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

HRPP Outlook

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

McLaren HEALTH CARE

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

A message from the director...

The Human Research Protections Program (HRPP) is a constantly developing program. We have continuously made adjustments / revisions throughout our four years of operation to better serve the research community at McLaren.

One very notable change came about recently, as MHC IRB identified the need to decrease review turnaround times. After much research a new, more flexible IRB model was implemented in November. Under the new model the IRB holds convened meetings on the first and third Friday of each month, rather than just once per month. This will allow for the reduction of overall turnaround time, greater flexibility, smaller agendas, and shorter meeting times.

As we look toward the completion of another very successful year, McLaren is undergoing re-accreditation in human research protections. The HRPP is currently in the midst of the first steps of completing the application for reaccreditation. This is a prestigious accreditation which is held by a limited number of research institutions globally. Adhering to their strict guidelines means that McLaren's program will consistently go above and beyond minimum federal regulations and will place our program in a position of high regard throughout the research community, and one of trust in the general public.

The HRPP family would like to extend to you and yours, wishes of hope, peace, and prosperity in the New Year!

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

EQuIP Corner

Protecting Research Records

The Principal Investigator (PI) is responsible for all aspects of study conduct including an obligation to record, maintain, retain and protect research records. Proper maintenance of research records is key to data integrity and reliability. Furthermore, research participants expect that the researcher(s) will protect their identity and the information obtained about them from inadvertent or inappropriate disclosure.

Before discussing how to protect research records, we need to clearly understand what constitutes a research record. Clinical research records are those records that describe or record the methods, conduct, and/or results of a clinical trial, and the actions taken. The records may be in any form, including written, electronic, laboratory, scans, x-rays, electrocardiogram, etc. Records include subject files which contain case report forms, signed and dated consent forms, supporting data or source documents, etc. It is important to note that research records are comprised of regulatory documents, and are commonly referred to as investigator files. Regulatory documents include all correspondences from the IRB submissions, sponsor or regulatory agencies correspondences, approved consent documents, brochures, etc. Depending on the type of study, it is possible that regulatory documents may include confidential and financial documents, training files, CV's, delegation logs, FDA 1572, dispensing records etc.

There are specific federal regulations and institutional policies that govern research record keeping practices. The following key guidelines will assist you and your study team with keeping in compliance with regulations, policies and guidelines:

1. **Destruction of Data:** Upon request of a monitor, auditor, the HRPP, or regulatory authorities, the investigator should make direct access available to all requested trial related records. This request can be made before, during, or after a study is completed and closed. Even if your project is a chart review study, it is still study data, which must not be destroyed. According to HRPP policy, research records must be maintained for at least 7 years. Some industry-sponsored studies may require retention for a longer period. Investigators should follow which ever retention period is greater.

2. **Transmission of Data:** As a rule, study personnel and research subjects should not transmit information that will be used

for research data via the computer or phone text messaging. Under certain circumstances, the IRB may grant permission and encryption requirements to exchange information in this manner. It cannot be stressed enough that you must have IRB approval prior to any such exchange of information.

3. **Collecting Identifiers:** Do not collect any subject identifiers you do not need. Identifiable data or "identifiers", are any data that can either directly identify an individual or link an individual to their identity, such as an address or medical record number. The HIPAA pprivacy rule lists 18 such identifiers. One frequently used identifier that researchers seem confused by is "date". A date is an identifier, if it includes all elements of the date except year.

4. **Storage of Data:** Do not store identifiable research data on moveable media such as laptops, PDA's, flash drives or, other portable devices. Such modes of storage may only be used to collect research data that has either been de-identified or collected using the participant's unique code. Collecting identifiable data on moveable media is a research violation. (This is spelled out in the eProtocol application). Participant identifiers and the means to link the participant names and codes with the research data should always be stored in separate locations, with distinct access controls.

5. **Restrict Physical Access to Data:** Areas or computer systems that contain research data subject identifiers should be secured at all times. Paper research records should be stored in a secure, locked location. Access to these locked records should be limited to IRB-authorized individuals only.

6. **Restrict Electronic Access to Data:** Electronic research records should be stored on McLaren or subsidiary-issued password protected computers. Restrict electronic access to any computer system that contains subject identifiers. Access to the database should always be password protected and each research team member is required to have a unique ID and password to gain access to the database.

Resident's Corner

Common Mistakes in IRB Submissions

The first step in the IRB review process is a pre-review of your submission. This pre-review is conducted by the IRB Analysts with the intention of ensuring submissions are "complete". The "completeness" of a submission is determined by looking a couple of factors:

- Are all sections answered completely? (i.e. Is each question posed addressed in the response provided?)
- Are all questions addressed appropriately? (i.e. Is the response provided complete? Is the response relevant to the question(s) being posed?)

Let's take a closer look at some basic 'issues' that are commonly identified in IRB submissions:

1. Incomplete and inappropriate answers:

h) **Will a unique subject identifying number, characteristic, or code be used to protect the confidentiality of the data? (This includes codes the investigator assigns to link the data to other identifiers such as the subject's name or medical record number.)**

☐ No

☑ Yes--Answer the items below.

If the data are coded, explain where the key to identifiers will be stored, how it will be protected, who will have access to it, and how long the link between the data and the identifiers will be maintained.

Patients will be identifed by patient age gestational age.

When providing responses, be sure to read the entire question and provide all requested information. In this example, the answer provided is not only incomplete, it is not relevant to the question being asked.

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5. Confidentiality

a) **Explain how you will protect subjects' privacy.**

N/A

b) **Describe how you will maintain the confidentiality of subjects' information.**

N/A

While N/A is an appropriate response in some circumstances, it is not always acceptable. For instance, in the example here, "N/A" clearly does not address the information being requested.

HINT: *If the question contains the words "explain" or "describe", it is a good indication that we are asking for detailed information.*

2. **McLaren-required human subject assurance (HAS) training (i.e. CITI) not completed for all personnel listed on the submission; training not current for all personnel.**

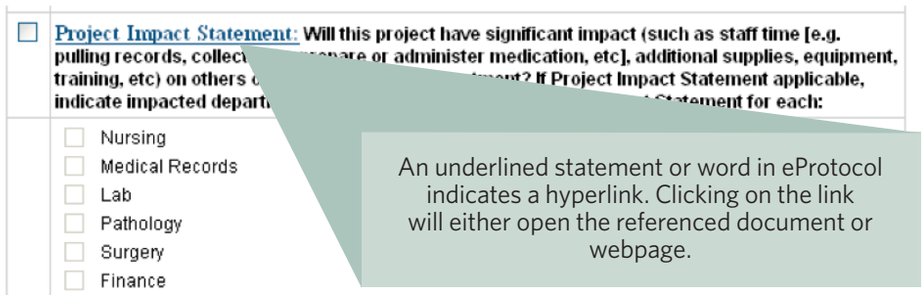
   REMEMBER: all principal investigators, co-investigators, and sub-investigators must complete the Conflicts of Interest course in addition to the Basic Biomedical (or Social Behavioral, whichever is most relevant to your project) course.

3. **Lack of required documentation** – We often find that pertinent documentation is missing from submissions. When submitting your project you should ensure that the following documents are provided and completed appropriately:

   Confirmation of Scholarly Review for Validity: All resident and student submissions must be accompanied by a "Confirmation of Scholarly Review for Validity" form signed by ***someone other than the PI***, such as the Academic Advisor or Program Director. Their signature confirms the soundness of the research design and the ability of the research to achieve its aims.

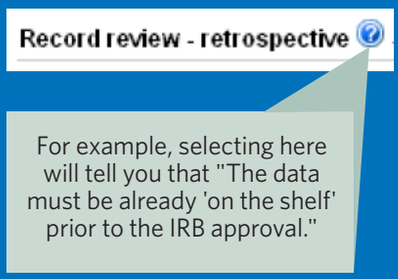
   Project Impact Statements: The "Project Impact Statement" (PIS) provides assurance that any department(s) that will be significantly impacted by the proposed research project are aware of the proposed project and that the department manager / director approves the involvement of their department. It is a common misconception that, because one is 'just doing a chart review', a PIS is not necessary. If you are conducting a chart review in which medical records must be pulled by the Medical Records Department staff, the Medical Records department is being impacted; therefore, the IRB Analyst would expect to see a signed PIS.

HINT:



Did you know...?

When you see this symbol – in eProtocol, you can click on it to find more information.



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

Transitions...

HRPP is sad to announce the resignations of one of our long-standing members. Nancy Smith, Privacy Officer at McLaren Flint, has served as a primary member of the MHC IRB since January 2012.

Ms. Smith has been an invaluable resource for the board, particularly in regards to privacy matters. We would like to take this opportunity to thank Ms. Smith for her years of service.

New Additions...

We would like to welcome aboard two new members:

Meet Stephen Franklin, MD

Dr. Stephen Franklin, joined the MHC IRB as an alternate member for Dr. Tom Boike. Dr. Franklin is a board certified radiation oncologist, and is an active research member in the McLaren community. He completed his residency in Radiation Oncology at Howard University Hospital in Washington D.C., and his fellowship in Radiation Oncology at the University of California Medical Center in Sacramento, CA.

Meet John Hyden, JD

John Hyden, JD, has also joined us as an alternate member for Maureen Decker. Mr. Hyden is the Compliance, Legal, and Risk Officer at McLaren Greater Lansing and has previous experience as an IRB member.

CORRECTION

In the last issue we stated that Mike Jamrog is the Privacy Officer at McLaren Greater Lansing. Mr. Jamrog was, in fact, the Privacy Officer at McLaren Bay Region.

NEW Active Research Projects

New studies open to enrollment at McLaren since September 2015. ***For a complete list of studies please visit our website at: http://www.mclaren.org/Main/ClinicalTrialsHRPP.aspx***

Amgen Protocol Number: 20140128

A Multicenter, Open-label Extension (OLE) Study to Assess the Long-term Safety and Efficacy of Evolocumab
- McLaren Bay Region

ROADSTER 2 Registry

REGISTRY of TRANSCAROTID ARTERY REVASCULARIZATION in PATIENTS with SIGNIFICANT CAROTID ARTERY DISEASE
- Michigan Vascular, McLaren Flint

SPIRE 1

Phase 3 Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Evaluation of the Efficacy, Safety, and Tolerability of Bococizumab (PF-04950615), in Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects
– McLaren Macomb

SPIRE 2

Phase 3 Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Evaluation Of The Efficacy, Safety, And Tolerability Of Bococizumab (PF-04950615), In Reducing The Occurrence Of Major Cardiovascular Events In High Risk Subjects

NRG-CC001

A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance in Patients with Brain Metastases
– Karmanos Cancer Institute - Radiation Oncology sites located at Flint, Petoskey, Mt. Pleasant, Mt. Clemens, Bay City, Owosso, Lapeer

Upcoming Education

2016 BROWN BAG SESSIONS DATES HAVE BEEN ANNOUNCED! Mark your calendars:

February 9, 2016 – Improving the Relationship Between the Researcher & IRB

April 12, 2016 – Use of Electronic Informed Consent in Research

June 14, 2016 – Incidental Findings During Research

August 9, 2016 – Challenges, Strategies and Tools for Patient Recruitment

October 11, 2016 – What is Genetic Research all About?

December 13, 2016 – QA Monitoring Results – A three year review

The McLaren HRPP is serving as one of the sponsors for the 2016 Michigan Research Ethics Conference!

SAVE THE DATE

Michigan Research Ethics Conference (MREC)

April 29, 2016

Hosted by:
Michigan State University
East Lansing, Michigan

For additional information:

hrpp.msu.edu/mrec2016

or contact Human Research Protections Program
hrpp@ora.msu.edu | 517.353.2976

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 Markeda Richards at (810) 342-1003 or (810) 342-4174 or via e-mail at Markeda.Richards@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 Markeda Richards at (810) 342-1003 or (810) 342-4174 or via e-mail at Markeda.Richards@mclaren.org for questions or more information.

Revised Policies

As a part of our AAHRPP re-accreditation process, all existing HRPP policies have been updated. Please visit our website to view all current policies.

The following are NEW recently published EQuIP policies:

- MHC_RP0301 Education and Quality Improvement Program
- MHC_RP0302 QA/QI Routine Review
- MHC_RP0303 Directed For-Cause Audits
- MHC_RP0304 QA/QI Review of IRB Files and Operations
- MHC_RP0305 Investigator Requested Services
- MHC _RP0306 Education and Training in Human Subject Research

A full list of current HRPP policies can be found on our website at: ***http://www.mclaren.org/Main/IRBPoliciesProcedures.aspx***

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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