The quarterly newsletter from Human Research Protections Program | ***Spring 2014***

HRPP Outlook

Corporate IRB ▪ Office of Research Education, Training and Resources ▪ Office of Research Compliance and Quality Improvement

McLaren's HRPP Welcomes a New Institutional Official

McLaren HEALTH CARE

MICHAEL MCKENNA, MD
Executive Vice President and Chief Medical Officer, McLaren Health Care

In April, McLaren's Human Research Protections Program (HRPP) will transition the duties of the Institutional Official (IO) from Alice Gerard, RN, MSN, to Michael McKenna, MD. Dr. McKenna serves as Executive Vice President and Chief Medical Officer for McLaren Health Care.

Ms. Gerard has played a key role in the evolution of McLaren's creation of a culture of protection for our research participants. It is the vision and leadership of Ms. Gerard that made McLaren's Human Research Protections Program a reality.

"I'm grateful for the opportunity to have worked with Alice closely for the last three years," said Lana Gevorkyan, Corporate Director of McLaren HRPP." Under Alice's leadership, human subject research protection at McLaren has become a strong program and is one of which we can be proud."

Since its inception in 2011, the HRPP program has:

- Achieved full accreditation in protection of human subjects
- Streamlined research review operations across all nine subsidiary hospitals
- Created a centralized IRB
- Implemented a system-wide electronic IRB system
- Enhanced compliance and operational efficacy across the research enterprise institution-wide
- Developed the educational system
- Created a number of new policies and processes to improve safety and compliance

"I'm pleased to welcome Dr. McKenna as the new IO and am looking forward to his leadership and guidance as we continue to build a strong research program while protecting the safety, rights and welfare of our research participants."
– Lana Gevorkyan

What is McLaren's HRPP?

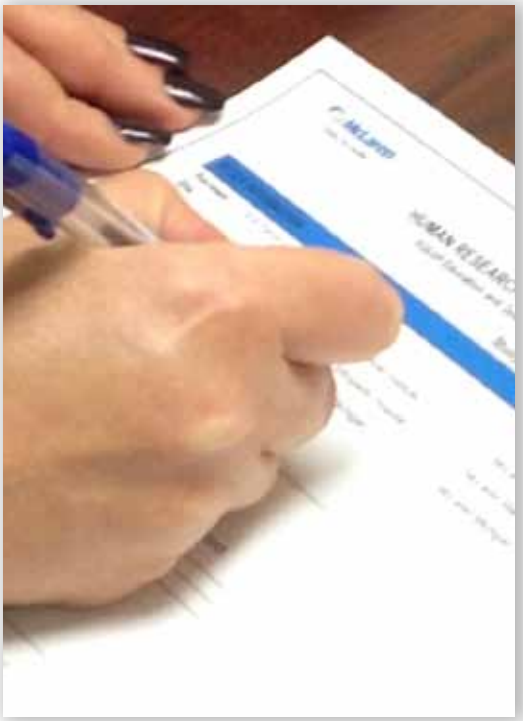
McLaren's HRPP creates a circle of protection for research participants and researchers by providing education and training, facilitating the Institutional Review Board (IRB) review and approval process, conducting post IRB approval monitoring and managing Conflict of Interest (COI) in Research.

Some of the responsibilities of HPPP include:

- Reviewing and monitoring of human subject research
- Assisting researchers in complying with federal, state and local policies regarding research involving human subjects
- Providing timely education to the research community
- Monitoring conduct of human subject research
- Ensuring compliance and address misconduct
- Developing standardized policies and procedures to ensure McLaren continues to meet accreditation standards in research

In partnership with the research community, the HRPP is responsible for ensuring the safety and welfare of participants in research projects conducted by McLaren's employees, physicians, and/or students using any McLaren facility.

EQuIP Quarterly



The Office of Research Education, Development, Training, and Resources, and the Office of Research Compliance and Quality Assurance work together to provide valuable resources to McLaren's research community in addition to conducting routine and 'for cause' study reviews. Our office provides:

- Corporate-wide training sessions geared toward all members of the research team

Look for our upcoming Educational Series!

- Specialized educational sessions for smaller groups (i.e. residents, coordinators)
- On-site review of human research studies
- Post-approval Quality Assurance (QA) and Quality Improvement (QI)

The submission of a research project can be intimidating, even for the most seasoned investigator. The good news is—HRPP is here to help! The Office of Research Education, Training, and Resources holds open office hours Monday, Wednesday, and Friday from 1:30-4:30 p.m. in our Burton Office located at 1198 N. Belsay Rd., Bldg #1, Burton, MI 48509. No appointment is necessary. Open office hours are intended to help researchers, including graduate students and residents, who are preparing Institutional Review Board (IRB) submissions and exemption requests. HRPP staff can assist you with:

- Navigating eProtocol (electronic IRB submission system)
- Steps required in submitting an eProtocol application
- Submitting a Request for Determination of Non-Human Subject Research
- Understanding policies and review procedures
- Exempt and expedited review processes
- Guidance on protocol development

Our website also holds a wealth of useful resources that can save you time; and perhaps a headache. Under "Guidance for Investigators" you can find the following and much more:

- Protocol templates for different types of studies
- Consent template
- Guidance on what is required to be submitted to the IRB
- The Investigator Handbook

Congratulations!

HRPP is happy to announce that Jodi Reetz has been promoted to Coordinator of Human Research Protections Program. In her new position, Jodi will provide coordination support of the operation of the HRPP department and will assist with program development. Her responsibilities will include assistance to our researchers, IRB members, and external agencies.

Conflict of Interest in Research

The recent change to McLaren HRPPs training requirements for investigators has sparked a number of questions, most commonly—"Why am I required to do more training if I have already completed my CITI course?" The answer lies in recent changes made by the Department of Health and Human Services (DHHS) regulations on conflicts of interest in research. In conducting human subject research, the well-being of the participants is paramount; their protection trumps the completion of the research. Conflicts of Interest (COI) in research must be taken into account by those determining the validity of a study to ensure research is being conducted ethically and within the best interest of the subjects.

Major changes to the regulations include:

- Requiring investigators to disclose to their institutions all significant financial interests related to their institutional responsibilities.
- Lowering the monetary threshold at which significant financial interests require disclosure, generally from $10,000 to $5,000.
- Requiring institutions to report to the Public Health Service awarding component additional information on identified financial conflicts of interest and how they are being managed.
- Requiring institutions to make certain information accessible to the public concerning identified significant financial interests held by senior/key personnel.
- Requiring investigators to complete training related to the regulations and their institution's financial conflict of interest policy.

In order to meet these requirements, McLaren's HRPP has contracted with the Collaborative Institutional Training Initiative (CITI). This online portal is the same used to meet our obligations for training in human subjects.

All investigators conducting human subject research are required to complete COI training (through CITI) by March 31, 2014.

Resident's Corner

Did you know?...

All research staff involved in abstracting data from medical records MUST be listed on the IRB application and approved to work on the study.

The HRPP office often receives questions regarding case reports, particularly from the resident population. It is important to be able to distinguish what is truly a 'case report' and what constitutes a 'case series'.

SINGLE CASE REPORT:

The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition of a single patient.* The following guidelines should be applied:

- Single case reports do not have to be reviewed and approved by the Institutional Review Board because they are not considered research
- Educational activities are considered part of health care operations; therefore, a HIPAA authorization is not required if the information in the case report does not allow the reader to identify the person
- Case reports should contain only de-identified information or pictures that totally conceal the identity of the individual.
  NOTE: Consultation with a privacy officer may be necessary to confirm that the data and pictures are de-identified. The privacy officer does have the authority to make this final determination.
- Written permission must be obtained from the individual if the data or the pictures are not de-identified.

CASE SERIES:

The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition in a ***series of patients**** (i.e., more than one patient).

- If the IRB determines that the case series meets the definition of human subject research then the investigator would need to submit an application for expedited/exempt review as long as patient identifiers are recorded (coded or none-coded) for later use.
- If it is determined by the IRB that the case series does not meet the definition of human subject research then no further action is required on behalf of the author.

Who do I call if I need help with an IRB submission?

The MHC IRB office has IRB analysts assigned based on subsidiary hospitals. The IRB analysts are available to assist you with your IRB submissions and answer any questions you have.
Please call (810) 342-1003.

** For a case series of two or more patients, review by the IRB would be required to determine whether or not it meets the definition of human subject research. For a more in depth definition, please see "Guidance on Case Reports / Case Series" under the Guidance for Investigators section of the HRPP website.*

Upcoming Educational Series
7 Habits of Highly Effective Coordinators

SESSION 1:
Ethics, Regulations and Responsibilities in Human Research Protection Part 1

March 28, 2014 • 8:30-9:30 a.m.

Tragic events in history involving human subject research have shaped the current state laws, United States federal code of regulations, and international good clinical practice guidelines governing clinical research today. This session will visit some of those tragic research events and discuss what the research community learned and took away to shape us today.

SESSION 2:
Ethics, Regulations and Responsibilities in Human Research Protection Part 2

April 11, 2014 • 8:30-9:30 a.m.

This session, a continuation of Session 1, will focus on McLaren Human Research Protection Program policies to protect human subjects. In addition, we will discuss the ramification of non-compliance and the responsibilities of the research team in protecting human subjects in research.

SESSION 3:
Informed Consent –Beyond the Basics

May 2, 2014 • 8:30-10:00 a.m.

Besides the who, when, where and how of consenting, this session will cover required and optional elements of the consent document, must-have documentation, consenting vulnerable populations, techniques to prevent undue influence, the framework of the ongoing consent process.

SESSION 4:
Essential Documents and Documentation

May 16, 2014 • 8:30-9:30 a.m.

Two common FDA and sponsor audit inspection findings are inadequate record keeping and lack of reliable, accurate and adequate source documentation. This session will focus on expected record keeping practices and the key principles of good documentation.

SESSION 5:
Subject Safety and Safety Monitoring

May 30, 2014 • 8:30-9:30 a.m.

Research subjects have the right to expect that the research team will watch out for their safety. This session will focus on key avenues ensuring your subjects safety including assessing, recording and reporting events involving the safe well-being on your research subjects.

SESSION 6:
Demystifying Clinical Research Audits

June 13, 2014 • 8:30-9:30 a.m.

The word audit seems to create dread and anxiety in those persons to be visited. Audits are a necessary exercise in ensuring research practices are operating in compliance. This session will cover the most common audit findings and how to prevent them. We will review the self-audit preparedness checklist tool that you can utilize to keep your study ready at all times for an audit.

SESSION 7:
Quality Improvement and CAPA Plan

June 27, 2014 • 8:30-9:30 a.m.

Education and Quality Improvement Program (EQuIP) is a proactive program to provide a resource to help facilitate high quality clinical research and compliance with applicable laws, regulations and SOPs. The quality improvement cycle is a planned sequence of activities aimed at improving a process. This session will review four steps of the quality improvement cycle (Plan, Do, Check and Act) and how the research coordinators can utilize these steps in their daily work.

Keep an eye on your email for registration details.

Getting to know the MHC IRB

The HHS Office of Human Research Protections and the FDA have specific requirements when it comes to the composition of an IRB. Per 45 CFR 46.107 and 21CFR56.107 an IRB must include:

- At least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution
- Both men and women. Every nondiscriminatory effort needs to me made to ensure that the membership is not composed of entirely men or entirely women
- At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas
- Include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution

In keeping with these guidelines the McLaren Corporate IRB member roster includes physicians, nurses, compliance personnel, teachers, clergy, privacy officers, and others with varying scientific and non-scientific backgrounds. By including such diversity, we are able to ensure the committee possesses the professional competence necessary to review specific research activities. We're grateful for our members' contributions, especially in the constantly evolving regulatory environment.

The IRB's decisions regarding the review of research are based on the ethical principles set forth in the Belmont Report, the Declaration of Helsinki, Michigan State Laws, Corporate HRPP policies, and the Code of Federal Regulations.

In this issue we would like to introduce two of our scientific members:

Dr. Tom Boike, MD

Dr. Boike is a board certified radiation oncologist currently serving as the Chief of Radiation Oncology at McLaren Northern Michigan. He previously served as Assistant Professor for Radiation Oncology at University of Texas Southwestern. Dr. Boike joined the MHC IRB as a primary scientific member in August 2012 and brings to the Board valuable experience in clinical trial development and enrollment.

Dr. Jonathan Abramson

Dr. Abramson is a medical oncologist with 35 years of experience. He is a private practice physician working out of McLaren Bay Region and is a long standing IRB member. Dr. Abramson brings a wealth of knowledge and experience in both study review and clinical trial development and enrollment to our IRB.

Transitions...

HRPP is sad to announce the resignation of Linda Schofield, RN, PhD. Linda has served as a scientific member of the MHC IRB since March 2012. We would like to thank Dr. Schofield for her participation and wish her well in her future endeavors.

This day in history...

The Belmont Report is 35 years old! On April 18, 1979 the Belmont Report was signed into law.

DON'T FORGET

Research CANNOT begin until the proposed study has been approved by the IRB. If you are conducting human subject research without IRB approval, you are in violation of Federal Regulations and subject to non-compliance.

Active Research Projects

Regulated PCI: A Randomized, Open-Label, Multi-Center, Active-Controlled, Parallel Group Study To Determine The Efficacy And Safety Of The REG1 Anticoagulation System Compared To BIVALIRUDIN In Patients Undergoing Percutaneous Coronary Intervention IND# 63,275 REG1 Anticoagulation System –McLaren Bay Region

A prospective, randomized study to assess treatment of renal calculi, renal injury, and cost at different rates of extracorporeal shock wave lithotripsy- McLaren Macomb

LPI-PE-1001: Observational Study on the Use of IV Iron Therapy Among Subjects with Iron Deficiency Anemia (IDA)- McLaren Cancer Institute (Medical Oncology Centers in Bay City, Flint, Lansing, Lapeer, Mt. Clemens, Mt. Pleasant, Petoskey, and West Branch)

Evaluation of Ischiofemoral Impingement and Predisposing Factors-McLaren Macomb, McLaren Oakland

Evaluation of Treatment Outcomes of Multichannel HDR Brachytherapy Skin Applicators for Treatment of Basal Cell Carcinoma and Squamous Cell Carcinoma of the Skin- McLaren Cancer Institute (Radiation Oncology Centers in Flint, Lapeer and Owosso

Depuy Polyethylene liner failures in THA patients-McLaren Orthopedic Hospital

Non-Invasive Treatment of Abdominal Aortic Aneurysm Clinical Trial (NTA^ 3CT)"-McLaren Northern MI

Inovate-HF: Increase of Vagal Tone in Heart Failure-McLaren Flint

Total Knee Arthroplasty: Comparative Outcomes of Four Total Knee Arthroplasty Designs-McLaren Orthopedic Hospital

Effect of Post-operative Brace Therapy on Knee Extension and Range of Motion Following Primary Total Knee Arthroplasty: A Randomized Controlled Trial-McLaren Orthopedic Hospital

A Phase III Randomized Double-Blind Placebo Controlled Trial to Evaluate the Efficacy and Safety of Nitazoxanide and Nitazoxanide plus Oseltamivir in the Treatment of Acute Uncomplicated Influenza-McLaren Bay Region

Safety of Same Day Discharge Post PCI in a Community Hospital-McLaren Macomb

Patient Experience after Diagnosis of a Heart Attack-McLaren Central MI

What is the Physician's Existential Experience of Medicine?- McLaren Flint

CRT Implant Strategy Using the Longest Electrical Delay for Non Left Bundle Brach Block Patients/(Enhance CRT) A Prospective, Randomized Post Market Pilot Study –McLaren Macomb

Prevalence of Statin Use in End Stage Renal Disease (ESRD) Patients and its Association with All-Cause Mortality, Cardiovascular Events – McLaren Flint

All-Polyethylene Unicompartmental Knee Arthroplasty: Outcomes and Survivorship at 5-7 years-McLaren Orthopedic Hospital

Implementation and Quantitative Evaluation of the PATH Program by McLaren for Patients with Cancer in Three Michigan Counties- MCI (Medical Oncology treatment centers in Clarkston, Lapeer, Mt. Clemens, and Pontiac)

McLaren HEALTH CARE

Mission statement: McLaren Health Care, through its subsidiaries, will be the best value in health care as defined by outcomes and cost.

If you have ideas for stories that you'd like to see in a future issue of ***HRPP Outlook***, lana.gevorkyan@mclaren.org.

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