McLaren

RESEARCH

Matters

SUMMER 2017

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McLaren RESEARCH Matters
Connecting the McLaren Research Community

The Future and Value of Graduate Medical Education Research

By Robert F. Flora, MD, MBA, MPH

The future of graduate medical education research

McLaren Flint has always required both residents and faculty to abide by the Accreditation Council for Graduate Medical Education's (ACGME) research requirements. The ACGME has now changed the requirement to scholarly activity which includes basic science, clinical science, education research, and quality improvement. Our goal by 2020 is to have the Bay, Greater Lansing, Macomb, and Oakland campuses, as well as Flint, meet these new requirements. We have been implementing systems to make this process go as smoothly as possible. We are trying to make it easier for faculty and residents to learn how to conduct research by hiring highly qualified PhDs to help teach them. In addition, we are integrating technology and computer systems that will help physicians work through development research protocols such as Protocol Builder. This is a cloud-based protocol writing technology which will help our physicians to develop investigator-initiated proposals that meet IRB and regulatory standards.

The physicians we train and retain will be able to keep up with the ever-increasing knowledge and provide evidence-based care on the most up-and-coming research.

Why research matters

Dr. Flora points out that the reason we are teaching research isn't specifically for physicians to go out and conduct scholarly activity. The purpose is that they understand it so when

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in practice if they read an article, they know whether the information in that article is credible based on knowing how to critically appraise the literature. The physicians we train and retain will be able to keep up with the ever-increasing knowledge and provide evidence-based care on the most up-and-coming research. This will allow physicians to stay current in medical practice, which will allow McLaren to produce better physicians and a higher level of care.

Meet Dr. Flora

At McLaren, we are steadfast in advancing research possibilities for our Graduate Medical Education (GME) Program. In October 2016, McLaren hired Robert F. Flora, MD, MBA, MPH as Chief Academic Officer and Vice President of Academic Affairs to help further facilitate reaching our GME research goals. In his most recent role prior to joining McLaren, Dr. Flora served as Director of Medical Education and Designated Institutional Officer for Providence Hospital and Medical Center in Southfield, Michigan. He is currently a Professor and Vice Chair for Education in the Department of Obstetrics, Gynecology, and Reproductive Medicine at Michigan State University College of Human Medicine. Among his many previous accomplishments, Dr. Flora also served as the Residency Program Director/Medical Student Clerkship Site Director of Ob/Gyn at Summa Health System/NEOMED from February 1997 through September 2008.

McLaren IRB Visited by the FDA

By Lana Gevorkyan, Corporate Director, Human Research Protections Program

The Food and Drug Administration (FDA) routinely inspects institutional review boards, clinical investigators, sponsors, monitors, etc. as a part of its Bioresearch Monitoring (BIMO) Program. Such inspections are conducted to ensure the protections of the rights, welfare and safety of human subjects and the quality and integrity of data submitted to the agency. Routinely auditing IRBs, allows the FDA to determine that IRBs and research organizations are operating in compliance with FDA regulations and local policies and procedures.

MHC IRB recently underwent such an audit which included interviewing key personnel to obtain information regarding the IRB's policies and procedures, an in depth review of all IRB documentation (IRB rosters, IRB Member files, SOPs, meeting minutes, etc.). The inspector also closely examined several studies that were reviewed and approved through MHC IRB.

I am very pleased to report that there were no findings subsequent to the audit. The FDA inspector found the MHC IRB to be very organized and consistent. This is a compliment to everyone throughout the McLaren Health Care research enterprise, as each of us serves a vital role.

EQuIP Corner

Using the "Teach Back" Method to Assess Subject Comprehension

By Patricia Ivery, QI and Education Specialist

Consenting is the process of providing potential subjects adequate information to make an educated and voluntary decision whether or not to participate in research. The Principal Investigator (PI) or designee must ensure potential research subjects are adequately informed of the following prior to their participation:

- Purpose of the study
- Study procedures
- Potential risks and benefits
- Expected duration of the study
- Confidentiality of study information

This goal is difficult to achieve as research forms become longer and more complex. Studies show that 40-80% of the information passed to patients is forgotten immediately or retained incorrectly[1]. Various strategies have been implemented in an effort to improve the informed consent process and subject comprehension. One such strategy includes the incorporation of electronic applications and devices. The ability to incorporate non-text mediums such as videos and interactive graphics help to improve participant comprehension. Unfortunately, these programs are quite new and not yet widely available, leaving most researchers to rely on the traditional method of using the hard copy ICF to provide information when consenting subjects.

A subject's understanding is critical for both ethical and legal reasons. Recent lawsuits have targeted researchers for not having an adequate process for obtaining informed consent. The majority of participants who have successfully sued researchers, have done so on the basis of not being properly informed prior their consent to participate. Researchers must work diligently to ensure potential research participants clearly understand what is involved before they consent to take part.

The Nuremberg Code, Declaration of Helsinki, and the Belmont Report all refer to informed consent in some fashion. The Belmont Report specifically addresses the need to provide adequate information in the principle of respect for persons. This principle demands that subjects enter into research voluntarily and with adequate information.

The Teach-Back Method

Confirming comprehension during the consent process can be challenging. One approach that has proven to be effective is the utilization of an interactive

Brown Bag Series

Impact of Research on Ancillary Departments
June 13, 2017 • 12:00 - 12:45 pm
LIVE WEBINAR

Consenting Subjects Using the VoICE Method
August 8, 2017 • 12:00 - 1:00 pm
LIVE WEBINAR

Contact Markeda at (248) 484-4952
or markeda.richards@mclaren.org

Upcoming Education and Conferences

SOCRA 2017 Annual Conference
October 6 - 8, 2017 • Orlando, FL

Public Responsibility in Medicine and Research (PRIM&R) 2017 Advancing Ethical Research Conference
November 5 - 8, 2017 • San Antonio, TX

communication technique called the "teach back" method.[2] This method is a research-based health literacy intervention that promotes adherence, quality, and patient safety, and also improves patient outcomes. The teach back method provides the researcher with the assurance that the information provided was explained clearly and comprehended appropriately, as it requires the subject (or their representative) to explain the information in their own words.

Teach-Back Part 1 Explaining the Information

Start by explaining the study. Use the ICF document headers as a guide, being mindful to present the information in a caring way. Discuss one section at a time and follow each section with open ended questions, such as:

- "I want to make sure we have the same understanding about this research. Can you tell me what this project is about in your own words?"
- "It's my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project."

Teach-Back Part 2 Assessing Subject Understanding

Give potential participants the time and opportunity to talk to you and allow them to consult the document when answering the questions. The purpose is to check comprehension, not memory. Listen for simple parroting and probe further if they use technical terms in their response. Do not ask "yes" or "no" questions. Instead, ask open-ended questions that prompt a well thought response, such as the following:

- Goal of the Research and Protocol
  - "Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study."
- Benefit and Compensation
  - "What do you expect to gain by taking part in this research?"
- Risks
  - "What risks would you be taking if you joined this study?"
- Voluntariness
  - "Will anything happen to you if you refuse to be in this study?"
- Discontinuing Participation
  - "What should you do if you agree to be in the study but later change your mind?"
  - "What will happen to information already gathered if you change your mind?"
- Privacy
  - "Who will be able to see the information you give us?"
- Contact Information
  - "What should you do if you have any questions or concerns about this study?"

Teach-Back Part 3 Clarifying and Re-Assessing

Be patient. Correct any misinformation until the potential research subject correctly answers all questions. Make it clear that the need to repeat information is due to the complexity of the material, rather than to the "fault" of the potential subject. For example:

- "Let's talk about the purpose of the study again because I think I may have not explained it clearly."
- "What questions do you still have about the research?"
- "What would you like to hear more about?"

It is important to be direct. Avoid asking questions that are broad and diffuse, such as "Do you have any questions?", or "Do you understand?"

When obtaining written consent, provide the subject with a copy of the document. Emphasize that they should keep the document for later reference, as it contains information regarding who they should contact if they have any questions or concerns about the research.

Remember it is ultimately the responsibility of the researcher to ensure subject comprehension. If there is any doubt that a potential research subject adequately understands the study protocol, they should not be enrolled.

References

[1]https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2- tool5.html

[2]https://www.ahrq.gov/funding/policies/informedconsent/ictoolkit2.html

What's New?

Certified IRB Professional

Congratulations to Jodi Reetz, MHC IRB Analyst, for becoming a Certified IRB Professional! The CIP credential was developed to promote ethical research practices and programs by ensuring that professional charged with their administration have demonstrated an advanced level of knowledge, understanding and experience.

Certified Research Professionals

Congratulations to the following staff at Karmanos Cancer Institute Clinical Trials Office for recently becoming certified research professionals!

Sri Vidya Yarlagadda
Research Coordinator II – SoCRA Certified

Erich Zechar
Research Nurse Float – SoCRA Certified

Meghan Wyse
Research Coordinator II, Phase I – ACRP Certified

Hemali Patel
Research Coordinator Regulatory, Phase I – SoCRA Certified

Mioka Hobson
Lead Eligibility Coordinator, Phase I – SoCRA Certified

Colleen Neveux
Research Nurse – SoCRA Certified

Melanie Smith
Research Nurse – SoCRA Certified

Allison Wolgast
Clinical Research Coordinator II – ACRP Certified

Michigan Vascular Center Partners with McLaren Flint to Study Tissue-Engineered Vessel Implant

Robert G. Molnar, MD

Robert G. Molnar, MD, of the Michigan Vascular Center (MVC) is pleased to announce that MVC has be selected as one of four sites to participate in HUMACYL Phase II trial to test the safety and efficacy of a human acellular vessel (HAV). In this non-randomized trial, 20 patients will be enrolled and have the HUMACYL HAV surgically implanted in the above-the-knee, femoral-to-popliteal artery in patients who suffer from peripheral arterial disease (PAD). The Michigan Vascular Center is partnering with McLaren Flint to offer this leading technology to our region. The other prestigious sites selected include Brigham and Women's Hospital in Boston, Massachusetts, UCSF in San Francisco, California and Duke University Hospital in Durham, North Carolina.

PAD is a progressive disease process that leads to hardening and narrowing of the arteries. As the disease progresses, organs and tissues can have diminished blood flow. In the US, it is estimated that up to 20 million people have PAD and up to 8 million have significant symptoms. Those with severe disease affecting the lower extremity often experience disabling claudication, rest pain, or the development of ulcers with a significant risk of limb loss. While the physicians of MVC are able to offer minimally invasive endovascular therapies to many patients, some will require surgical bypass. If the patient's autogenous veins are not adequate to use for a bypass, prosthetic and cadaveric bypass grafts are available, but offer diminished patency and durability compared to the use of autogenous vein. The HAV is an exciting development which offers promise of an off-the-shelf product that is available for all patients.

The HUMACYL HAV is a tissue-engineered blood vessel that is being investigated in the current trial as a surgical option for peripheral arterial bypass. The HAV is a sterile, vascular tube, composed of human connective tissue and proteins. The complex connective tissue has similarities to human vascular tissue, but HAV is non-living. Twenty patients with symptomatic PAD that meet all inclusion and fail to meet exclusion criteria will undergo femoral to above-the-knee popliteal bypass. The active study will be for 12 months, with an additional follow up for 60 months post-implantation. The primary outcome measurements will be the incidence of aneurysm formation, anastomotic bleeding, HAV infection or removal, frequency of adverse events, patency rates and hemodynamically significant stenosis.

Dr. Molnar is Principal Investigator for this trial and Director of the Michigan Vascular Research Center (MVRC) which has conducted 68 clinical trials since 2001, with most of those trials conducted at McLaren Flint.

The HAV is an exciting development which offers promise of an off-the-shelf product that is available for all patients.

McLaren Flint Residents Recognized by American College of Physicians

Two McLaren Internal Medicine residents received national recognition at the 2017 American College of Physicians (ACP) national meeting for their research.

Mahin Khan, MD, and his co-authors for the following case report:

"A Curious Case of Recovery from Cardiogenic Shock in a Nonagenarian"

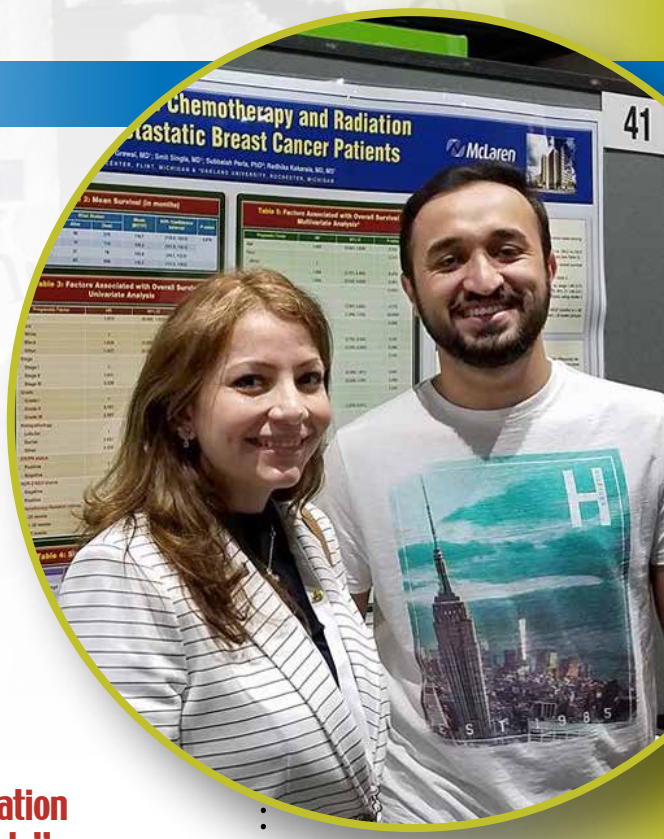
Mahin Khan, Hafiz Khan, Ahsan Wahab, Siddique Chaudhary, Susan J Smith, Marian Mocanu

Ruaa Al-Ward, MD, and her coauthors for the following study:

"Association of time Interval between Chemotherapy and Radiation Therapy with Prognosis in Non Metastatic Breast Cancer Patients"

Al-Ward R, MD; Al- Shweiat W, MD; Talasila L, MD; Grewal S, MD; Singla S, MD; Subbaiah P, PhD; Kakarala R, MD

Dr. Al-Ward was also recognized by the ACP with the "Young Achiever Award". ACP Young Achievers are members in training or in their early career who have been selected for an ACP award or who have been successful in a College competition. Among the accomplishments recognized for this designation are the National Abstract Competition Winners and Finalists; National Award Winners; ACP Doctor's Dilemma Participants; ACP Travel Grant Awardees; ACP Academic Advisory Board Delegates; ACP Dragon's Lair Competition Finalists; and the Waxman Scholars.



Ruaa Al-Ward, MD (left) and Mahin Khan, MD (right) at a recent medical research show.

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