The quarterly newsletter from Human Research Protections Program | ***Issue 2 Fall 2012***

HRPP Outlook

Corporate IRB • Office of Research, Education, Development, and Training • Office of Research Compliance and Quality Improvement

Message from the President of McLaren – Bay Region and Institutional Official of McLaren Human Research Protections Program.

McLaren HEALTH CARE

In early 2011, McLaren Health Care Corporation's (MHC) leadership made the decision to develop a corporate Human Research Protection Program (HRPP). A tremendous amount of planning and consensus building went into the development of this program.

MHC leadership had a number of reasons to create this corporate structure. The main reason was to regulate and monitor research with human participants within our healthcare system. Corporate standards, policies and guidelines to ensure protection of research participants' rights and welfare were created. We are now even more confident that all MHC subsidiaries are following the same standards for research, as well as ensuring that the entire MHC is in compliance with Federal regulations for the conduct of research.

There are many advantages of centralization. They include:

- Minimizing duplication, allowing one single transition with the Centralized Institutional Board (IRB) for our Principle Investigators to initiate research
- Keeping abreast and responding quickly to regulatory changes
- Centralizing data tracking
- Creating consistency and better accountability.

We are still in the infancy stages of our Human Research Protection Program. Our plan is to continue to develop the program through education of our staff, Principal Investigators, Central IRB members, and Medical staff. Our hope is to grow our program and be the model for other organizations that wish to create programs similar to ours.

The HRPP staff is exceptionally talented and experienced. I am confident that they have the ability to create a best practice model of Human Research Protection Programs in the country.

ALICE GERARD, R.N., M.S.N., President/CEO McLaren Bay Region, Institutional Official of the MHC Human Research Protections Program

Meet the IRB Chairman

M. Ammar Hatahet, MD, MPH, FACP, is an internist and diabetologist in solo private practice. He was appointed the as the Chairman of the McLaren Health Care Institutional Review Board (MHC IRB) in January 2012. Dr. Hatahet is very passionate about research and the protection of human subject participants. He promotes a culture consistent with the objectives of McLaren's Human Research Protection Program (HRPP), with special emphasis on the respect for, and protection of individuals participating in research at all McLaren subsidiary hospitals.

In addition to his private practice, Dr. Hatahet serves as the Director of Clinical Research and Education and as the Chief of Internal Medicine at McLaren Oakland hospital. As the Director of Clinical Research, his activities include lecturing, mentoring residents, overseeing all research activity at McLaren Oakland, in addition to overseeing the abstracts and activity for their annual Research Day.

Prior to joining McLaren Oakland, he served as the Director of Ambulatory Practices and Interim Chief of General Internal Medicines at Wayne State University where he also sat as a member of the WSU IRB. In addition, he directed the Medical Weight Loss Program and was involved with clinical research surrounding diabetes and weight loss. Dr. Hatahet also served as the Director of the Primacy Care Initiative at the Medical College of Wisconsin.

Dr. Hatahet has been in clinical practice since 2004 where he continues to teach residents and students from Michigan State University. In 2002, Dr. Hatahet received an MPH in Health Management and Policy from the University of Michigan. This, and additional involvement in practice initiatives such as Improving Performance in Practice initiative (IPIP), led to Dr. Hatahet's practice being designated as a Patient Centered Medical Home in July of 2010.

The Three Things to Remember When Doing Research!

1. Do not enroll more participants than stated in the protocol and IRB application without prior IRB approval!

The number of participants to be studied in the research must be stated in the original protocol and should be based on sound research methods. When approving research, MHC IRB will consider the number of participants who will be exposed to the research interventions to evaluate the risks and benefits of the study. If it appears that the number of participants will need to be increased to meet the goal of research, investigators must submit and receive IRB approval for an amendment before proceeding.

2. Do not change your protocol, consent form, survey or interview questions without IRB approval.

By regulation, changes may not be made to approved research without prospective IRB review, except when necessary to eliminate hazards to participants (very rare). Proposed changes must be submitted to the MHC IRB via Amendment using eProtocol. Investigators will receive written confirmation of IRB approval of amendments when approved and should not enact changes until then.

3. Do not begin recruitment or data collection without IRB approval.

McLaren Investigators may not begin research, including recruitment of participants or data collection, without first receiving written notice of approval from the IRB.

Understanding the IRB Review Processes

It is important to understand the various review processes when submitting a study for IRB review. The types of review are exempt, expedited, and convened (full).

Exempt research must fit into categories specified by federal regulation. Common examples of exempt research are surveys not linked to identities of subjects and study of existing data (records, specimens) that do not have links or codes to identifiable information. Other examples of human subject's research that may be exempt include: anonymous surveys, (non-sensitive) interviews, observations of public behaviors. Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization is not exempt. Surveys or interviews involving children are also not exempt. Investigators who believe their research is exempt should complete the exempt application and submit it along with a research proposal and any required attachments using eProtocol (electronic submission system). Exempt determinations are made by the McLaren Corporate IRB Office.

If Investigators are not sure whether their study is ***"research"*** or involves ***"human subjects"***, they may request a determination from the McLaren Corporate IRB Office using the "Request for Determination of Non-Human Subject Research" located on our website.

Expedited review can be performed when there is not greater than minimal risk to subjects and the research falls into one (or more) of nine categories listed in 45 CFR 46.110. Examples of research that can receive expedited review are focus groups, noninvasive procedures (e.g., electrocardiography), use of specimens collected for non-research purposes, and videotaping of teaching methods. Minor changes to research and continuing reviews may also qualify to be reviewed by expedited procedures. Expedited review is performed by the IRB Chair and/or an experienced IRB member.

Convened or full board review is required for research that poses greater than minimal risk. These risks include physical, psychological, social, legal, and economic harms. The processing time for a protocol requiring convened review varies, depending upon how complete the application is at submission. The minimum amount of time to process an application is three to four weeks. Investigators are encouraged to start working on the applications as soon as possible and submit in time for the next convened meeting. Meeting dates/times and submission deadline dates are available on our website at http://www.mclaren.org/Main/IRBMeetingDates.aspx

Did you know.....?

Investigators play a key role in ensuring a strong program of human research protections. Following policies and procedures, and professional practice standards helps ensure the ethical conduct of human subject research.

IRB Members are Invaluable

According to Federal Regulations, an IRB must have "at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution". Each IRB should consist of both men and women, from varied professions. In addition to members who have expertise in science, the IRB should also have at least one member whose primary concerns are in non-scientific areas, and one member who is not otherwise affiliated with the institution. IRB members are charged with the responsibility to protect the rights and welfare of people involved in research. Members who are not affiliated with the institution are asked to reflect community attitudes and often also represent vulnerable populations that may participate in research. Moreover, IRBs are charged to ensure that the basic criteria needed for IRB approval of human subjects' research are met.

The Basic Criteria for IRB Approval of Human subject research are listed below and adapted from 45 CFR Part 46.111.:

1. Risks to participants are minimized:
   a. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
   b. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the advancement of knowledge.
3. Selection of participants is equitable.
4. Informed consent will be sought from each prospective participant or his/her legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect participants.

McLaren Corporate Institutional Review Board (IRB) consists of 20 primary members plus alternates whose membership is shared by representatives from each McLaren subsidiary hospital. Members have the professional competence necessary to completely and adequately review human subjects' research activities commonly conducted by McLaren Investigators.

Special thanks are extended to our dedicated members for agreeing to serve on the Corporate IRB to ensure that the rights, safety and well-being of the research participants are protected.

McLaren Corporate IRB Members

McLaren Bay Region

Jonathan Abramson, MD
David Cook, MD
Mike Jamrog, BBA
Khalil Masri, MD
Jay Summer, MD
Sue Vasquez, RN

McLaren Central Michigan

Henry Armah, MD
Ashok Vashishta, MD

McLaren Greater Lansing

Dale Thompson, BBA, CMA
Linda Peterson, MD
Sandra Russell, MD

McLaren Flint

Aamir Ahsan, MD
Fr. Gene Geromel
David Hoff, CCP, MAOM
April Scrimger
Nancy Smith
Cathleen Hipps
Jim Offrink
Jean Valley
David Wiese, MD

McLaren Macomb

Maureen Decker, MBA
Carol Fossee, JD
Jessica Gherardini, PharmD
John Kazmierski, MD
Kathy Malfroid

McLaren Northern Michigan

Thomas Boike, MD
Harry Colfer, MD
David Corteville, MD
Maggie Daniels, RN, MA
Justin Klamerus, MD
Barbara Kurtz, RN, MSN
Linda Schofield, RN, PhD
Barbara Stone, RN

McLaren Oakland

M. Ammar Hatahet, MD
Jim Phillips
Michael Remley, DO
Michelle Thatcher, PharmD
Mary Jo Voelpel, DO
Angela Xavier, MD

McLaren Health Care

Elizabeth Mihailoff, BBA, CIM
Mary O'Connor, RN, BSN

McLaren Human Research Protections Program (HRPP) is saddened to announce the departure of one of our very valuable scientific members, Dr. Justin Call. Dr. Call was appointed as a primary member to serve on the McLaren Corporate IRB in March of 2012 and was representing McLaren Northern Michigan. Dr. Call and his family relocated to Salt Lake City, Utah. We wish him well in his new endeavors.

HRPP is pleased to announce the addition of the scientific members to our Corporate IRB. Please welcome our newly appointed members from:
McLaren Northern Michigan: Dr. Thomas Boike and Dr. David Corteville
McLaren Central Michigan: Dr. Henry Armah
McLaren Greater Lansing: Dr. Linda Peterson

Did you know.....?

Meeting the submission deadline allows adequate time for processing, IRB review, and investigator responses prior to approval expiration dates. Thanks to the diligence of our Investigators and research staff, the number of last-minute continuing review submissions has decreased.

Recently Updated Policies

The following policies were recently revised as part of our ongoing, behind-the-scenes efforts to bring conformity to our policies and procedures. Please take a few minutes to review these and other policies located on our website at:
http://www.mclaren.org/Main/IRBPoliciesProcedures.aspx

MHC_RP0103	Determination of Human Subject Research
MHC_RP0104	Exempt Review of Human Subject Research
MHC_RP0105	IRB Documentation and Records
MHC_RP0106	IRB Membership
MHC_RP0107	IRB Evaluation Criteria
MHC_RP0108	Record Retention and Accessibility
MHC_RP0114	Full Board Review of Human Subject Research
MHC_RP0122	Protocol Deviations in Human Subject Research
MHC_RP0123	Humanitarian Use Device
MHC_RP0124	Use of Medical Devices in Human Subject Research
MHC_RP0125	Use of Drugs and Biologics in Human Subject Research
MHC_RP0128	Emergency Use of Investigational Drugs and Devices

As a reminder, in addition to complying with all the policies and standards of the governing regulatory bodies, the Investigators and research staff must comply with institutional requirements for conducting research. The McLaren Health Care Human Research Protections Program (MHC HRPP) strongly encourages researchers and research staff to familiarize themselves with these and other policies that are available on the Intranet and our website. Policies should be referenced regularly as they are revised to stay current with evolving issues and regulations related to human subject research.
If you have any questions or require additional assistance, please do not hesitate to contact MHC HRPP Office.

Recently Created Form(s)

As we strive to improve our processes, McLaren Health Care Institutional Review Board (MHC IRB) has developed a form entitled "Request for Determination of Non-Human Subject Research". This form can be found at http://www.mclaren.org/Main/IRBForms.aspx and must be utilized when Investigators are unsure whether their study is "research" or involves "human subjects".
As a reminder, it is the requirement of McLaren Health Care Human Research Protections Program (MHC HRPP) that all research involving human subjects at McLaren Health Care subsidiary hospitals must be reviewed by the McLaren Health Care Institutional Review Board (MHC IRB). If you are unsure whether your study is "research" or involves "human subjects", you may request a determination from the MHC IRB. Please allow ample time for MHC IRB to review your request and make the determination, keeping in mind that you might be asked to submit an Initial Application if your study is determined to be "research" or involves "human subjects".

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.

Research is constantly evolving along with new techniques and guidelines. We would like to use this newsletter as a means to keep the research community and others aware of these changes.

Additional emails will be provided in a timely manner when they consist of the following issues:

- **new federal regulations**
- **revised policy and procedures**
- **revised applications**

Active Research Projects

APPROVED BY MHC IRB since JUNE 0f 2012

For a complete list of all research project that are open to accrual, please visit our website at htt://www.mclaren.org/main/researchclinical.aspx or contact HRPP office at (810) 342-1003.

- NSABP B-49: A Phase III Clinical Trial Comparing the Combination of Docetaxel plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer Available at McLaren – Bay Region, McLaren - Flint, McLaren – Lapeer, McLaren – Macomb and McLaren – Northern MI

- RTOG 0924: Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial Available at McLaren – Flint

- RTOG 1012: Phase II Randomized Trial of Prophylactic Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis-Related Pain During the Treatment of Lung Cancer
Available at McLaren – Macomb and McLaren – Flint

Upcoming Educational Session:

The next Educational Session presented by the HRPP:

Research Coordinators and Others: "Ask the IRB" and "Informed Consent form and Process". In these sessions IRB Analysts will discuss all the elements that are required in the informed consent form and will provide some examples of the informed consent process. Audience will have an opportunity to ask questions about IRB submissions, eProtocol and IRB applications.

Date and Time to be Determined. The session will take place at the McLaren Cancer Institute in Flint, MI. Watch your e-mail for further details.

Additionally, the following sessions were conducted by members of the HRPP staff and the IRB chairman. Anyone interested in these topics can call our office to obtain information or schedule a presentation.

- "Research Design and IRB Application"
- "McLaren Health Care Human Research Protections Program and IRB"

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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