McLaren

RESEARCH

Matters

WINTER 2016/17

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McLaren RESEARCH Matters
Connecting the McLaren Research Community

Why Accreditation Matters...

By Michael McKenna
Executive Vice President and Chief Medical Officer, McLaren Health Care

The mission of McLaren Health Care (MHC) is, through its subsidiaries, to be the best value in health care as defined by quality outcomes and cost. Education and research are critical to this mission, providing the driving forces essential to the continuous advancement of patient care and the health of the community. The MHC Human Research Protections Program (HRPP) provides not only the infrastructure necessary for the core functions of review, education, and oversight, but also provides the means for the institutional coordination that is essential to promote and support the conduct of research in accordance with the highest standards of quality.

Obtaining AAHRPP accreditation and the recent re-accreditation, reinforces that McLaren is focused on quality, ethics and regulatory compliance in the conduct of human subject research. Most importantly, it ensures that our research participants are protected.

I trust we all realize that accreditation is not a one-time event of compliance and quality, rather a meaningful process of coordination and commitment, in which all units of research work together toward common goals of excellence in research.

Accreditation is an important process of continuous evaluation and improvement that helps to strengthen research initiatives conducted throughout the McLaren system. I am proud of the hard work and dedication of our entire research team in seeking and securing AAHRPP accreditation.

This recognition affirms to our research participants, their families, and other research organizations that McLaren Health Care, as a system, adheres to the most stringent research standards. Thank you and congratulations to all who were a part of this vital process.

In this issue...

McLaren HRPP Awarded 5-Year Reaccreditation

By Lana Gevorkyan, Corporate Director, Human Research Protections Program

I'm happy to announce that on December 19, 2016 the McLaren Human Research Protections Program (HRPP) was awarded full reaccreditation for 5-years by the Association for the Accreditation of Human Research Protections Programs (AAHRPP).

The McLaren HRPP first received AAHRPP accreditation in 2013. AAHRPP accreditation is the gold-standard for U.S. and international organizations that conduct biomedical, behavioral or social sciences research involving research participants. More than 60 percent of U.S. research-intensive universities and 65 percent of U.S. medical schools are either AAHRPP accredited or have begun that process. Accredited organizations include community and teaching hospitals, universities, research institutes, and contract research organizations.

It is often believed that accreditation applies only to the IRB. This could not be further from the truth. The accrediting entity is looking at all facets of research including research education, research compliance and quality improvement, handling of investigational drugs, management of contracts and grants, researchers and research staff, etc.

I would like to extend a sincere thank you to all investigators, research staff, support staff, our leadership team, and other key personnel who were interviewed by site visitors or provided information / resources of any kind during this intense process. Your organization, dedication, and commitment to ethical research conduct did not go unnoticed by the site visitors.

I look forward to working with all of you as we continue to enhance our Human Research Protections Program through quality improvement initiatives designed to facilitate research, ensure regulatory compliance while minimizing administrative burdens, and strengthen protections for participants.

George Yoo, MD

Karmanos' BioBanking Protocol Exceeds Expectations Due to Community Site Involvement

Despite improvements in cancer treatments and outcomes, a need still exists for further research into the identification of molecular targets for treatment and biomarkers of risk and prognosis. This type of research requires the availability of biospecimens. Newer technology makes it possible to evaluate the molecular and genetic subtypes of complex cancers and is moving the field toward personalized medicine.

The Barbara Ann Karmanos Cancer Institute has established a BioBanking Protocol to expand the size and diversity of its human tissue samples needed for research purposes. George Yoo, M.D., chief medical officer and physician-in-chief at Karmanos, led the effort to reach out to Karmanos' community-based cancer centers to assist in collection efforts. With the community sites contributing nearly half of all new enrollments this year, Dr. Yoo was pleasantly surprised with the results.

"The community is doing a phenomenal job of enrolling patients and obtaining blood and tissue specimens, almost doubling our efforts downtown," he said. "Downtown we collected 765 specimens. With Karmanos community site involvement, we have 1,319 specimens this year."

Dr. Yoo credits two factors to the abundance of specimens submitted through the community sites. "There have been champions at each site that have driven the importance of this research," he said. "Also, I think patients are very excited when they are told it may help somebody's future."

Karmanos was named a National Cancer Institute (NCI) designated Comprehensive Cancer Center in 1978. With this prestigious designation comes a commitment by Karmanos to meet specific criteria for breadth and depth of basic cancer research; clinical cancer research; prevention, control and population/behavioral sciences research in cancer; and strength of interaction among these major research areas.

"Having a biobank core is critical for the mission of a NCI-designated Comprehensive Cancer Center," Dr. Yoo said.

A well-stocked biobank is the foundation needed to advance personalized medicine and to improve patient outcomes.

"It all starts by having a biobank to study molecular and genetic changes, so at the most basic molecular level we can understand why cancer cells have an advantage over normal cells and overgrow," Dr.

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Resident's Corner

Is My Project Human Subjects Research and Who Makes This Determination?

By Markeda Richards, HRPP Coordinator

There are often questions regarding who can determine whether a project qualifies as human subjects research. So, who is qualified to make such a decision? The investigator, researcher, research staff, etc. cannot make the determination that a project is NOT human subjects research, this determination can ONLY be made by the IRB.

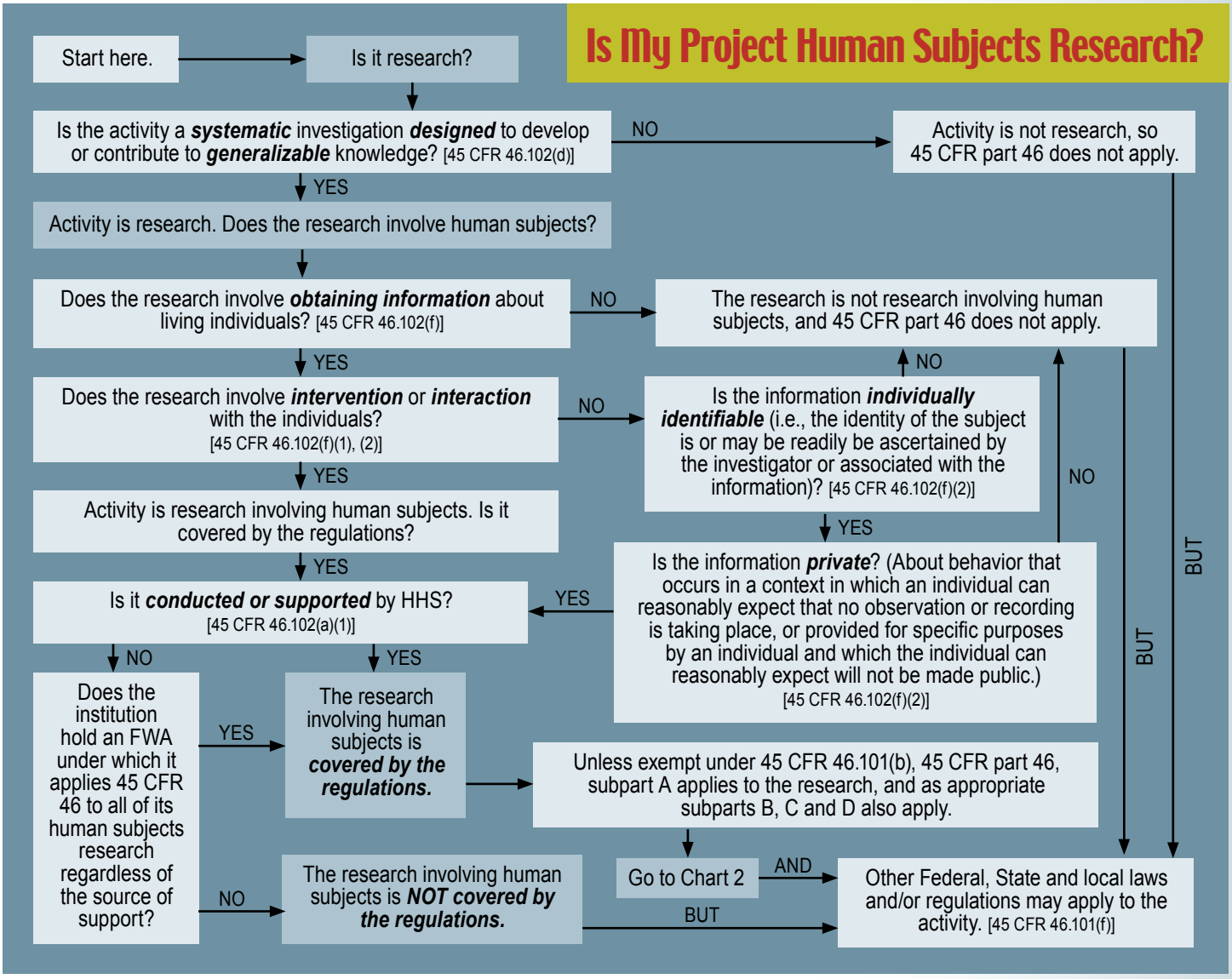
The chart on the next page was developed by the Office of Human Research Protections as a guide to determining if a project is research involving human subjects. (Keep in mind that, whether or not you think your project qualifies as human subject research, you must submit to the IRB for final determination).

In order for the IRB to make the final determination as to whether or not your project is human subject research, you must submit a Request for Determination of Non-Human Subject Research. The IRB will review your request and issue a determination letter. You may access the request form by following the hyperlink, or by going to the "Guidance for Investigators" section of our website, where it can be found in the "Documents" section at the bottom of the page. It is important to ensure that the request form is completed in its entirety and personally signed by the appropriate personnel prior to submission to the IRB. All supporting documentation for your project, such as the protocol document, data collection forms, etc. must be submitted along with the request form. The more information you provide regarding your project, the better. Instructions for submitting your request are provided at the top of the form.

For more information, visit our website at http://www.mclaren.org/main/research-hrpp.aspx or call the HRPP office at 248-484-4950.

Remember

Investigators cannot make the determination whether or not a project is human subjects research. The IRB must make this determination.



Karmanos' BioBanking Protocol Exceeds Expectations

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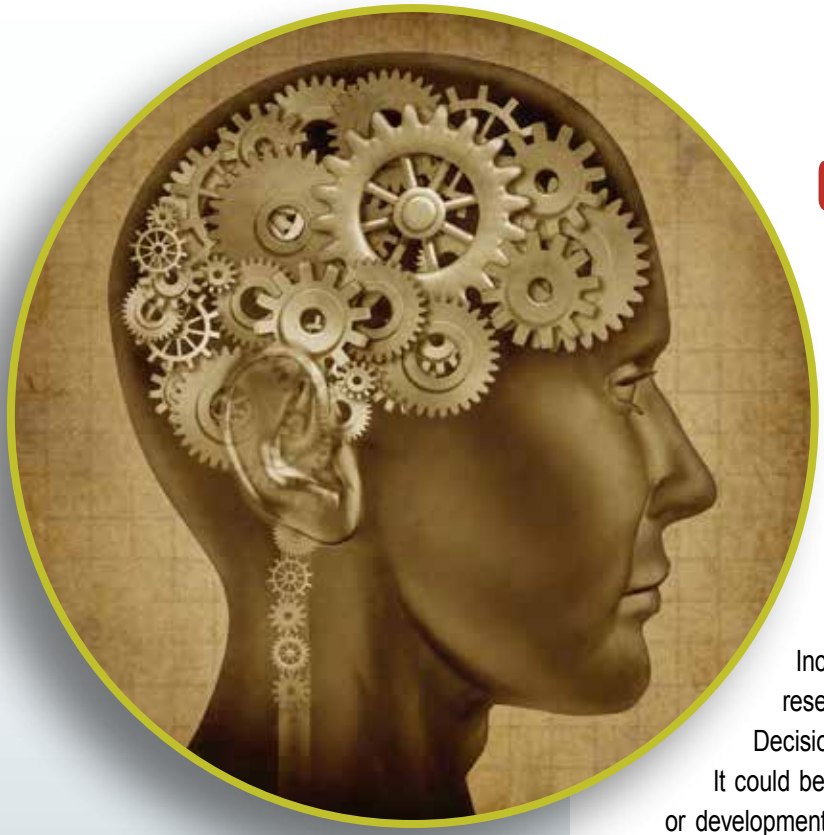
Yoo said. "These changes can also be linked to prognosis. If you have a particular genetic change it can either make your prognosis better or worse. The most likely next step is to ask whether tumors with these alterations respond better to a certain therapy. That's where we arrive at personalized treatment," he added.

The team of experts responsible for the processing, storage and distribution of the samples is the BioBanking and Correlative Sciences Core (BCS) at Karmanos. The BCS Core was established to support clinical trials at Karmanos, as well as to increase investigator-initiated clinical trials by providing preclinical laboratory support. The BCS Core also provides an organized, central biorepository of a diverse selection of high-quality human tissue specimens that meet the best practices of the NCI for quality biospecimens for cancer research. The Core facility is charged with collecting, banking and transferring fresh and frozen human tissue samples for investigative purposes.

The McLaren Corporate Research team assisted with the coordination between Karmanos in Detroit and the community-based sites to achieve these successful outcomes for all patients. Dr. Yoo has found the service a welcome boost to patient accruals on this protocol.

"Participation with McLaren Research has only strengthened our work at Karmanos and our ability to renew the NCI grant," Dr. Yoo said.

To learn more about the BioBanking Protocol and the BCS Core, contact Julie Boerner, Ph.D., at (313) 576-8351 or Renee Edelhauser at (313) 576-9794, or visit www.karmanos.org/biobank.



EQuIP Corner

Research Involving Decisionally Impaired Human Subjects PART 1

By Patricia Ivery, QI and Education Specialist

Including decisionally impaired persons in research presents researchers with unique ethical and legal dilemmas, and risks. Decisional impairment may be due to a number of different factors. It could be due to one of many disorders, including psychiatric, organic, or developmental disorders; drugs or sedation; or one of a number of other disorders that affect cognitive or emotional functions. Decisional impairment is not always permanent. It may be temporary or it may even fluctuate. Regardless of any of the above-mentioned factors, decisionally impaired subjects are considered vulnerable and susceptible to coercion and undue influence. Therefore, they may not provide legally effective informed consent.

Before enrolling decisionally impaired persons as subjects in research, you must first be aware of the ethical considerations, federal regulations, legal requirements, and institutional policies regarding decisionally impaired individuals.

Ethics

The Belmont report identifies three ethical principles that are relevant to research, the first being respect for persons, which incorporates the concept of self-determination. Decisionally impaired individuals may not understand the risks and benefits for participation in research, or have the capacity to communicate a choice. Therefore, decisionally impaired persons are not capable of self-determination. Lack of the capability of self-determination, thus makes them unable to autonomously provide informed consent. In order to adhere to the principle of "respect for persons" in such cases, a legally authorized representative (LAR) is involved in the consenting process.

Federal regulations

The Office for Human Research Protection (OHRP) and Food and Drug Administration (FDA) define (45 CFR 46.102, 21 CFR 50.3(1)) a LAR as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research". Both OHRP and FDA further state that the designation of a subject's legally authorized representative is to be determined by "applicable law", which typically means state

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Brown Bag Series

Protecting Vulnerable Subjects
February 14, 2017 • 12 - 12:45 pm
LIVE WEBINAR
Contact Markeda at (248) 484-4952

Upcoming Education and Conferences

ACRP 2017 Meeting & EXPO
April 29 - May 2, 2017 • Seattle, WA
https://www.emedevents.com/conferenceview/united-states-of-america/washington/seattle/medical-conferences-2016/association-of-clinical-research-professionals-acrp-2017-meeting-and-expo-49600

AAHRPP Annual Conference
May 9 - 11, 2017 • Detroit, MI
http://www.cvent.com/events/aahrpp-2017-annual-conference/event-summary-647e053fa9474296aeb1d95ed1f0283b.aspx

or local statutes, regulations or cases. In other words, not just anyone can sign as an individual's legally authorized representative. They must be able to provide appropriate legal documentation.

Federal regulations (45 C.F.R.46.116; 21 C.F.R. 50.20) also require that researchers obtain and document the informed consent of the subject or the subject's legally authorized representative before involving a subject in any research, unless the IRB has waived the requirement for informed consent.

Michigan Law

Michigan law (MCL 700.1105) defines an "incapacitated individual" as one "who is impaired by reason of mental illness, mental deficiency, physical illness or disability, chronic use of drugs, chronic intoxication, or other cause, not including minority, to the extent of lacking sufficient understanding or capacity to make or communicate informed decisions." Per MCL 700.5314, the legal guardian may consent to medical treatment for a legally incapacitated individual. However, Michigan laws does not specifically have language regarding consent for research on behalf of the cognitively impaired adults.

This may lead some to question whether or not those authorized to make medical decisions for a patient also have the right to make research decisions based on the best interest of the person. For McLaren Health Care researchers, the answer is clarified in our policy.

Human Research Protection Policy

McLaren policy (MHC_RP0115 - Obtaining Informed Consent) defines a legally authorized representative as an individual or body authorized by a court of competent jurisdiction as the legal guardian of an incapacitated person, pursuant to court order that grants the legal guardian the authority to approve the ward's participation in medical research studies. This policy also outlines the process researchers must follow when obtaining informed consent from a subject's LAR. Part 2 of this article, which will discuss specific consideration for including decisionally impaired persons in research, will continue in our next newsletter.

Photo Contest

Do you work in research? Would you like to have a photo of yourself, or your research team, featured in an upcoming Research Matters newsletter? Send us your best photo. Here's what to do:

- Make sure your photo is a resolution of 300 dpi or greater. (We will not be able to publish fuzzy photos).
- Dress nicely. Clothing doesn't need to be fancy, just neat and professional.
- Get close. If more than one person is featured in the photo, don't have a lot of space between you.
- Surprise us! We know you spend a lot of time on a computer, but we would like to show a variety of work duties and research work.
- Take credit. Let us know the department and the names of everyone in the photo.
- Have fun! Don't forget to smile!
- Email photos to Markeda.richards@mclaren.org by February 1, 2017

Chandan Gupte

Staff Updates

Congratulations to Chandan Gupte in her new role as Vice President for the Office of Clinical Excellence. Chandan will oversee the business operations of Research Administration [HRPP & MCRI], Quality, Safety, Value Analysis, CME and Regulatory. The Office of Clinical Excellence will facilitate the setting and adoption of system-wide standards that will help improve the quality of care and service that we deliver to our patients.

What's New?

If you have an idea for an article, or would like to share your comments on the Research Matters newsletter, please contact the newsletter coordinator, Markeda Richards at (248) 484-4952.

Karmanos Ranked Among Top Leading Academic Sites for Radiation Oncology Clinical Trials Patient Accruals

The Barbara Ann Karmanos Cancer Institute and Wayne State University have for the first time been ranked in the top 5 in clinical trials patient accruals for lead academic participating sites by NRG Oncology from January 1-June 2016. Karmanos received their number 4 ranking among the 30 lead academic participating sites that represent the nation's top centers for clinical trials.

The other top-ranked institutions include the University of Oklahoma Health Sciences Center in the top spot; Case Western Reserve University-Case Comprehensive Cancer Center in No. 2; Washington University-Siteman Cancer Center in No. 3; Karmanos/WSU in No. 4; Emory University-Winship Cancer Institute in No. 5; Memorial Sloan-Kettering Cancer Center in No. 6; and University of Texas M.D. Anderson Cancer Center in No. 7.

"By having a top 5 ranking, it not only demonstrates our capacity to grow in just one year, but also provides a level of prestige in a group that is already held in such high esteem," said Kiran Devisetty, M.D., member of the Department of Radiation Oncology at Karmanos Cancer Institute at McLaren Flint and medical director of Karmanos' Community Based Programs Radiation Oncology Research. "This demonstrates commitment of community physicians to the NCI and will enhance opportunities for Karmanos investigators to become leaders in the NRG."

At Karmanos' Community Based Programs, the increase in patient accruals to clinical trials has been driven by growth in radiation oncology research. In 2016, 39 patients were recruited to radiation oncology clinical trials in the community sites.

Clinical trials that have opened at the community-based sites involve brain, breast, head and neck, lung and prostate cancers, along with cancers that have metastasized to the brain and spine.

"Doctors are actively discussing with their patients the benefits of participation in clinical trials," added Dr. Devisetty. "This allows us to improve outcomes for our patients. That is very exciting."

"In 2014 when Karmanos joined McLaren Health Care, a driving goal was to expand the scope of research in Michigan," said Justin Klamerus, MD, MMM, interim president of the Karmanos Cancer Hospital and chief quality officer of Karmanos Cancer Institute. "The results of our NRG accrual show the power of integrating NCI comprehensive cancer centers with community partners."

"We had real growth in our clinical trials program, but we have much more work to do in the community," said Dr. Devisetty. "In order for patients to participate in a radiation oncology study, multiple levels of certification are required to take part in the clinical trials, including the establishment of treatment planning systems, completion of benchmark cases, and physician credentialing. That is a very labor intensive process and it truly is a team effort."

"I want to congratulate everyone who helped expand Karmanos' research mission to our patients in the community," said Dr. Klamerus.

Office of Clinical Excellence

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