

Human Subject Protections in Clinical Research Annual Report

January 2009-December 2009

This report is to inform SJMHS researchers, hospital colleagues, and interested community members about the protection of human subject activities conducted during the past year by the Institutional Review Board (IRB) and the Health System's Clinical Research Office. This document is a summary of the important events and salient changes that have been performed to enhance the human protection program regarding research at SJMHS.

Background

The IRB is an independent committee designated by SJMHS to safeguard the rights and welfare of all human subjects who volunteer to participate in clinical research studies. The IRB oversees compliance and adherence to Federal regulations, the requirements of applicable law, Federal Wide Assurance, and institutional policies. There are two Institutional Review Boards, IRB#1 and IRB#2. IRB #1 serves as the IRB for all research activities except oncology research. The Oncology IRB (IRB#2) is the exclusive IRB reviewing and approving all

Michigan Cancer Research Consortium trials. Both IRBs are registered with the Office of Human Research Protections and designated by Federal Wide Assurance # FWA00000188 (**Expires:** 8/26/2012 1:28:18 PM).

Our mission is to facilitate clinical research at SJMHS by protecting the rights and welfare of research participants. This is accomplished through maintaining professional relationships with investigators and interested citizens who are dedicated to the promotion and execution of ethical science.

Responsibilities

The IRBs oversee all research involving human subjects conducted at SJMHS. This involves assuring the equitable selection of participants, ensuring that potential research-related risks are minimized, and disclosing any possible conflicts of interest by investigators. These efforts are important to volunteers so that they can make an informed decision about whether or not to participate in clinical trials being conducted at SJMHS.

All research protocols under the auspices of SJMHS that involve human subjects,

including protocols conducted through the Michigan Cancer Research Consortium, must be formally reviewed and approved by the IRB prior to initiation of the study. The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations for drugs and medical devices apply to all research involving investigational drugs and/or devices conducted at this institution, and adherence to the rules are required to uphold our commitment to research participants and the pledge made in the Federal Wide Assurance (FWA).

IRB Committee Members

Each IRB committee consists of at least five members who are sufficiently qualified, through expertise and experience, to review the research presented to them. Each IRB committee also has at least one

member whose primary background is in a nonscientific area and at least one community member who is not affiliated with SJMHS. All IRB members are volunteers.



IRB Membership Changes, Internal Audit Program and Expanded Responsibilities

IRB board membership has undergone changes in regard to community/lay person membership. Betty Linzy served on IRB #1 for most of the year. We are currently seeking a replacement for her since she left for a part time job appointment. We thank Betty Linzy for her involvement and volunteer efforts and we wish her well in her new endeavors.

Mr. Elmer Benson, who previously served on both IRBs, returned in December to serve on the Oncology IRB (IRB #2). Welcome back Elmer!

This year the IRB Office implemented an internal audit program for ongoing research studies. The first study selected for audit was the Comparison of **Standard CardioPulmonary Resuscitation (S-CPR) Alone versus Active Compression Decompression CardioPulmonary Resuscitation (ACD-CPR) plus an inspiratory Impedance Threshold Device (ITD) on Survival from Out-of-Hospital Cardiac Arrest.** This study is more commonly known as the **RES Q Trial.** On April 27, April 28 and June 18, study records were reviewed and a favorable report to the investigator was issued on June 22. Conducting these types of audits helps us to understand the educational needs of principal investigators and study teams. It also assists us in developing improvements to the IRB Policies and Procedures and template offerings. The audit program's objective is to build strong relationships between disparate research entities and the IRB and staff.

It is important to note that the expansion of the Saint Joseph Mercy Health System (SJMHS) affects the IRB and the Clinical Research Office. SJMHS is the IRB of record for Ann Arbor, Livingston, Saline, Livonia, Port Huron, Mercy Primary Care and Chelsea locations. The expansion of the resident education program at St. Mary Mercy Hospital in Livonia will also impact the IRB workload since research is an integral part of the graduate medical education experience. The first class of residents at St. Mary's is expected in July 2010.

Key IRB Activities This Year for Assisting Researchers

To streamline the submission process, the IRB application was revised to include the significant financial conflict of interest and HIPAA Authorization forms. The all-in-one document eliminates the confusion regarding which forms were necessary to submit as part of a new study submission. This effort made the process of submission to the IRB as straightforward as possible. The improved new study application form was issued in August 2009.

New/Updated Policies and Procedures:

In response to researchers' and review boards' needs, IRB Policies and Procedures are constantly updated by IRB Staff, Darlene Wahlberg and Trista Koehler, to reflect the most current regulatory mandates and to outline best practices for enhancing the conduct of research.

The policy entitled *Unexpected/Adverse Event Reporting* was revised and issued in September 2009 after significant work reviewing background information, discussion with regulators, and deliberations with other research institutions. The changes in reporting requirements for those unexpected/adverse events that occur externally and are from other research affiliations were many in number. In most cases, these unaffiliated, external adverse event reports were not only voluminous but they rarely provided salient information in the format provided. The new *Unexpected/Adverse Event Reporting* policy now requires more meaningful information to be forwarded to the IRB and in turn makes the review by the IRB more consequential. *Unexpected/Adverse event reporting for internal reports remained unchanged.*

A new policy and procedure entitled *Definition of Research* was issued on March 24, 2009. This document provides researchers with information regarding the types of endeavors that are classified as "research" at this institution. It is also a starting point for the IRB submission process, which helps researchers focus on the type of research that is most appropriate for their needs.

The policy for *Continuing Review* was revised in April 2009. The updated policy provides a much more succinct process for this activity, and addresses the role and responsibilities for expiry of approvals or lapses in annual reviews.

Other new policies or revisions in 2009 include:

1. Emergency Use of a Test Article
2. Institutional Official
3. The Privacy Rule (HIPAA)
4. Research, Functions and Operations of the IRB
5. Vulnerable Populations-Children

Internal and External Education:

Again this past year the IRB staff participated in Graduate Medical Education Academic Skills Week (October 2009), where presentations were given on regulatory requirements and SJMHS policies when residents are conducting human subject research.

Unfortunately, due to travel budget constraints, the IRB Staff did not attend the 2009 annual national IRB meeting, sponsored by

Public Responsibility in Medicine & Research (PRIM&R), in Nashville, Tennessee. It is our hope that we will be able to attend this important meeting in 2010 as this venue provides access to, and discussions regarding, updates in ethical research practices, trends in the industry and current thinking on regulatory interpretations.

The IRB staff attended a Research Community Forum (SJMHS was a sponsor), "Reducing Regulatory Burden: Real Strategies for Real Change," on Thursday, May 14, 2009 at the University of Michigan, which was co-hosted by the federal Office for Human Research Protections (OHRP) and the University of Michigan. The conference focused on using the flexibility within the regulations to decrease administrative burdens for researchers and Institutional Review Board (IRB) activities. Darlene Wahlberg led a breakout discussion session that focused on principal investigator conflict of interest. The next day Darlene Wahlberg attended an annual "Big Ten" meeting where IRB compliance staff gathered to discuss the latest research regulatory hurdles within their institutions. She was pleased to be included and was able to share with the other attendees our challenges as well. Attending this meeting was a great opportunity to connect with many large academic institutions and be a part of the overall discussion on improving the clinical research process.

In 2009 all IRB members had the opportunity to attend three continuing education sessions on clinical research. These important offerings provide insights into regulatory interpretations and research developments, offering dedicated time for thorough discussion on salient topics.

On January 29, the IRB viewed a keynote address by Ivor Pritchard, Senior Advisor to the Director of the Office for Human Research Protections (OHRP) that was previously given at the PRIM&R meeting on November 18, 2008. This address was especially poignant as it focused on a quality improvement initiative called "**Keystone**", a study in which SJMHS is a participating site. This John Hopkins University initiative led to a national debate, discussed in the peer-reviewed medical literature and the popular media, of ethical principles and regulations that challenge the definition of research and what it means in regard to quality improvement endeavors. To supplement the presentation, the following reference material was provided to each IRB member and SJMHS research colleagues: *Health Care Quality Improvement: Ethical and Regulatory Issues*, published by the Hastings Center in 2007. This publication provides a compilation of articles authored by industry experts that provide guidance on the research implications of quality improvement endeavors.

On April 30, Darlene Wahlberg presented a talk on exempt and expedited reviews to IRB members. The regulations were reviewed along with the decision trees published by the OHRP. This session proved helpful as the IRB is challenged daily to offer the most efficient route of review while keeping careful watch over human subject protections.

On July 30, guest speaker William Hamman, MD, PhD, from Western Michigan University's School of Aviation, presented to the IRB on the technique of simulation and how it is used in research. This interesting and thought-provoking presentation summarized a unique method of conducting research. Talking to the expert allowed IRB members the opportunity to develop their thoughts regarding patient protections using novel approaches. Simulation and the "avatar" have many uses in the healthcare arena, and it behooves us to prospectively think about these methods before they are routinely employed.

IRB Paperless Administration

In October 2008, IRB#1 began using IRBANA for electronic review of initial study protocols and informed consent documents. As a result, all new studies are now reviewed electronically. In 2010, electronic review of all materials submitted to IRB#1 will be implemented.

On March 18, 2009 the ***Signatory Policy*** was issued to define the use of the electronic signature for all IRB study approval letters. This method has improved distribution and eliminated traditional hard copy reports.

Oncology IRB Updates

The Michigan Cancer Research Consortium Community Clinical Oncology Program (MCRC CCOP) led the national efforts to lower the regulatory burden for CCOPs nationwide. At a recent National Cancer Institute (NCI) CCOP meeting in March, Dr. Philip Stella, CCOP PI; Beth LaVasseur, CCOP Administrator; and Ms. Koehler presented a proposal to encourage the clinical research cooperative groups to follow national FDA and OHRP guidelines by reviewing external adverse events centrally. The efforts of this action are expected to save up to 41,000 hours per year at CCOP sites and IRBs nationally. This led to the updated policy entitled *Unexpected/Adverse Event Reporting* that was adopted by both SJMHS IRBs.

The MCRC CCOP is now ranked the #1 member institution within the North Central Cancer Treatment Group (NCCTG), headquartered at the Mayo Clinic in Rochester, MN. This ranking system, initiated by NCCTG in 2007, ranks member institutions on the basis of performance in several areas, including subject accrual, data, participation in development of studies, and audit outcomes. MCRC was ranked the highest out of 40 other institutions outside of Mayo Clinic.

Ms. Trista Koehler was appointed to the NCCTG Audit Committee. By serving

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as a member of the committee, she will be auditing other NCCTG member institutions. She will review regulatory, pharmacy and patient chart compliance, and will provide an important regulatory compliance perspective to the committee. Her experience as a guest auditor for NCCTG over the past several years has proven valuable to her appointment.

Ms. Trista Koehler also continues to serve on the National Cancer Institute Central Institutional Review Board (NCI CIRB) Local Site Advisory Panel. This panel was formed to help identify and provide solutions for critical issues associated with NCI CIRB-approved clinical research trials.

IRB Descriptive Statistics (January 2009-December 2009)

	IRB #1	IRB #2
Initial Reviews - Full Board	30	43
Tabled Studies for Initial Review - Full Board	6	1
Expedited New Study Reviews	16	0
Renewals	127	262
Addenda / Revisions	98	161
Adverse Events - External	754	3190
Adverse Events - Internal	37	117
Expedited Reviews	325	696
Reviews - Exempt	68	0
Facilitated Reviews - New Study	0	10
Facilitated Reviews - Addenda/Revisions	0	58
Facilitated Reviews - Continuing Reviews	0	76
New Studies NOT Approved	0	0
Total Submissions to the IRB	1461	4614
Average of Days Until Approval =	61 days	33 days
Range of Days Until Approval =	0 - 133 days	12 - 39 days

IRB #1 Staff

IRB#1 is chaired by James Mitchiner, M.D., and meets on the first Tuesday of the month. Staff support for IRB#1 is provided by Darlene Wahlberg, Senior Research Coordinator. Questions regarding IRB#1 should be referred to Ms. Wahlberg at 734-712-3283.

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IRB #2 Staff

IRB#2, the OCIRB, is chaired by Andrew Eisenberg, M.D., and meets on the third Thursday of the month. Staff support for the OCIRB is provided by Trista Koehler, Senior Research Coordinator. Questions regarding the OCIRB should be referred to Ms. Koehler at 734-712-1029.

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On the Internet since 2005 at: <http://www.sjmercyhealth.org/body.cfm?id=873>