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

HRPP Outlook

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

2014 Clinical Trials Awareness Day

The Human Research Protections Program (HRPP), along with the McLaren Center for Research & Innovation (MCRI) participated in the 2014 Clinical Trials Awareness Day held at the State Capitol building on June 4. This is the second year for this event coordinated by Representative Gail Haines, R- Waterford. Representative Haines, chair of the House Health Policy Committee has sponsored a resolution designating June 2014 Clinical Trials Awareness Month.

This event was designed to highlight Michigan's role in the development of new drugs and devices. We showcased our very unique Human Research Protections Program structure and diverse range of research conducted throughout our subsidiaries.

McLaren HEALTH CARE

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

Research Participants

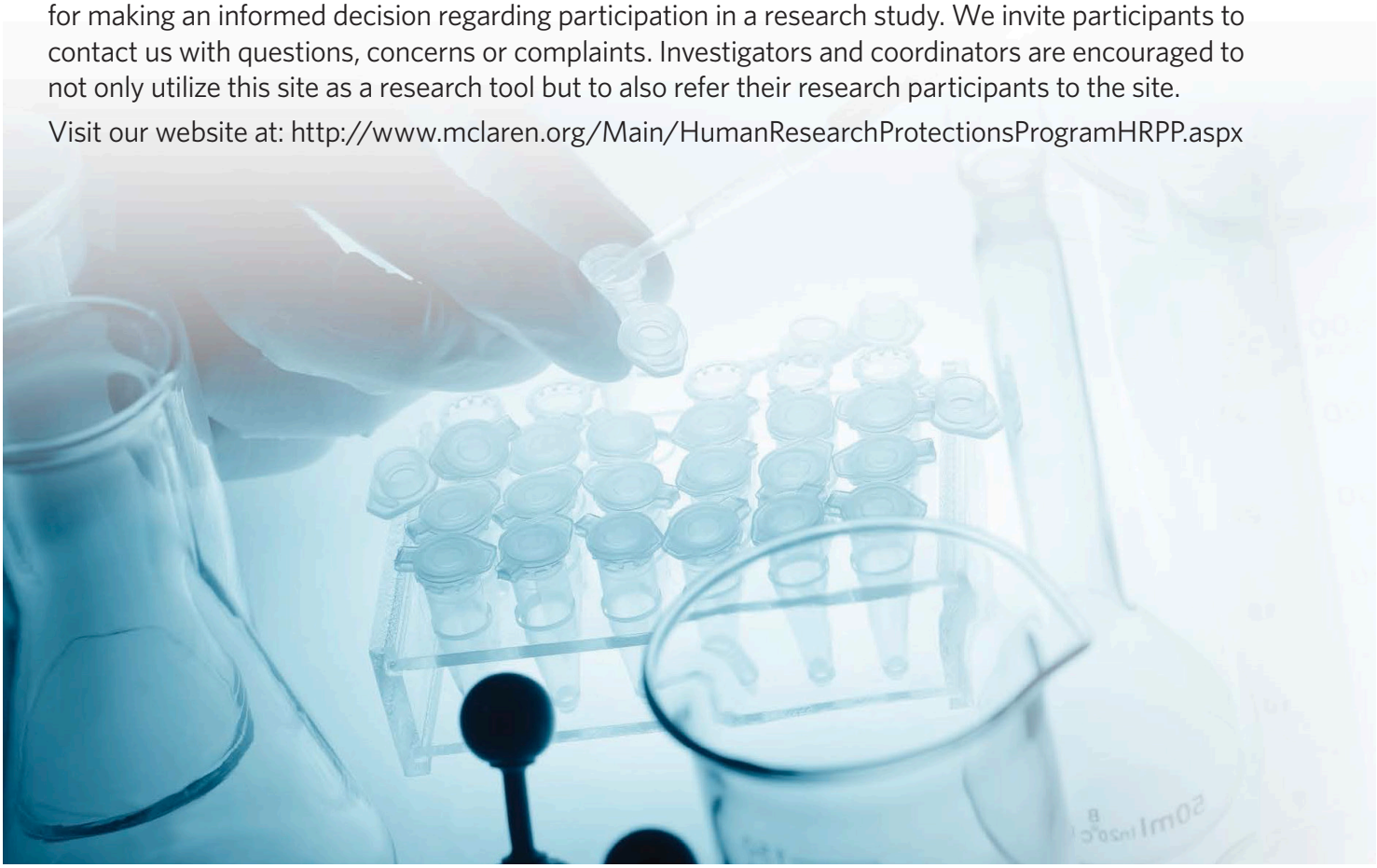
MHC HRPP's website provides investigators and coordinators with to access many useful tools that contribute to research compliance. With the click of a button, one has access to:

- IRB forms
- frequently asked questions
- federal regulations
- IRB meeting dates
- training requirements
- links to educational opportunities and much more.

Research participants are a vital part of the research community. By volunteering to take part in research studies, participants contribute to the better understanding of how various treatments or interventions work in people of different ethnic backgrounds and genders and, perhaps, help to improve medical procedures in the future. Without research participants, advancement in many areas would be very difficult.

As a way of reaching out to the community, we have created the Research Participant Information page on our website. This page is designed to allow the community access to information relative to the research participant; or potential research participant. It provides information regarding the background of the human subjects protection system, some frequently asked questions, resources for information regarding participant rights, a glossary of common medical terms, and other information that is useful for making an informed decision regarding participation in a research study. We invite participants to contact us with questions, concerns or complaints. Investigators and coordinators are encouraged to not only utilize this site as a research tool but to also refer their research participants to the site.

Visit our website at: http://www.mclaren.org/Main/HumanResearchProtectionsProgramHRPP.aspx



The Role of the Study Coordinator

The research enterprise is made up of many roles, each as important as the next. At the very center of the enterprise are the study coordinators. According to the Association of Clinical Research Professionals (ACRP) definition, a clinical research coordinator (CRC): works at a clinical research site, with study subjects, under the immediate direction of a principal investigator, whose research activities are conducted under good clinical practice (GCP) guidelines.

So, what does all of that mean? What exactly does a clinical research coordinator do? Listed below is a basic sample of some of the activities a clinical research coordinator is responsible for:

- Assist PI with protocol development
- Write consent forms
- Recruit, screen and enroll participants
- Obtain informed consent from research subjects
- Schedule tests and procedures
- Collect clinical research data
- Ensure accuracy of documentation

Aside from the listed administrative activities, the study coordinator must maintain 3 critical roles; that of the patient advocate, subject advocate, and study advocate. It takes a delicate balance to ensure all 3 roles are being maintained efficiently. In a 2002 focus group, coordinators identified patient advocacy, or commitment to the patient's welfare as their primary responsibility. As a subject advocate, the coordinator is dealing with the same patients, but on an altogether different level. As the subject advocate, a coordinator is responsible for ensuring the subject understands the purpose of the study, that participation in the study is voluntary, and that not participating will in no way affect their current health care. The third role is that of the study advocate. As the study advocate, a coordinator is responsible for advancing the research goals of the study and properly gathering valid data via subject recruitment and retention.

To maintain a balance of roles, the clinical coordinator must possess the ability to be caring and compassionate when interacting with subjects while maintaining the ability to be detached and analytical in order to accomplish the data gathering necessary for the research aspect of their job. Not an easy task. Research would not be possible without competent coordinators to manage recruitment and retention of subjects and oversee the informed consent process.

RESIDENT'S CORNER

Did you know....that all research staff involved in abstracting data from medical records MUST be listed on the IRB application and approved to work on the study?

Did you know.... that all research staff listed on the IRB application must complete CITI training?

WELCOME!

With the beginning of Summer comes the beginning of a new chapter as many resident's join the McLaren team. HRPP would like to take this opportunity to welcome those who are joining us for the first time.

Back to the Basics

Many of you will be embarking on your first research projects this year as you move through your residency programs. It will be very helpful for you to take a moment to review the information below, as it will provide you with some useful information prior to getting started.

Before you begin

Get acquainted with the HRPP website. (http://www.mclaren.org/MainHumanResearchProtectionsProgramHRPP.aspx)

Things you will find here:

- Information about the McLaren Health Care Institutional Review Board (MHC IRB)
- IRB Forms
- IRB Meeting and Submission Dates
- Guidance for Investigators
- Office of Education Training and Resources
- Training Requirements
- Policies and Procedures

Academic Advisor

All research submitted to the IRB by a resident or student, whether novice or seasoned, must be reviewed and approved by an academic advisor before it is received by the MHC IRB for review. Approval by the academic advisor indicates that the study is found to be scientifically sound and can reasonably be expected to answer the proposed question.

Everyone listed on the study application must meet the institutional requirements for human subjects assurance training. As such, academic advisors are required to complete the same CITI training requirements as the investigator; either the Biomedical or Social & Behavioral course and the Conflicts of Interest course. Academic advisors are also responsible for ensuring that the PI has sufficient resources and facilities to conduct the proposed research.

Congratulations!

At McLaren-Flint we are extremely proud of the resident researchers and the faculty that work with them. With the support of our administration and the McLaren Foundation, we have grown from local to national and even international presentations and look forward to future accolades! Jami Foreback M.D., Ph.D., Director of Medical Education - McLaren Flint.

Special congratulations to McLaren Flint award winners at the 16th Annual MSU/FAME Community Research Forum:

McLaren Resident Investigator-- Marcello Schmidt MD

McLaren Faculty Investigator—Radikha Kakarala MD

1st Place Best Case Poster—Maureen Muke MD, Anteneh Tesfaye MD, Bhavana Siddegowda MD, Radhika Kakarala MD

Specialty Award (Internal Medicine) – Maureen Muke MD, Anteneh Tesfaye MD, Bhavana Siddegowda MD, Radhika Kakarala MD

Specialty Award (Orthopedic Surgery) –Jeffrey Peck MD, Paul Charpentier MD, Brian Flanagan MD, Ajay Srivastava MD, Patrick Atkinson PhD

msufame

IRB Members are Invaluable

Getting to know the MHC IRB

In this edition we would like to introduce you to two of our non-scientific community members. Non- scientific community members play a key role on the IRB, as their views reflect the concerns of potential research subjects and the broader community.

Meet Mr. Jim Phillips

Mr. Phillips, a retired teacher, joined the MHC IRB in January 2012. Mr. Phillips previously served on the Ethics Committee at POH Medical Center (now McLaren Oakland). Jim provides a great deal of feedback to the board regarding consent forms and the process of consenting subjects. It is his goal to help find ways to make the informed consent process more effectively educational.

Meet Fr. Gene Geromel, SSC, PhD

Fr. Geromel has been a parish priest for 40 years, having served St. Bartholomew's in Swartz Creek for the last 30 and is also a licensed social worker and published author. Fr. Geromel's extensive experience with the general community allows him to provide valuable feedback to the board regarding the consent process.

Do non-affiliated members need to attend every IRB meeting?

No. Although 21 CFR 56.108(c) does not specifically require the presence of a member not otherwise affiliated with the institution to constitute a quorum, FDA considers the presence of such members an important element of the IRB's diversity. Therefore, frequent absence of all non-affiliated members is not acceptable to FDA.

Active Research Projects

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

IG1202: A Prospective, Randomized, Double-blind, Phase II Study to Evaluate the Safety and Efficacy of Topical Thrombin (Human) Grifols as an Adjunct to Hemostasis during Vascular, Parenchymous, Soft Tissue, and Spinal Open Surgeries [Topical Thrombin (Human) Grifols IND#: 15791]-McLaren Flint

RTOG-0920: A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer-MCI Flint, Lapeer, Mt. Pleasant, Owosso, and Petoskey

ALLIANCE A041202: A Randomized Phase III Study Of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone In Untreated Older Patients (≥ 65 Years Of Age) With Chronic Lymphocytic Leukemia (CLL). [Ibrutinib, IND# 117241]-MCI Bay City, Clarkston, Flint, Lansing, Lapeer, Mt. Clemens, Mt. Pleasant, Petoskey, West Branch

SWOG S0931: EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study [Everolimus, IND# 75,093]-MCI Bay City, Clarkston, Flint, Lapeer, Petoskey

SWOG S1202: A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer [Duloxetine, IND-exempt]—MCI Bay City, Clarkston, flint, Lansing, Mt. Clemens, Mt. Pleasant, Petoskey, West Branch

E1A11: Randomized Phase III Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients With Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE) [Carfilzomib, IND# 118503]-MCI Bay City, Clarkston, Flint, Lansing, Lapeer, Mt. Pleasant, Petoskey, and West Branch

NEW POLICY**

The following new policy is now available:
MHC_RP0127 Investigational Drugs and Biologics Used in Clinical Research.
You can find a full list of current policies 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.

Upcoming Education

We are wrapping up our 7 part webinar series entitled "7 Habits of the Highly Effective Coordinator".

7/18/14 Session 6: 8:30 -9:30 a.m. Demystifying Clinical Research Audits

8/08/14 Session 7: 8:30 -9:30 a.m. Quality Improvement and CAPA Plan

For more information contact Jodi Reetz at 810-342-1024.

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 an idea for a story that you would like to see in a future issue of HRPP Outlook, please contact Jodi Reetz at jodi.reetz@mclaren.org.

1198 North Belsay Road | Building #1 | Burton, Michigan 48509
tel (810) 342 1003 | fax (810) 342 1514