVIVORS

Discrimination experienced by Black people can affect their health and increase their frailty, which can be particularly impactful for cancer survivors, according to a new study by researchers at Barbara Ann Karmanos Cancer Institute and colleagues at Georgetown University's Lombardi Comprehensive Cancer Center in Washington, DC. "Association between major discrimination and deficit accumulation in African American cancer survivors: The Detroit Research on Cancer Survivors Study" was published in Cancer, a peer-reviewed journal of the American Cancer Society. The researchers assessed frailty by several factors, including whether a participant had several chronic diseases, poor muscle strength and difficulty performing activities of daily living.

"Discrimination can act as a chronic stressor which can throw the body off balance, resulting in increases in blood pressure, heart rate, metabolism, inflammation, and numerous other factors. These stressors can also increase rates of aging, leading to greater risk of frailty," said the study's lead investigator, Jeanne Mandelblatt, MD, MPH, director of the Georgetown Lombardi Institute for Cancer and Aging Research. "We hypothesize that discrimination can lead to an older biological age than a person's actual chronological age. This is important to understand as there have been virtually no studies of the relationships between discrimination and aging in the setting of cancer survivorship."

The investigators looked at associations between discrimination and frailty among 2,232 Black breast, lung, prostate and colorectal cancer survivors within five years of their diagnoses and were no longer being treated for their cancers. Survivors were 62 years of age on average (with ages ranging from 23 to 84) at the time of the study, but they may

have experienced discrimination over many decades of their lives. All participants were part of the Detroit Research on Cancer Survivors (ROCS), the largest U.S. study of Black cancer survivors.

The researchers surveyed the participants, via phone, in writing, or online about any aging-related diseases they had, their ability to maintain a healthy lifestyle, and most importantly, about major discrimination events they may have experienced over their lifetimes, specifically targeting seven areas:

- being unfairly fired or denied a promotion in their job;
- not being hired for a job;
- being unfairly stopped, searched, questioned, physically threatened or abused by police officers;
- being unfairly discouraged by a teacher or advisor from continuing their education;
- unfairly receiving worse medical care than other people;
- being prevented from moving into a neighborhood because a landlord or realtor refused to sell or rent them a house or an apartment; and/or
- moved into a neighborhood where neighbors made life difficult.

Based on the survey results, the majority of cancer survivors were classified as either prefrail (42.7%), meaning they had some health difficulties, or frail (32.9%). Only 24.4% of those surveyed had few or no signs of frailty. When queried about the seven discrimination areas, 63.2% of the participants reported experiencing major discrimination, with an average respondent reporting 2.4 types of discrimination.

“For those cancer survivors who reported four to seven types of discrimination events, we observed a large, clinically meaningful increase in frailty scores compared to survivors with fewer discrimination events,” explains Dr. Mandelblatt, also a professor of oncology and medicine at the Georgetown University School of Medicine. “Significantly, this pattern of discrimination affecting frailty was consistent across the four types of cancer surveyed, indicating that discrimination is an important factor to study and understand in Black cancer survivors in order to improve their quality and length of life.”

“Our results indicate that after considering the effects of traditional factors on poor health, such as income, education and types of cancer treatment, discrimination was a significant factor explaining frailty and it acted independently of the other variables,” said Ann Schwartz, PhD, MPH, co-lead author on the paper and co-principal investigator of the Detroit ROCS. “Regardless of whether you were rich or poor, if you experienced more discrimination, you had greater frailty.”

Dr. Schwartz is also professor and associate chair of Oncology at Wayne State University (WSU) School of Medicine and deputy center director and executive vice president for Research and Academic Affairs at Karmanos.

For their next steps, the researchers hope to study the relationships between major discrimination, other chronic life stressors, and markers of biological aging and test how cancer and its treatment further contribute to biological aging among racial and ethnic minorities.

CONTINUED ON PAGE 13

RESEARCH AROUND McLAREN

KARMANOS RESEARCHER APPOINTED CHAIR OF THE DEPARTMENT OF FAMILY MEDICINE AND PUBLIC HEALTH SERVICES AT WSU

Jinping Xu, MD, MS, member of the Population Studies and Disparities Research Program at the Barbara Ann Karmanos Cancer Institute and professor in the Department of Family Medicine and Public Health Services at the Wayne State University School of Medicine, has been appointed as chair of the department after serving as interim chair since February 2021.

Jinping Xu, MD, MS

Dr. Xu is a board-certified practicing family physician and an accomplished physician-scientist. Her research has focused on the psychosocial aspects of cancer care that emphasize health disparities and health equity in African American populations, particularly in men's decision-making in prostate cancer screening, treatment and survivorship care. She is the principal investigator of the ongoing multi-site study that the Department of Defense funds, titled "Racial Disparities in Active Surveillance Adherence and Quality of Life in a Population-based Prospective Cohort of Men with Low-risk Prostate Cancer." Dr. Xu has recently completed the project "Best Practices to Engage Black Men in the Development of a Cancer Health Equity Research Agenda," and "Supporting Detroit Communities as Leaders and Partners in COVID-19 Research," which she co-led with Hayley Thompson, PhD. Dr. Xu and Dr. Thompson's team were awarded funding for both projects through the Patient-Centered Outcomes Research Institute Eugene Washington Community Engagement Awards program.

Dr. Xu has demonstrated her wide scope of knowledge and expertise through various other projects she has taken on, including directing the MetroNet, a primary care practice-based research network in metro Detroit that supports evidence-based primary care and reducing racial disparities in health outcomes, as well as leading the Michigan Area Health Education Center. This statewide program seeks to increase access to quality primary care providers in underserved and rural communities.

RELATIONSHIP BETWEEN DISCRIMINATION AND FRAILTY IN BLACK CANCER SURVIVORS

CONTINUED FROM PAGE 11

"We have long since recognized the impact of discrimination on health and well-being in Black communities," says study co-author Lucile Adams-Campbell, PhD, a professor of oncology and associate director for Minority Health and Health Disparities Research at Georgetown Lombardi. "We hope that this study leads to more discussions between providers and their patients about the types of discrimination they have experienced and gives providers a greater understanding of how discrimination impacts frailty."

Additional authors include the following members of the Population Studies and Disparities Research Program at Karmanos: Julie Ruterbusch, MPH, research assistant at WSU; Hayley Thompson, PhD, associate center director of Community Outreach and Engagement, faculty supervisor of the Office of Cancer Health Equity and Community Engagement (OCHECE) at Karmanos, professor of oncology and leader of the Center for Health Equity and Community Knowledge in Urban Populations (CHECK-UP) at WSU; and Kristen Purrington, PhD, MPH, associate professor at WSU School of Medicine.

Xingtao Zhou, MS, and Traci Bethea, PhD, at Georgetown Lombardi were also authors of this study.

This research was supported by National Cancer Institute grants, a National Institute on Aging grant, and the Epidemiology Research Core and the National Cancer Institute Center Grant awarded to the Barbara Ann Karmanos Cancer Institute and Wayne State University.

EQuIP CORNER

Susmita Jain

HUMAN RESEARCH PROTECTION PROGRAM

EMERGENCY PREPAREDNESS PLAN: LESSONS LEARNED FROM COVID-19 PANDEMIC

By Susmita Jain, MS, Research QI and Education Specialist

At McLaren Healthcare our researchers are engaged in a variety of clinical trials and maintaining the safety and well-being of our research participants is always our priority.

Research organizations are required to develop disaster plans for localized crisis, such as major weather events or data breaches, but none had anticipated a disaster that would shut down the entire nation, as well as many international supply chains. According to a recent study on the impact of the COVID-19 pandemic on human subject research presented at the PRIM&R Advancing Ethical Research Virtual Conference in December 2020, Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs) nationwide responded quickly and efficiently to changing processes and policies during the early months of the COVID-19 pandemic.

The COVID-19 pandemic in last few years, emphasized the need for the HRPP to have a robust contingency plan to ensure continuity of the research operations, ensure effective communications among all involved parties and to ensure the safety of the research participants.

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) recognizes the importance of having and implementing an emergency preparedness plan to protect human research subjects during emergencies in its newest accreditation element: Element I.1.H. **https://www.aahrpp.org/resources/for-accreditation/tipsheets/emergency-preparedness-and-response**

The Element includes four essential requirements:

1. Emergency preparedness plan should be appropriate to the size and complexity of the HRPP. There is no one-size-fits-all emergency preparedness plan.

2. The plan should be periodically evaluated and as needed to be adjusted to ensure continuity of operations.
3. Educating the Research Community members including IRB members, Researchers and HRPP members about our emergency response plan.
4. HRPP members should be knowledgeable about the McLaren Healthcare's expectations during emergencies.

AAHRPP's guidance on emergency preparedness plans is risk-based and tailored to the size and complexity of the organization's HRPP planning. There is no "one-size-fits-all" emergency preparedness plan.

As emergencies and disasters may vary in significance, scope and impact, they also may come without warning or advance notice. These emergencies may be natural disasters, man-made disasters, public health emergencies, war or terrorist actions. The key components of any emergency management plan are **Advance Preparation, Communication and Recovery**. The plan should address general expectations and strategies to manage impact on the HRPP IRB operations, handling of on-going studies and continued protection of human subjects in research. To simplify, the plan should help to maintain patient safety while limiting the impact and allowing the flexibility and adaptability to research operations with a plan to return to normal as quickly as possible.

The plan should clearly specify who is responsible for developing / updating the plan, implementing the plan when an emergency arises and evaluating the plan on an ongoing basis. The plan should also designate an alternate or backup in case the individual primarily responsible is unavailable.

Developing an HRPP-focused plan begins by identifying and assessing potential emergencies affecting our organization's HRPP and their impact on the HRPP's operations. It is essential to understand the types of risks involved, such as public health emergencies like the COVID-19 pandemic, weather-related events (e.g., hurricanes, tornados), cybersecurity incidents (e.g., data breaches) impacting our Information Technology system like IRIS and other electronic record systems. These emergencies would all require a different set of actions.

Following are some points to consider and include while preparing the Emergency Preparedness plan:

Points to consider for all research members in HRPP

- Determine and prioritize your essential functions and resources.
- Make a list of People, Places and Things such as equipment, supplies, contact information for IT vendors and alternate providers. Update the contact list for all research staff and distribute to each team member. Keep a copy of the staff contact list in a secured off-site location.

Points to consider for IRB members

- Whether to consider suspending non-interventional research during an emergency.
- How the IRB will continue operational processes if it no longer has access to study records or an Information Technology portal like IRIS.
- Consider whether to continue studies such as socio-behavioral or

CONTINUED ON PAGE 16

EQuIP CORNER

UPCOMING RESEARCH EDUCATION

WCG

WCG Web Series: The Participant Playbook
Part 4: Safeguarding Participant Rights and Safety: Duties of Sponsors, Sites and IRB
May 3, 2023 • 11 am ET / 8 am PT
TO REGISTER:
www.wcgclinical.com/

2023 WCG Avoca Quality Consortium Summit
May 17 - 18, 2023
Industry-wide Virtual Event
TO REGISTER:
www.theavocagroup.com/

WCG MAGI Clinical Research Conference – 2023 East
Loews Philadelphia Hotel,
Philadelphia, PA
May 21-24, 2023
TO REGISTER:
wcg.swoogo.com/magi-east23

ACRP

ACRP Chicagoland Chapter: Clinical Trial Budgets and Billing Compliance
May 3, 2023 • 6:00 pm - 7:00 pm (CT)
TO REGISTER:
acrpnet.org/event

ACRP 2023 Annual Conference
Dallas, Texas
April 28 - May 1, 2023
TO REGISTER:
2023.acrpnet.org/registration

HUMAN RESEARCH PROTECTION PROGRAM'S EMERGENCY PREPAREDNESS PLAN

CONTINUED FROM PAGE 15

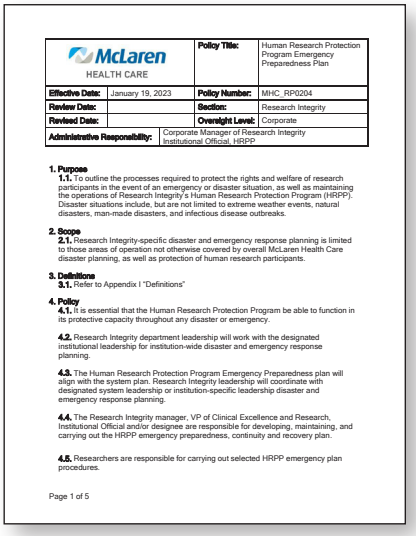
educational as they already conducted many online and virtual research activities.

- How to ensure safety and continuity of ongoing biomedical research.
- Whether the organization might put a temporary hold on review of ongoing or newly proposed research if their IRB couldn't operate due to an emergency.
- How the IRB staff will communicate with each other at the time of emergency.
- Consider establishing reliance agreements with other IRBs, so collaborative emergency sites are available.

Points to consider for Investigators and study staff

- How the research participants will receive their study drug/ investigational product.
- How study teams will obtain informed consent to enroll new participants
- What if the disaster impacts transportation or causes damage to buildings? Consider including plan for relocation, remote working, or remote research patient visits.
- Include the plan for extended loss of power or power interruptions that safeguards research equipment, research data, biological specimens etc.
- Plan for securing all research records, both paper and electronic format, and the process to inform the research staff of the method and location.

Once the plan is developed, educating our research community including researchers, IRB members, HRPP staff and leadership about the plan is very crucial step for the successful implementation. At McLaren, education is provided through a brown bag session, during a planned IRB meeting and at regular intervals through various educational programs. Here is the link for the Emergency Preparedness Plan Policy:
https://www.mclaren.org/Uploads/Public/Documents/corporate/Research-Polices/MHC_RP0204-Emergency-Preparedness-Plan.pdf



McLaren HEALTH CARE

		Policy Title:	Human Research Protection Program Emergency Preparedness Plan
Effective Date:	January 19, 2023	**Policy Number:**	MHC_RP0204
Review Date:		**Section:**	Research Integrity
Revised Date:		**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Manager of Research Integrity Institutional Official, HRPP		

1. Purpose
1.1. To outline the processes required to protect the rights and welfare of research participants in the event of an emergency or disaster situation, as well as maintaining the operations of Research Integrity's Human Research Protection Program (HRPP). Disaster situations include, but are not limited to extreme weather events, natural disasters, man-made disasters, and infectious disease outbreaks.

2. Scope
2.1. Research Integrity-specific disaster and emergency response planning is limited to those areas of operation not otherwise covered by overall McLaren Health Care disaster planning, as well as protection of human research participants.

3. Definitions
3.1. Refer to Appendix I "Definitions"

4. Policy
4.1. It is essential that the Human Research Protection Program be able to function in its protective capacity throughout any disaster or emergency.

4.2. Research Integrity department leadership will work with the designated institutional leadership for institution-wide disaster and emergency response planning.

4.3. The Human Research Protection Program Emergency Preparedness plan will align with the system plan. Research Integrity leadership will coordinate with designated system leadership or institution-specific leadership disaster and emergency response planning.

4.4. The Research Integrity manager, VP of Clinical Excellence and Research, Institutional Official and/or designee are responsible for developing, maintaining, and carrying out the HRPP emergency preparedness, continuity and recovery plan.

4.5. Researchers are responsible for carrying out selected HRPP emergency plan procedures.

Page 1 of 5

Following the emergency event

To access the McLaren Health Care Research Integrity portal to find any new or updated information at **https://www.mclaren.org/main/iris-research**. This web page will also be used to provide updates on any damage and actions being taken to address research patients' safety and HRPP operational changes.

IRBs and HRPPs should look for continuous and updated guidance by referring to Federal websites, such as the U.S. Department of Health and Human Services (HHS), The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) for information on creating and updating policies and procedures during the emergency situation.

Post-event recovery

Planning for recovery is just as essential as planning for response. During the COVID-19 pandemic, there was noted to be some challenges with research study backlog due to limited capacity and resources. This led to delays in the completion of studies which may have resulted in a reduction in the number of studies able to recruit effectively and close on time.

Some points to consider in recovery phase

- Assess the status of our research team members by using the phone, text or email communication. Then, start to communicate with study participants.
- Confirm the safety of clinical trial staff and participants.
- Ensure the stability of the research samples, Investigational drug, research data, etc.
- Contact research participants to provide direction regarding any medications or study visits.
- Review all current, active patients and studies to determine if there were deviations to treatment or follow-up requirements.
- Contact the industry sponsor/Federal agency to discuss any impact on the protocol.
- Identify any serious adverse events that require reporting that may have occurred during the emergency period.
- Identify any protocol modifications that may be required to address on-going issues following the emergency and submit to the IRB for review and determination.
- The IRB may reconsider the ongoing status of studies that may have been suspended during the emergencies.

In summary, effective education and communication both internally and externally, is crucial during any emergency, but also a most common reason of failure and criticism after an event.

UPCOMING RESEARCH EDUCATION

SOCRA

SOCRA – Clinical Research Monitoring and GCP Virtual Workshop for Monitors, Site Coordinators and Auditors
May 16 - 19, 2023
TO REGISTER:
www.socra.org/

SOCRA – Quality Management Virtual Conference
June 7 - 9, 2023
TO REGISTER:
www.socra.org/

ADVARRA

ADVARRA – Privacy and Confidentiality in the Age of Mobile Apps and Connected Devices
May 4, 2023 | 1 pm ET
TO REGISTER:
www.advarra.com/webinars/

FACULTY, FELLOWS & RESIDENTS

SCHOLARLY ACTIVITY NEWS

Carlos F. Rios-Bedoya, ScD

AN APPROACH TO QUICKLY APPRAISE MEDICAL LITERATURE

By Carlos F. Rios-Bedoya, ScD, MPH

Medical literature has experienced an exponential increase in quantity and publication speed. In addition, it has become more accessible to lay people. The combination of these factors adds another area where physicians should become proficient. Not only do they need to keep up to date with the advances in their field of expertise, but also have a way to quickly appraise the quality of the medical literature. The expanded access of medical information can place additional burden on physicians, as patients may come to a clinical encounter without a clear understanding of what they have read in medical literature as lay people. The physician will need to explain medical information to their patients in a manner that the patient is capable of understanding.

There are several templates available for use in evaluating medical literature. Some examples include QUADAS (Quality, Assessment, Diagnostic, Accuracy, Studies) for diagnostic accuracy of research studies, PRISMA (Preferred Reporting Items for Systematic Reviews), STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies, and CONSORT (Consolidated Standards for Reporting of Trials). However, even though these are excellent tools, their implementation and use require more time than what is often available to a physician during a clinical encounter. This time limitation is especially true in the primary care arena, where the provider has many required preventive guidelines to implement during such an encounter. Therefore, I am suggesting another way to quickly appraise the quality of medical literature. I consistently use this method to prepare for journal clubs. I want to disclose that this method is based on my personal experience of more than 25 years reading the medical literature and teaching residents how to appraise its quality. There is no data or published studies documenting or supporting the use of this approach.

My process consists of reading and focusing on only three sections of a manuscript. These sections are the Abstract, the Methods, and the

Results. The Abstract is a very short section that can provide you with the "what, why, and how" of the study, as well as a summary of the findings. Thereafter, I skip the Introduction and Conclusions sections as these are most often subjective in nature. In the Introduction section, the authors will choose mostly the literature that justifies the need for the study. Similarly, in the Conclusion the authors will often select the literature that further supports or explains their findings.

The Methods sections is the most critical and important section to determine the quality of an article. This section includes information on the study design, main hypothesis, primary outcome, assessments used, number of participants, how participants were selected, rationale for the sample size chosen, minimum clinically significant difference to be tested, adjustment for multiple testing or lack of it, and statistical tests used. This is a completely objective section that allows the reader to assess any potential biases, methodological and analytical adequacy, and the internal and external validity of the manuscript. These are all important criteria to determine the quality of the study.

The Results section provides the findings of the study presented in an objective manner. However, instead of reading this section, my recommendation is to focus on the tables and figures. Well-designed tables and figures will provide 80-90% of the results of the manuscript in a visual representation that saves time. Therefore, the reader will be able to quickly access the results of the manuscripts without having to navigate through the written portion of the results section.

I do want to clarify that nothing is better than reading the whole manuscript, however, when your time is limited, or your patient brings medical information to you to for evaluation and explanation, the approach described could be a useful tool to learn and master. The journal clubs at McLaren follow a format that mimics this process to assist residents/fellows in learning and practicing this approach. The Division of Scholarly Inquiry is committed to support and facilitate scholarly activity for McLaren residents, fellows, and faculty.

For additional information contact Dr. Carlos F. Ríos-Bedoya at **carlos.rios@mclaren.org**.

ANNOUNCEMENTS AND WHAT'S NEW

Carolyn Harrison

MCRI is pleased to announce **Carolyn Harrison**, CCRP has joined the McLaren Bay Region site as a Clinical Research Coordinator. She obtained her Bachelor of Arts in Integrated Physiology from the University of Colorado in Boulder, Colorado. Carolyn has 12 years of experience in regulatory affairs, data management and clinical research coordination in the areas of Oncology and blood and bone marrow transplant.

THE DIVISION OF SCHOLARLY INQUIRY

CONGRATULATES THE FOLLOWING RESIDENTS FOR AWARDS RECEIVED:

Basel Abdelazeem, MD

Internal Medicine Resident – McLaren Flint

Title: Which Sodium-Glucose Cotransporter 2 Inhibitors Agent Is More Effective in Patients with Heart Failure? A Systematic Review and Network Meta-analysis Of Randomized Clinical Trials

Authors: Ahmed K. Awad, Mohammed Tarek Hasan, Mohamed Shih, Amir N. Attia, Heba Aboeldahab, Basel Abdelazeem, Nischit Baral, Pramod Savarapu, Annabelle S Santos Volgman

Award: Paul Dudley White International Scholar Award to recognize the high ranked abstracts

Conference: American Heart Association #AHA22 meeting.

Stephanie Behme, DPM

Podiatry Resident – McLaren Oakland

Title: Impact of Podiatric Surgery Consultation for Foot and Ankle Wounds on Patient Outcomes in a Community Hospital

Authors: Stephanie Behme, DPM, Zeeshan Husain, DPM FACFAS, and Olga J. Santiago, PhD MHSA.

Award: Second position in the research presentation category

Conference: 2023 the Michigan Podiatric Medical Association (MPMA) Great Lakes Conference, February 2023, Michigan.

Please note these are award recipients only. Publications and presentations will be published in a future issue.

Daniel Kielminski, MD

Ortho Resident – McLaren Flint

Title: Crash Characteristics for Classic/Historic Vehicles and Comparisons for Newer Vehicles

Authors: Daniel Kielminski MD, Elise Atkinson BS, Diane Peters PhD, Seann Willson MD, Jack Mason BS, Theresa Atkinson PhD.

Award: First Place Study

Conference: MSU College of Human Medicine Flint Campus Research Forum.

Sean Kipp, DPM

Podiatry Resident – McLaren Oakland

Title: Staged multiple tendon transfer for semi-rigid equinovarus deformity

Author: Sean Kipp, DPM

Award: Third place in the case presentation category

Conference: 2023 the Michigan Podiatric Medical Association (MPMA) Great Lakes Conference, February 2023, Michigan.

Sydney Wonski DO

Diagnostic Radiology Resident – McLaren Oakland

Title: Shoulder Dislocations: What the Surgeons Really Want to Know

Author: Sydney Wonski, DO

Award: Third place exhibit

Conference: 2023 American Osteopathic College of Radiology Conference (AOCR) in Phoenix, AZ.

Office of Clinical Excellence

VICE PRESIDENT
Chandan Gupte
chandan.gupte@mclaren.org

ADMINISTRATIVE ASSISTANT
Tamara Leo
tamara.leo@mclaren.org

McLaren Corporate Research
2701 Cambridge Court, Ste. 110
Auburn Hills, MI 48326

McLaren Center for Research and Innovation
mclaren.org/Main/Research.aspx
(248) 484-4960

CORPORATE DIRECTOR. MCLAREN CENTER FOR RESEARCH AND INNOVATION
Pam Wills-Mertz
pamela.wills-mertz@mclaren.org

CORPORATE RESEARCH MANAGERS
Jill George
jill.george@mclaren.org

Melissa Szemites
melissa.szemites@mclaren.org

REGULATORY SPECIALISTS
Tanya Gardner-Mosley
tanya.gardner-mosley@mclaren.org

Vidya Yarlagadda
srividya.yarlagadda@mclaren.org

FINANCIAL ANALYST
Quinn Warwick
quinn.warwick@mclaren.org

CONTRACT AND BUDGET SPECIALIST
Lakeeshi Williams
lakeeshi.williams@mclaren.org

DIRECTOR OF RESEARCH FUNDING
Barb Rauschendorfer
barb.rauschendorfer@mclaren.org

CLINICAL RESEARCH INFORMATICS MANAGER
Donna Mott
donna.mott@mclaren.org

Research Integrity
hrpp@mclaren.org
(248) 484-4950

CORPORATE RESEARCH INTEGRITY MANAGER
Patricia Ivery
patricia.ivery@mclaren.org

IRB ANALYSTS
Michael Flores
michael.flores@mclaren.org

Jacki Wilson
jacki.wilson@mclaren.org

RESEARCH QI COMPLIANCE AND EDUCATION SPECIALIST
Susmita Jain
Susmita.jain@mclaren.org

RESEARCH INTEGRITY ASSISTANT
Lauren Thomas
lauren.thomas@mclaren.org

Karmanos Cancer Institute Clinical Trials Office

INTERIM DIRECTOR
Sarah Bigelow
bigelows@karmanos.org

MANAGERS
Elizabeth Bowie
bowiee@karmanos.org

Jaclyn Ventimiglia
ventimij@karmanos.org

Kasha Donahue
krulk@karmanos.org

Elizabeth Cunningham
cunninge@karmanos.org

Paige Dykema
dykemap@karmanos.org