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.

Upcoming Educational Sessions:

On July 11, 2013 and July 26, 2013, HRPP's Office of Research Education, Training and Resources will be providing a Webinar for the IRB members entitled: "Regulatory Criteria for Approval and Risk/Benefit Assessment: A Reviewer's Responsibilities"

On August 6, 2013, IRB analysts will be conducting a session for new residents entitled: "You've been told you need to do a research project.....Now What?" The session will take place at McLaren Bay Region at 7:00 a.m.

Contact us to receive e-mail announcements for future educational sessions. Please send comments, questions, suggestions for future issues to Jodi Reetz, HRPP Administrative Assistant at Jodi.Reetz@mclaren.org.

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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The quarterly newsletter from Human Research Protections Program | ***Summer 2013***

HRPP Outlook

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

From the Corporate Director ...

McLaren HEALTH CARE

LANA GEVORKYAN

The Human Research Protections Program (HRPP) has been in operation for just over a year now, and what a year it has been! As a department we have conducted 17 Independent Review Board (IRB) meetings, reviewed over 800 submissions, and provided numerous educational sessions for investigators, coordinators, and others involved in research throughout the corporation.

As with anything new, this has been a learning process and we have met several challenges that provided us with opportunities for process improvement. The biggest milestone /challenge came with our first Food and Drug Administration (FDA) audit in June 2012. Having only been in operation for six months and having consolidated nine subsidiaries into one centralized program, there was some degree of uncertainty as to what the FDA might find. The auditor reviewed policies and procedures, study files, the electronic submission system, and a handful of open studies. She also interviewed some of the HRPP staff regarding operating procedures. We are pleased to report that the FDA was satisfied with our program and operations.

My goal from the creation of the HRPP has been to gain Association for the Accreditation of Human Research Protections Program (AAHRPP) approval for our institution and become a model for other Human Research Protections Programs. This is a prestigious accreditation that is held by a limited number of research institutions worldwide. Adhering to their strict guidelines means that our program will go above and beyond minimum federal regulations and will place McLaren's research program in a position of high regard throughout the research community and trust in the general public.

The HRPP staff is here to help. Should you have questions regarding the HRPP program, need IRB assistance, or would like more information, the HRPP staff is available from 8:30 a.m. – 5 p.m. Monday – Friday. Remember – a few minutes on the phone can save hours of stress and confusion.

Accreditation of Human Research Protection Program:
What it means to you (the Investigator)

Because AAHRPP standards are often even more stringent than those required by Federal regulations, AAHRPP accredited institutions:

- Operate more efficiently, provide more comprehensive protections, and produce higher-quality data than non-accredited organizations.
- Tend to have more highly trained physician researchers and research staff.
- Are less likely to be cited for non-compliance when inspected by the FDA.
- Tend to have fewer protocol deviations and to require fewer sponsor audits.

A number of major research organizations have achieved accreditation or are in the midst of applying for accreditation. At this time, AAHRPP is in the process of reviewing McLaren's structure, all applicable policies and procedures, and various other documentation to understand how McLaren works as a research institution.

First, the process of applying will bring the evaluators to McLaren to examine our human subject review process from top to bottom. Researchers, research teams, and departments will be selected and examined for compliance to federal regulations, including the reporting of all projects involving human subjects. They will also examine the determination of "exempt from further IRB review" versus expedited or full review status. The site-visitors will randomly select research projects conducted at McLaren's subsidiary hospitals to determine whether reviews and status are in compliance with federal regulations. As an investigator, if one of your projects is selected you will be asked to show all your records pertaining to that project, including your original IRB approved protocol, approval letters, any amendments, etc. If you are using consent forms, you may be asked to show that you have retained all signed consent forms. (Please keep in mind that per McLaren's policy, investigators are required to retain signed consent forms for seven years beyond the close of the research project).

Second, the AAHRPP site visitors will investigate researcher education and knowledge of federal regulations regarding their research specialties. Site visitors will interview the Institutional Official and may choose to interview department chairs and pharmacist(s) responsible for investigational drugs. They will also select researchers to interview at random in order to evaluate organization-wide knowledge of human research protection issues. Accreditation will be dependent not just on McLaren's Human Research Protection Program, but also on an evaluation of whether researchers and officials are cognizant of their responsibilities for the protection of human subjects.

Did you know?.....

The PI is ultimately responsible for the conduct of research. Principal Investigators may delegate research activities. However, PIs retain ultimate responsibility for the conduct of those whom they delegate responsibility. If a research protocol requires skill beyond those held by the PI, it is the PI's responsibility to see that the protocol is modified to meet the PI's skills to or to include one or more additional qualified individuals as the co-investigator(s).

New and Recently Updated Policies

Listed below are policies that have either been recently created or revised. As we move forward in our AAHRPP accreditation process we have improved our operating procedures and policies. Please take a few minutes to review these and other policies located on our website at: http://www.mclaren.org/Main/IRBPoliciesProcedures.aspx

**New

Appex I_	Definitions
MHC_RP0201	Human Research Protections Program
MHC_RP0202	Research COI Committee Procedures
MHC_RP0114	IRB Documentation and Research Record Retention
MHC_RP0109	Criteria for Approval of Human Subjects Research
MHC_RP0110	Additional Consideration during IRB Review and Approval
MHC_RP0115	Obtaining Informed Consent from Research Subjects
MHC_RP0116	Vulnerable Subjects in Research

Revised

MHC HRPP	Manual
MHC_RP0103	IRB Membership
MHC_RP0106	Expedited Reviews of Human Subject Research
MHC_RP0107	Initial Review of Human Subject Research
MHC_RP0108	Full Board Review of Human Subject Research
MHC_RP0112	Continuing Reviews
MHC_RP0117	Use of Medical Devices in Human Subject Research
MHC_RP0118	Use of Drugs and Biologics in Human Subject Research
MHC_RP0119	Emergency Use of Investigational Drugs and Devices
MHC_RP0123	Complaints and Non-Compliance in Human Subject Research
MHC_RP0125	Investigator Responsibility
MHC_RP0126	COI for IRB Members

In the day and age of instant gratification it is not unusual to want things done as quickly as possible. The HRPP staff, the IRB, and the Investigator working together and communicating effectively is key to ensuring timely processing of research protocols.

IRB Members are Invaluable

As schedules and duties have shifted, ebbed, and flowed we have had to say goodbye to the following members:

- Dr. David Corteville- McLaren Northern Michigan (Scientific Member)
- Dr. Justin Klamerus-McLaren Cancer Institute (Scientific Member)
- Ms. Michelle Thatcher- McLaren Oakland (Scientific Member)
- Ms. Cathleen Hipps-McLaren Flint (Scientific Member)
- Ms. April Scrimger-McLaren Flint (Non-Scientific Member)

We would like to take this opportunity to extend our sincere appreciation and gratitude for their dedication during their time of service on the MHC IRB. On the bright side, this has allowed us to gain some new, equally valuable members. HRPP is pleased to announce the addition of three new members to our Corporate IRB.

Please welcome:

- **Gary L. Roth, D.O., FACOS, FCCM, FACS**
  Dr. Roth is a caridovascular and thoracic surgeon. Dr. Roth serves as Medical Director of Quality Improvement and Patient Safety at McLaren Greater Lansing. Dr. Roth joined MHC IRB as a scientific member.

- **Andrew Teklinski, MD**
  Dr. Teklinski is a cardiologist at McLaren Northern Michigan. He joined MHC IRB as a scientific member.

- **Ike Iyioke, M.A.**
  Mr. Iyioke is a doctoral candidate in Bioethics at Michigan State University. He joined MHC IRB as an unaffiliated non-scientific member from McLaren Greater Lansing.

- **Maureen Decker, MBA, CHC**
  Maureen Decker, has moved from Alternate Member to a Primary Member with McLaren's IRB. Ms. Decker is Director of Financial Assurance and Compliance, as well as the Privacy/ Security Officer at McLaren Macomb. Maureen serves as a non-scientific member.

Advice to Investigators

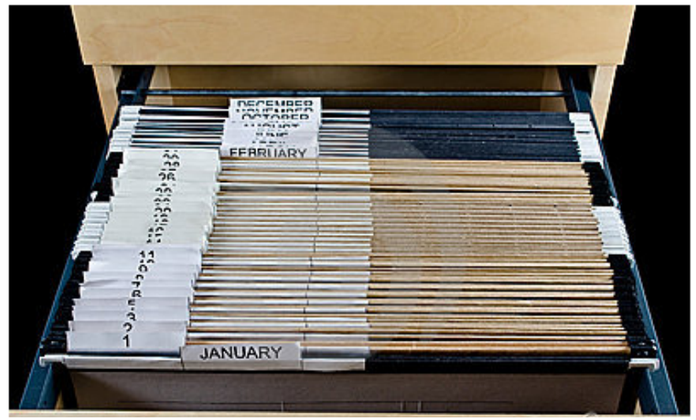
Informed Consent:

1) Obtain and document informed consent from the subject or, if appropriate, the subject's legally authorized representative using the most current and approved consent form(s). Sign and date the consent form at the time consent is obtained. DO NOT use outdated (expired) consent forms. Check the validation and expiration date on the consent form before obtaining consent.
2) Keep the executed consent form with the original subject's signature in your study records, and give the subject a copy.

Continuing Review Submission:

(1) Complete and submit continuing review application through eProtocol on time to fulfill the federal requirement for IRB review at least once every 12 months or as requested by the MHC IRB

- Expedited Projects: Submit your Continuing Review report no later than 3 weeks prior to the expiration date. 4 weeks is ideal.
- Full Board Projects: Submit your Continuing Review report before the deadline for two meetings prior to the expiration date. This allows you time to obtain timely approval if your project requires explicit changes, is tabled, or has other issues. For IRB deadlines visit:



Good Record Keeping:

Keep good records! Each study should have a study file that contains all study-related information, e.g., all correspondence and protocol information from the sponsor and all IRB correspondence. In general, each subject enrolled or screened for a study should have a file that contains a copy of the signed consent form, copies of case report forms, etc. After the study is completed, retain records as required by the sponsor and/ or other applicable record keeping requirements. It is McLaren's policy that all records are kept for 7 years after the closure.

- Read your protocols and consent forms before submitting for IRB review. A proofread application can help you receive a favorable IRB review. We recommend that the PI personally write at least the section about "Purpose" and "Study Procedure" in lay language (sections 1 & 9 of the eProtocol Initial Application).
- Attend an IRB meeting as a guest – you will learn about the review process and pick up ways to make your submissions more likely to require only administrative changes as opposed to having to be returned for another review by a convened Board (This must be approved by the Corporate Director of HRPP in advance). To send your request, please contact the IRB office at hrrp@mclaren.org or (810) 342-1003.
- Consider becoming an IRB member. IRB members in general find the experience to be both rewarding and educational.

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.

Did you know?.....

If your study expires, you cannot: (1) Collect, use or report data. (2) Perform study interventions (unless the IRB finds that it is in the best interest of the subjects to continue interventions/ interactions). (3) Enroll or screen new subjects. (4) Receive funding.

McLaren's HRPP Introduces the Research Conflict of Interest Committee

August 24, 2012 marked the deadline for which ALL institutions and organizations receiving Public Health Service (PHS) funding for research (including research with human subjects) must comply with the **August 25, 2011 Final Rule.** The 2011 regulation was revised from the former 1995 regulation, further outlining the disclosure, review and reporting requirements for financial conflicts of interest in PHS-funded research.

The Public Health Service includes the following offices and agencies within the U.S. Department of Health and Human Services (DHHS):

- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Office of the Assistance Secretary for Preparedness and Response (ASPR)
- Office of Global Affairs (OGA)

McLaren is one of the Institutions that receive PHS funding for conducting research with human subjects.

Please go to http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html to view the major changes between the 1995 and 2011 regulations.

As the McLaren Human Research Protections Program (HRPP) continues the journey toward gaining AAHRPP accreditation we continue to identify opportunities for process improvement. One such area we recently identified is the management of conflicts of interest (COI) in research. McLaren's HRPP worked very closely with the Corporate Compliance Department to put policy and procedure(s) in place to address and fully comply with the new regulations. The policy now addresses how our institution complies with the requirements and specifies the internal procedures that McLaren will use to identify Conflict of Interest in research.

In March of 2013, the Research Conflicts of Interest (COI) Committee was given a responsibility, on behalf of the institution, to evaluate potential institutional COI disclosed by McLaren investigators and research personnel. In addition, the committee was asked to take actions as required to avoid, or to appropriately manage, apparent institutional COI. The Research COI Committee serves as an Ad-Hoc Committee to the Corporate Conflict of Interest Committee.

What is a Conflict of Interest (COI)?

McLaren's Definition of COI as following:

"A conflict of interest (COI) occurs when any financial arrangement, situation or action affects, or is perceived to exert inappropriate influence on, the design, review, conduct, results, or reporting of research activities or findings".

Keep in mind that the conflict lies in the situation, and not in any behavior or lack of behavior of the individual. A conflict of interest is not intrinsically a bad thing.

Once a conflict is disclosed, it will be up to the Research COI Committee to determine whether or not a COI involves a 'significant financial interest' and develop a management plan for any such interests that are identified. The U.S. Department of Health and Human Services (DHHS) has set the monetary threshold at which significant interests require disclosure at $5,000 per year. This means that any investigator or research personnel receiving monetary gain greater than $5,000 per year from a sponsor is required to disclose this information to the MHC IRB. The IRB will then defer to the Research COI committee for determination.

The Research COI committee is made up of five members from various McLaren subsidiaries; each of them having a background in compliance. The committee will meet on an 'as needed' basis to review potential conflicts of interest.

McLaren's HRPP department continues to work with the Corporate Compliance Department to streamline the processes on how to identify the Institutional Conflict of Interest on an annual basis from everyone who is involved in human subject research.

Any changes regarding this topic will be communicated to the entire McLaren Research Community.

Active Research Projects

Approved by MHC IRB since September of 2012

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

A Randomized Double Blinded Controlled Trial of an Oral Nutritional Supplement Containing AN 777 in Older Hospitalized Patients

ATTAIN: Medtronic Attain® Performa™ Quadripolar Lead Clinical Study

GLAGOV: A Randomized, Multi-Center, Placebo-Controlled, Parallel-Group Study to Determine the Effects of AMG 145 Treatment on Atherosclerotic Disease Burden as Measured by Intravascular Ultrasound in Subjects Undergoing Coronary Catheterization

DECLARE: Dapagliglozin Effect on Cardiovascular Events: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Dapagliflozin 10mg Once Daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Ischemic Stroke in Patients with Type 2 Diabetes

PROTOCOL 10-392 ABSORB RANDOMIZED CONTROLLED TRIAL III A Clinical Evaluation of Absorb™ BVS, the Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects with de novo Native Coronary Artery Lesions.

ODYSSEY: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of SAR236553/ REGN727 on the Occurrence of Cardiovascular Events in Patients Who Have Recently Experienced an Acute Coronary Syndrome

MPP: MultiPoint™ Pacing IDE Study

PROCEED: PROTOCOL EC-FV-06: A randomized double-blind phase 3 trial comparing VINTAFOLIDE (ec145) and pegylated liposomal doxorubicin (PLD/DOXIL®/ CAELYX®) in combination versus pld in participants with platinum-resistant ovarian cancer.

E1609: A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected High Risk Melanoma

RTOG 1115: PHASE III Trial of Dose Escalated Radiation therapy and Standard Androgen Deprivation Therapy (ADT) With a GNRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GNRH Agonist and TAK-700 for Men with High Risk Prostate Cancer

SWOG S0820: A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)

S1013: A Prospective Study of Epidermal Growth Factor Receptor (HER-1/EGFR) Inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of Cancer Therapy-EGFRI 18 (FACT-EGFRI 18) Questionnaire for EGFR-Induced Skin Toxicities

An MRI Investigation of Soft Tissue Following Total Hip Arthroplasy

CALGB 90802: Randomized phase III trial comparing everolimus versus everolimus plus bevacizumab for advanced renal cell carcinoma progressing after treatment with tyrosine kinase inhibitors.

Transition From Fully Open to Fully Robotic Surgical Oncology Cases Without Laparoscopic Experience-Is It Possible?

The Roadster Plus Study: Investigation of Flow Altered, Short Transcervical Carotid Artery Stenting In Patient With Significant Carotid Artery Disease With Filter

Grand Study: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study to Evaluate Cardiovascular Outcomes of TAK-875, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events

Overview of New HIPAA Omnibus Rule

The U.S. Department of Health and Human Services (DHHS) released a new regulation effective March 26, 2013 to strengthen the privacy and security protections for health information established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Omnibus Rule went into effect on March 26, 2013. While covered entities and business associates have until September 23, 2013 to comply with new restrictions and obligations, they can take advantage of the rule's benefits immediately. These benefits include:

- Greater ability to combine research authorization forms;
- More flexibility with future research

The previous HIPAA Privacy and Security Rules focused on healthcare providers, health plans and other entities that process health insurance claims. The new Omnibus Rule greatly enhances a patient's privacy protections, provides individuals new rights to their health information, and strengthens the government's ability to enforce the law.

Of interest to researchers, the final rule reduces burden by streamlining subject's ability to authorize the use of their health information for research purposes. The rule appears to allow the subject to authorize research on their health information for "future use" as long as the future plans are sufficiently specific. The rule simplifies authorization paperwork. For example, a researcher will be able to rely on a single authorization for a clinical trial that requires execution of the authorization to participate in the trial and that also includes an opt-in (such as a check box or a second signature line) authorizing the covered entity to use and disclose the individual's protected health information (PHI) for a tissue bank. The authorization must make clear that the individual may choose not to opt in to the tissue bank and that the choice will not impact treatment, payment, or benefits. Our HRPP Privacy and Compliance Officers are evaluating options to see whether we need to make the current Research HIPAA Authorization more flexible and consistent with McLaren's standard HIPAA Authorization Form.

For clinical care, individual rights are expanded in important ways. When individuals pay for health care services by cash, they can instruct their provider NOT to share information about their treatment with their health plan. Patients can also ask for a copy of their electronic medical record in an electronic form. The final Omnibus Rule sets new limits on how information is used and disclosed for marketing purposes and prohibits the sale of individuals' health information without their permission.

Any changes to policies and procedures have been, and will continue to be, communicated to McLaren's research community. There are many additional requirements in the final rule. To read the final Omnibus Rule, please go to www.hhs.gov/ocr/privacy/hipaa/administrative/omnibus/.

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**

Summer 2013 | HRPP Outlook

RESIDENT'S CORNER

Research tips for medical residents

Retrospective Chart Reviews

Retrospective chart review studies are one of the most common studies utilized by residents completing research for their program. Over the past 17 months MHC IRB has learned that individual McLaren investigators have a different understandings of the term "retrospective chart review". In an effort to streamline our processes and ensure everyone is on the same page, MHC IRB has defined a Retrospective Chart Review as "a study using data that exists at the time of the research proposal". In other words, the data must be already "on the shelf" prior to the IRB approval.

A common question that is often asked of the MHC IRB is:

- ***Q:*** I am a fourth year resident and am going to get started on a research project that involves retrospective chart review. I know that I will have to get IRB approval for my project, however, this is something I have no experience with. Any advice on where to start?
- ***A:*** The IRB takes a number of factors into consideration when determining how to process research involving retrospective medical record reviews. Two major considerations are the sensitivity of the data being collected, and the way the data will be recorded and stored. If you wish to collect particularly sensitive information as part of your record review (such as illegal drug use, alcohol use, information about psychiatric diagnoses and treatment, sexual abuse, and HIV status), the IRB will not likely allow this study to be done under the Exempt review process; it will most likely require additional protections to be put in place to insure the privacy and the confidentiality of the patients and their medical records. The IRB will also take into consideration how you will be recording the information that you collect when making the decision about the review pathway.

For simplicity's sake, let's say that you wish to do a review of the medical records of patients seen from 05/01/2008 – 09/30/2012 at McLaren- Flint for a primary diagnosis of hypertension. You wish to collect data about the medications that these patients took to treat their hypertension based on age, sex, and ethnic background. Depending on a few factors, this protocol MIGHT qualify for Exempt review by the MHC IRB.

Under the "exempt review" process, the IRB conducts an initial review of the protocol. If the protocol qualifies as "exempt" then the IRB will provide you with a letter stating this project is "exempt from further IRB review", providing no changes are made to the research plan.

Requirements to qualify for Exempt review

In order for a medical record review to qualify for Exempt review, in accordance with Federal regulations (45 CFR 46.101(b) and institutional policies;

a. The record review does not involve collection of very sensitive information from the medical records
b. All data to be collected must be retrospective (meaning it is on the shelf prior to the proposed research/ IRB approval)
c. No personal identifiers can be recorded, and there must be no way that the data can be linked back to individual subjects

Requirements for investigators

- As a resident, you will need to list an Academic Advisor on the proposed project.
- You and everyone listed on the application (including Academic Advisor) will need to meet the institutional requirements for human subjects training. The requirements for human subjects training and recertification can be found on the IRB website at:

http://www.mclaren.org/Main/IRB.aspx or by contacting MHC IRB office at (810) 342-1024.

NOTE: 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.

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

- MHC IRB utilizes an electronic submission system called eProtocol. If this is your first time submitting an application through eProtocol, you will need to request a Username and Password from the MHC IRB Office at 810 342-1024 or hrpp@mclaren.org before you can start the submission process.
- In addition to eProtocol application, you will need to submit a formal Protocol document along with your data collection form and any other supporting documents you are going to use for your project

Important notes about the protection of the data:

Remember: In order to qualify for exempt review, you must not record any personal identifiers. There must be no way to link the recorded "research" data back to the individual subjects. This means that you can have a separate list of medical record numbers (MRNs) that you are going to review, but you cannot link the data that you collect to those MRNs. For example, you can maintain a list of MRNs for the records that you will review, and then cross the numbers off the list as you review them. You cannot put these MRNs or any other "linking numbers" on the data collection form that you will use to record the data about the subjects. The list of medical record numbers must be destroyed after data collection is complete, but BEFORE data analysis begins. The protocol that you submit must clearly explain your process so that the reviewer can clearly determine that there is no way for the data that is collected on the data collection forms to be linked back to individual subjects.

Because you will be accessing Protected Health Information from a "covered entity" (the McLaren Medical Records) for research purposes, you will need to comply with the institutional HIPAA requirements. Since it is likely that you do not intend to contact each patient to obtain his/her HIPAA Authorization, you will need to complete a request for Waiver of HIPAA Authorization in your eProtocol application. The MHC IRB website has a wealth of valuable information including a newly created Protocol Template for the Chart Review. Information can be obtained by either visiting our website at: http://www.mclaren.org/Main/IRB.aspx or by contacting MHC IRB office at (810) 342-1024.

HELPFUL TIPS

While completing a residency program it is quite probable that you will be asked to complete a research project. The first and most important tip is DO NOT wait until the last minute! Review of your proposed research project requires a thorough review and the IRB may need clarification or have questions regarding the proposed study.

*****Please be sure to contact the MHC IRB office if you are graduating or leaving the institution to ensure that any active studies are appropriately managed prior to your departure.**