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

HRPP Outlook

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

McLaren HEALTH CARE

Full Accreditation

2014 – The Year in Review, From the Corporate Director, HRPP

2014 was a busy year for the McLaren's Human Research Protections Program (HRPP). One of our major focuses for this year was completing goals that were set for the department toward the end of 2013. Introducing our program at a national research conference was toward the top of that list. This goal took some time to achieve but, alas, it came to fruition as we were selected for a poster presentation at the 2014 Advancing Ethical Research (AER) conference held by Public Responsibility in Medicine & Research (PRIM&R) in December 2014. This provided us the perfect opportunity to introduce the unique structure of our centralized Human Research Protections Program to a captive audience.

You may have noticed changes made to our website as well as the addition of some new educational offerings throughout the year. These changes were brought on by our goal to extend and improve our outreach and education activities throughout the McLaren research community. As with any program, education and consistency are major keys to success. With this goal in mind, the newly formed Education Quality Improvement Program (EQuIP) stepped up to the plate and began providing targeted educational sessions to streamline the approach to research throughout all McLaren subsidiaries. Patricia Ivery, our QI and Education Specialist, conducted a series of webinars entitled "7-Habits of Highly Effective Coordinators". This series, targeted toward research coordinators throughout the organization, was kicked off with a two-part session on ethics, regulations, and responsibilities of research coordinators. Subsequent webinars focused on providing coordinators with information regarding informed consent, documentation, subject safety monitoring, and audits. Most recently, EQuIP began

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Academic Advisors

Do you know if your student or resident's research project is compliant?

by Patricia Ivery

McLaren Health Care (MHC) presents a mecca of opportunities for medical students and residents to complete their required research projects. Key to their success is an effective academic advisor. As the academic advisor it is your responsibility to ensure that students/residents conduct their projects in compliance with McLaren Human Research Protection Program (HRPP) requirements. All proposed research activities must be submitted to the MHC Institutional Review Board (IRB) for review and approval. Investigators, including students and residents, must have an IRB approval prior to the commencement of any human subject research. Without proper direction, a seemingly simple chart review or abstracting data from a current study can become unnecessarily difficult.

Details on what training is required and how to access CITI can be found on the HRPP Office of Education and Training website (http://www.mclaren.org/Main/OfficeofEducationTrainingandResources.aspx).

If it is discovered that proper IRB procedures have not been followed for a study all resulting data, poster presentations, etc. will be disallowed.

McLaren Health Care has a centralized IRB which operates within the HRPP department. The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Before a resident or student is given clearance to begin their research projects they should be familiar with the IRB process. The MHC IRB website (http://www.mclaren.org/Main/IRB.aspx) is a terrific resource for information, including a step-by-step flow chart of the IRB submission process. This document can be found under the "Resident Corner".

One of the most commonly asked questions at the start of a research project is, "Does the research project meet the definition of "research" or "clinical investigation" and "human subject"?". Determination of human subject research is outlined in the HRPP policy MHC_RP01014 which can be found on the HRPP website under "Policies & Procedures". The most important thing to remember here is that the investigator, resident, student, or academic advisor shall not make the determination; determination of human subject research **can only be made by the IRB**.

Another commonly asked question is "Does research project qualify for exempt review? Again, this determination can only be made by the IRB. A detailed explanation of exempt review can be found

in HRPP Policy "MHC_RP0105 Exempt Review of Human Subject Research". Information on all IRB review categories is available under the "Guidance For Investigators" section of the MHC IRB website. All investigators proposing human subject research conducted at any McLaren subsidiary hospital or by employees, students, or agents of MHC or its affiliates, believed to meet the federal criteria for exemption must submit an exempt initial review application to MHC IRB using the eProtocol electronic submission system.

MHC IRB requires that all staff involved in the research process (IRB members, IRB staff, researchers, and others involved in the review of human research) be certified via the Collaborative Institutional Training Initiative (CITI) program, which provides research ethics education to all members of the research community. This includes residents and students conducting human subject research projects. In the event that you review the requirements and are still in need of assistance you may contact Jodi Reetz – HRPP Coordinator, at 810-342-1024. Jodi can assist you with getting set up in CITI and eProtocol as well as connect you with the IRB analyst for your site.

The Office of Research Compliance is here to answer any of your research compliance questions. In addition, this office conducts QA study reviews and for-cause audits as deemed necessary. Serious non-compliance or continuing non-compliance will be reported to the convened IRB and possibly to the Institutional Official including applicable federal regulatory agencies.

2014 – The Year in Review

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offering bi-monthly 'Brown Bag' education sessions. These sessions will take place around the noon lunch hour and are designed to accommodate all levels of personnel from investigators to coordinators.

Through EQuIP, we also started to measure and improve, when necessary, compliance with organizational policies and procedures and applicable laws, regulations and guidance as well as ensuring the effectiveness and efficiency of our Human Research Protections Program. To help achieve these goals, McLaren's Office of Research Compliance and Quality Improvement started to conduct on-site visits to identify the strengths and weaknesses of our program and to help increase quality, efficiency and effectiveness of the research enterprise at McLaren.

In the last 12 months the members of the MHC IRB have conducted more than 800 reviews. This includes review of new protocols, review of amendments to ongoing protocols, continuing review of ongoing protocols, etc. While it is difficult to directly compare the workload from institution to institution and the turnaround time for IRB review and approval, I'm happy to report that MHC IRB's turnaround times have improved. The average review of studies going to the FULL board takes 23 days from submission to approval; while expedited reviews take an average of 18 days. We will be working diligently to continue to improve the turnaround time. We would love to see our research portfolio grow year after year!

Lana Gevorkyan, Corporate Director, McLaren Health Care Human Research Protections Program

Evaluation of our program and subsequent policies and procedures is a perpetual process. We are continuously researching ways to improve our processes. As we look to the future, we would like to introduce multi-site capability in the eProtocol system, provide new and improved application forms, and introduce a new audit system (Comply Track) within the next 12 months. Additionally, we will make regular updates to our website with the hopes of providing as much information as possible, as efficiently and concisely as possible.

I would like to extend my sincere thanks to McLaren's research community including the HRPP team, IRB members, investigators and research personnel for all their dedication and hard work and all stakeholders for their continued support with our program.

Resident's Corner

Tis' the season to get a jump on your research projects for the coming year. Although events such as FAME, ACP, MOS and the like seem like an eternity away, it is best to start thinking about your project now. It is also wise to keep in mind that the IRB may have questions regarding your proposed project; early submission allows more time to address any questions the IRB may have. Remember, no project can be submitted for presentation without prior IRB authorization.

In order to conduct research at McLaren, all research personnel must complete human subject assurance training via the CITI program, as outlined on the HRPP Office of Education, Training, and Resources website (http://www.mclaren.org/Main/OfficeofEducationTrainingandResources.aspx). This training should take 2-3 hours in total to complete; however, you are not required to complete it in one sitting. You can start and stop in the middle of modules as needed. It is advisable to get started on training in the short term, as it will save you from racing to complete it later. Any questions regarding registration for or the completion of CITI training can be directed to Jodi Reetz, HRPP Coordinator at (810) 342-1024 or jodi.reetz@mclaren.org.

Where do I start?

The MHC IRB website (http://www.mclaren.org/Main/ForInvestigators.aspx) is a great resource for information regarding what is required to be submitted to the IRB, what types of reviews the IRB conducts, and how to go about submitting a project. Reviewing this information prior to beginning the submission process will save you time, headaches, and unnecessary time on the phone.

The "Guidance on What is Required to Be Submitted to the IRB" document will be of particular assistance, as it provides definitions of the various types of research and whether or not they are required to be submitted to the IRB. The last installment of the "Resident Corner" provided a flowchart to guide you from project conception through the IRB process. Residents should discuss all proposed research projects with an experienced academic advisor to ensure compliance with all applicable guidance and requirements prior to beginning the submission process.

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

The MHC IRB office.

Case reports... case series... what is the difference?

The two most common submissions we see from the resident population are case reports and case series projects. It is important to know the difference between the two and what is required by the IRB.

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:

- A Single Case Report does 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 conceal the identity of the individual completely. **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). For a case series of 2 patients or more, review by the IRB would be required to determine whether or not it meets the definition of human subject research.

- If the IRB determines that a case series meets the definition of human subject research then the investigator will 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.

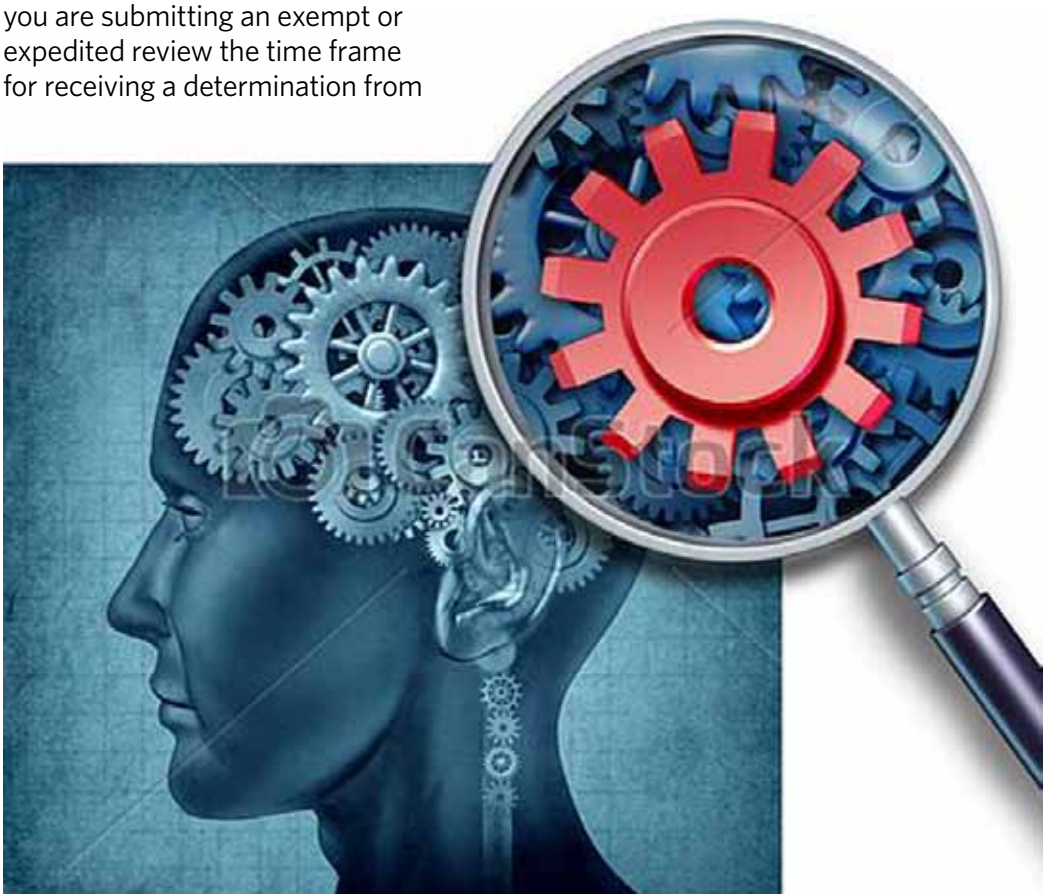
For more in depth definitions regarding case reports and case series, please see the "Guidance on Case Reports / Case Series" document under the Guidance for Investigators section of the HRPP website.

How long will it take the IRB to make a determination on my submission?

The timeframe for reviewing submissions varies. If you are submitting a simple Determination for Human Subject Research, you can expect an answer within 7 days of submitting the form to the IRB. In that time, the IRB analyst will carefully review the information you have provided. If you are submitting an exempt or expedited review the time frame for receiving a determination from the IRB will vary, as these types of submissions may be assigned to IRB members for review. It is vital that you respond to any questions / concerns posted by the reviewer in the eProtocol system during this process. Checking your email regularly is highly advisable, as the eProtocol system will send you an email to alert you when comments have been posted. Your timeliness in addressing these issues will directly affect the amount of time it takes to complete the review process.

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

The MHC IRB office staff is available to assist you with your IRB submissions and answer any questions you have. Please call (810) 342-1003.



Getting to know the MHC IRB

In addition to the 23 primary members that serve on the MHC IRB, there are 12 alternate members. Alternate IRB members are qualified voting members of the IRB and their role on the IRB is every bit as vital as that of primary members. Should a primary member be unavailable to attend an IRB meeting, an alternate member who has equivalent expertise may be called upon to attend IRB meetings to ensure a quorum is maintained, or may be invited to draw on his / her expertise in an area that may be relevant to deliberations at a particular meeting. Additionally, alternate members serve as reviewers on the many submissions received by the IRB throughout the year, allowing the IRB to draw on their expertise in various areas.

In this edition, we would like to introduce you to two of our long-standing alternate members, Dr. Andrew Teklinski and Dr. David Cook:

Meet David Cook, MD

Dr. Cook is board certified in internal medicine and medical oncology. He has served on the MHC IRB since April 2013. Dr. Cook regularly conducts study reviews for studies related to oncology and he serves as alternate member for Dr. Jonathan Abramson. Dr. Cook also has many years of experience as a researcher.

Meet Andrew Teklinski, MD

Dr. Teklinski is board certified in internal medicine with a subspecialty of cardiology. He has served on the MHC IRB since March 2013. He has conducted a number of study reviews in his time serving on the MHC IRB as an alternate member for Dr. Thomas Boike. Dr. Teklinski is also an active researcher, conducting studies out of McLaren Northern Michigan.

McLaren Healthcare Institutional Review Board

Listed here are the 2015 meeting dates for the MHC IRB. Our meetings take place the 3rd Friday of each month. Make note that the deadline for submissions to the MHC IRB is the last Friday of each month.

Meetings will be from 9:00 – 11:00 a.m. in the Garden Level Conference Room of McLaren Cancer Institute Flint at 4100 Beecher Road, unless otherwise specified by HRPP staff.

2015 Full Board Meeting Dates and Submission Deadline

MEETING DATE	SUBMISSION DEADLINE
January 16, 2015	December 26, 2014
February 20, 2015	January 30, 2015
March 20, 2015	February 27, 2015
April 17, 2015	March 27, 2015
May 15, 2015	April 24, 2015
June 19, 2015	May 29, 2015
July 17, 2015	June 26, 2015
August 21, 2015	July 31, 2015
September 18, 2015	August 28, 2015
October 16, 2015	September 25, 2015
November 20, 2015	October 30, 2015
December 18, 2015	November 27, 2015

NEW Active Research Projects

New studies open to enrollment at McLaren since September 2014. ***For a complete list of studies please visit our website at: http://www.mclaren.org/Main/ClinicalTrialsHRPP.aspx***

GraftMaster RX Coronary Stent Graft System (Humanitarian Device Exemption)

Now open at McLaren Port Huron

SCUSF 0806, "Phase II placebo-controlled trial of lisinopril and Coreg CR® to reduce cardiotoxicity in patients with breast cancer receiving (neo)adjuvant chemotherapy with trastuzumab (Herceptin®)"

MCI (Medical Oncology centers in Bay City, Clarkston, Flint, Lapeer, Mount Clemens, Mt. Pleasant, Petoskey, and West Branch)

Inflammation Pathways and COPD in the Development of Lung Cancer: The INHALE Study

McLaren Greater Lansing

Upcoming Education

BROWN BAG SESSIONS!

The Education Quality Improvement Program (EQuIP) has begun offering Brown Bag education sessions. These sessions are provided in a webinar format and take place around the noon lunch hour. Sessions are open to all research professionals, coordinators, residents, students, staff or faculty.

Topics will vary based on feedback / suggestions from the McLaren research community. If you have suggestions for a topic please contact Patricia Ivery, Education & QI Specialist at patricia.ivery@mclaren.org.

Our next Brown Bag Session:

Legal Liabilities of Clinical Trials

Tuesday, December 16, 2014 • 12:00 - 12:45 p.m.

For details, please contact Jodi Reetz at (810) 342-1024.

IRB TIP

The Submission deadline for research projects that need to be reviewed by the full board is the last Friday of the month prior to the meeting. Keep in mind that the following factors can delay your submission:

- **Unclear summary of the proposed research. Clear concise documentation will eliminate many questions from the reviewer. Remember, this is the first time they are reading this information!**
- **Not responding to comments/questions posted by the reviewer. The longer it takes for the researcher to provide answers to questions posted in eProtocol or address issues that need to be corrected regarding the study, the longer it takes for approval. Checking your email often is advisable.**
- **Missing documentation/training. Study-related documentation that is not provided in a timely manner delays the review process. Additionally, the IRB cannot issue an approval if the PI has not completed required Human Subject Assurance training. Please visit our website for details on required training. http://www.mclaren.org/Main/OfficeofEducationTrainingandResources.aspx**

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.

Assistance for Researchers:

Do you have questions related to eProtocol, IRB forms, policies, or review procedures?

Our Office of Research Education, Training and Resources holds office hours to help Researchers, including graduate students and residents, who are preparing Institutional Review Board (IRB) submissions and exemption requests. Sessions are intended to help researchers, students and their advisors navigate eProtocol (electronic IRB submission system) and learn about policies and review procedures.

No appointment is necessary. Please contact Jodi Reetz at (810) 342-1003 or (810) 342-1024 or via e-mail at Jodi.Reetz@mclaren.org for questions or more information.

Assistance for IRB Members:

Do you have questions related to eProtocol, IRB member checklists, policies, IRB review process or IRB criteria for approval?

Our Office of Research Education, Training and Resources holds office hours to help IRB Members to navigate eProtocol (electronic IRB submission system) and learn about policies and review procedures, including newly developed checklists. Sessions could be done either in person or via telephone.

No appointment is necessary. Please contact Jodi Reetz at (810) 342-1003 or (810) 342-1024 or via e-mail at Jodi.Reetz@mclaren.org for questions or more information.

Q. Regulations pertaining to Human Subjects Research can be found where in the Code of Federal Regulations?

Submit your answer to HRPP@mclaren.org. The first person to submit the CORRECT answer to the following question will receive a **$10 Starbucks gift card**!

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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