The quarterly newsletter from Human Research Protections Program | ***Spring 2015***

HRPP Outlook

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

McLaren HEALTH CARE

Full Accreditation

EQuIP Corner

Quality Assurance and Quality Improvement in Clinical Research

Within the arena of patient care or medical services, we often hear and see the words quality assurance (QA) and quality improvement (QI). Both QA and QI are referenced to involve measurement and improvement in patient care outcomes, better system performance and better professional development. What is the difference between quality assurance and quality improvement?

Quality assurance (QA) is a program of systematic monitoring and evaluation of the various aspects of a project, service or facility to ensure that standards of quality are met. Quality improvement (QI) is an ongoing and continuous process initiated to improve a practice or procedure; and to institutionalize that practice in order to achieve the desired standard or outcome.

Hospitals are monitored and evaluated on the quality of care they provide to patients according to standards set by accrediting bodies such as the Joint Commission. Insurance companies such as Medicare or Blue Cross Blue Shield also evaluate hospitals by quality measurements. The care of research subjects is monitored and evaluated as well. Specific regulatory authorities and groups have been charged with protecting human research subjects.

Most of the regulatory authorities governing human subject protection fall under the umbrella of the Department of Health and Human Services. These include the Food and Drug Administration (FDA) and Office of Human Research Protection (OHRP). Both the FDA and OHRP have codes of federal regulations (CFR) that can be seen as measurements of standards to be followed by those conducting human subject research.

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EQuIP Corner

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Codes exist to cover the activities of the clinical investigator, the sponsor, and the Institutional Review Board (IRB). The responsibility of ensuring that these CFRs are upheld falls onto groups monitoring research studies, such as the IRB and the Human Research Protection Program (HRPP).

The McLaren Health Care Human Research Protections Program (HRPP) encompasses the IRB, the Office of Research Compliance and the Office of Research Education, Training and Resources. The mission of the IRB is to ensure human research subjects are protected; while the role of the Office of Research Compliance is to ensure the mission of the IRB is carried out. The role of the Office of Research Education, Training and Resources is to provide timely and high quality education, guidance and resources for the research community. In 2014, the Education and Quality Improvement Program (EQuIP) was created. This program is a joint venture between HRPP's Office of Research Compliance and the Office of Education, Training and Resources. EQuIP performs QA/QI activities as a method to protect the rights and welfare of human research subjects. These activities are geared toward ensuring the compliance of research activities with state and local laws, regulations, and institutional policies governing the conduct of research and ethical behavior. Compliance, together with applicable facets of each area, represent the standards which all involved in clinical research must follow. The QA/QI activities performed by EQuIP include:

Quality assurance

- Random routine QA reviews
- Directed or 'for-cause' audits
- Investigator-requested QA reviews
- IRB & HRPP reviews
- Point of contact for research-related complaints
- Assistance with preparation for external audits by sponsors or Federal agencies
- Assistance with IRB submissions, reporting and record-keeping
- Consultation to investigator and study personnel

Quality assurance (QA) is a program of systematic monitoring and evaluation of the various aspects of a project, service or facility to ensure that standards of quality are met. Quality improvement (QI) is an ongoing and continuous process initiated to improve a practice or procedure; and to institutionalize that practice in order to achieve the desired standard or outcome.

Quality improvement

- Develop and implement corrective action plans in response to internal and external investigations and inspections
- Data collection and analysis to identify performance gaps
- Provide educational sessions to the research community through webinars, formal and informal in-person guidance, as well as providing study tools and resources
- Policy development

The cycle of quality assurance and quality improvement is continuous. Assessment, evaluation, analysis, improvement plans, and institution of plans are all critical steps necessary to measure and improve standards of care. All research sites will undergo a QA/QI review at some point in the future.

For questions regarding the process or to request a QA/QI review of your study, please contact the EQuIP office at 810-342-1028. We are here to help!

In our next issue we will discuss the nuts and bolts of the QA review/audit.

What does it mean if my project qualifies for 'Expedited Review'?

A very popular misconception throughout the research community is that the term 'expedited review' is synonymous with 'quick review'. Not true. An expedited review is still a thorough review. The Office for Human Research Protections (OHRP) website states that "An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110." In order to qualify for expedited review, research activities must present no more than minimal risk to human subjects, AND involve procedures in one or more of the following research categories:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3) Prospective collection of biological specimens for research purposes by noninvasive means.
4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and

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Resident's Corner

HELP! I have a research project and I don't know where to start!

As a new researcher, it is easy to feel like a deer caught in the headlights of oncoming traffic. With so much new information being thrown at you at once, feeling overwhelmed is normal. GOOD NEWS! There are many resources available to assist you. The first, and most important, is your academic advisor. Meeting with your academic advisor to review your research proposal is an essential first step. Review your project in depth with your advisor(s) to ensure that your project includes all of the elements necessary for compliance with local and federal regulations prior to IRB submission. For all student research (residents, nursing students, etc.), the IRB requires a Confirmation of Scientific or Scholarly Review for Validity form **signed by the academic advisor or your program director**. This indicates to the IRB that the academic advisor finds the study to be scientifically sound and that it can reasonably be expected to answer the proposed question. Academic advisors are also responsible for ensuring that enough resources are available to conduct the research in a way that it will protect the rights and welfare of research participants.

Additionally, the McLaren Center for Research and Innovation (MCRI) offers researchers resources such as protocol development and statistical analysis. To learn more about MCRI, please contact them at either MCRI@mclaren.org, or (810) 342-1025. You may also visit their website at http://www.mclaren.org/Main/ClinicalTrialsManagementProgram.aspx

HRPP/MCRI

Going forward, the HRPP and MCRI will be working together to provide an introductory session to all new residents during the orientation period. This will help introduce both programs and to allow new researchers the opportunity to tap into the available resources.

Are you participating in FAME?

If you are submitting a single case report for FAME, the Guidance on Case Reports sheet found on our website can be uploaded to the FAME database in lieu of IRB approval.

Other available resources:

MHC HRPP website
www.mclaren.org/Main/HumanResearchProtectionsProgramHRPP.aspx

Here you will find information regarding the IRB, local policies and procedures, federal regulations regarding human subject research, training requirements, education offerings, and much more. This is definitely a site to bookmark in your favorites! It is advisable to familiarize yourself with this information prior to beginning the submission process. It will save you time, headaches, and unnecessary frustration.

Office for Human Research Protections (OHRP)
www.HHS.gov

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.

HHS.gov Code of Federal Regulations (45 CFR 46)
www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Provides the basic HHS policy for the protection of human research subjects.

MHC HRPP Office
Our staff is available via telephone Mon.-Fri. from 8:30 a.m. to 5:00 p.m.

We also hold open office hours Mon., Wed., and Fri. from 1:30-4:30 p.m. No appointment is necessary. Open office hours are designed to help researchers, students and their advisors navigate eProtocol (electronic IRB submission system) and learn more about policies and review procedures. Please contact Jodi at (810) 342-1003 or jodi.reetz@mclaren.org for more information.

Expedited Review

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social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:
   (a) where :
      (i) the research is permanently closed to the enrollment of new subjects;
      (ii) all subjects have completed all research-related interventions; and
      (iii) the research remains active only for long-term follow-up of subjects; or,
   (b) where no subjects have been enrolled and no additional risks have been identified; or,
   (c) Where the remaining research activities are limited to data analysis.
9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories 2 - 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

A more comprehensive list of specific criteria can be found on our website:

http://www.mclaren.org/Main/ForInvestigators.aspx.

Did you know?

The role of the IRB member involves much more than a meeting once a month. In addition to attending regularly scheduled IRB meetings, our IRB members:

- **Review all study submissions scheduled for full board review**
- **Perform reviews of expedited study submissions, as assigned**
- **Keep current on local and federal regulations and policies regarding human subjects research**
- **Participate in educational activities**
- **Maintain current human subjects assurance training via Collaborative Institutional Training Initiative (CITI)**

Getting to know the MHC IRB

Meet Majid Mughal, MD

In this edition we would like to introduce you to one of the newer members of our team. Majid Mughal, MD, joined the MHC IRB in April 2014. He is an interventional cardiologist with McLaren Cardiovascular Group in the Lansing area. Dr. Mughal is board certified in cardiovascular disease, pulmonary disease, critical care medicine, and sleep medicine. Welcome Dr. Mughal!

Transitions...

HRPP is sad to announce the resignations of two of our long-standing members. Dr. Jonathan Abramson has served as a primary member of the MHC IRB since January 2012. Dr. Angela Xavier joined us an alternate member in January 2012, transitioning to the role of primary member in October of the same year. We would like to thank both Dr. Abramson and Dr. Xavier for their time, dedication, and participation and wish them well in their future endeavors.

New IRB Analyst...

Jodi Reetz has been promoted to IRB Analyst within McLaren's Human Research Protections Program. Jodi joined the program three years ago and has climbed the professional ladder with absolute adeptness from an administrative assistant to HRPP Coordinator and now to IRB Analyst.

During her time in the HRPP department, Jodi has taken on additional responsibilities and worked very hard to learn about IRBs, ethics, research compliance and research in general. In her new role, Jodi will be responsible for working with our researchers and supporting the operations of the MHC IRB office.

You spoke. We listened!

After talking to our researchers and research coordinators and re-evaluation of the current applications in our electronic submission system, key areas for improvement were identified. As a result, the MHC IRB office has been working diligently with KSI (the vendor for the eProtocol electronic IRB submission system) to develop new forms such as Humanitarian Use Device (HUD) and Chart Review forms and to make improvements to our existing submission forms. The new and improved forms should be available in the beginning of April.

NEW Active Research Projects

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

A Multinational, Randomised, Double-Blind, Placebo-Controlled Trial to

Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus [THEMIS - effect of Ticagrelor on Health outcomes in diabEtes Mellitus patients Intervention Study] [Ticagrelor IND# 119,344]

– McLaren Macomb

A prospective Randomised, open label, blinded endpoint (PROBE) study to

Evaluate DUAL antithrombotic therapy with dabigatran etexilate (110mg and 150mg b.i.d.) plus clopidogrel or ticagrelor vs. triple therapy strategy with warfarin (INR 2.0 – 3.0) plus clopidogrel or ticagrelor and aspirin in patients with non valvular atrial fibrillation (NVAF) that have undergone a percutaneous coronary intervention (PCI) with stenting. (Re-DUAL PCI) [Dabigatran IND# 65,813]

– McLaren Bay Region

Patient-centered Research into Outcomes Stroke patients Prefer and Effectiveness Research (PROSPER)

– McLaren Northern Michigan

Evaluating the Role of Capsule Endoscopy Through Michigan Gastroenterology Institute

– Michigan Gastroenterology Institute

SPIRE LL - A 52 Week, Phase 3 Double-Blind, Randomized, Placebo-Controlled,

Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of PF-04950615 in Subjects with Primary Hyperlipidemia or Mixed Dyslipidemia at Risk of Cardiovascular Events (SPIRE LL - Studies of PCSK9 Inhibition and the Reduction of Vascular Events - Lipid Lowering) [PF-04950615 - IND# 104,872]

– McLaren Flint

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

Upcoming Education

2015 BROWN BAG SESSIONS ANNOUNCED!

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. Keep an eye on your email for registration information.

UPIRSO Revisited

June 9, 2015

Privacy and Confidentiality

September 8, 2105

HUDs and Emergency Research

December 8, 2015

NEW POLICY**

The following new policy is now available:
MHC_RP0128 Relying on an External IRB as an IRB of Record
A full list of current HRPP policies can be found on our website at:

http://www.mclaren.org/Main/IRBPoliciesProcedures.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.

Congratulations to our very first trivia winner!

Susan Baade from Dr. Sukamal Saha's office!
Enjoy your Starbuck's gift card, Susan!

Question: Who are investigators required to notify of complaints from subjects? HINT: this can be found in an HRPP policy!

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!

Winter 2014 Trivia Question: *Regulations pertaining to Human Subjects Research can be found where in the Code of Federal Regulations? A: 45 CFR 46*

McLaren HEALTH CARE

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