



ST. JOHN HOSPITAL & MEDICAL CENTER

Summer – July 2005
Issue 2

Research Quarterly

News for and by the IRB and Research Professionals of St. John Healthcare System

Welcome to the Second Edition of the Research Quarterly!

The St. John Hospital & Medical Center Institutional Review Board (IRB) feels that the distribution of information to research professionals is important, and imperative to good clinical practice (GCP), and effective research within our organization. It is for this purpose that the IRB has created the Research Quarterly Newsletter. This newsletter will be published in May, July, October, and January of each year to further the education and knowledge base of IRB professionals, primary Investigators, research coordinators, and other research personnel.

The IRB would like to invite all researchers, investigators, coordinators, and other research personnel to submit ideas, articles, research tidbits, and updates to Mary Barnhart, the IRB Coordinator, by fax at 313-343-7840 or through email at mary.barnhart@stjohn.org. or to Lee Booze-Battle, IRB Assistant at 313-343-3863 or by email to lee.booze-battle@stjohn.org. This newsletter is by and for research professionals. If you have an area of interest, exciting study developments, need for specific research, or research updates, please submit them for publication. We hope this newsletter will provide you with information to assist you in the research process and help make the St. John IRB a

trendsetter in the research community.

Peter A. Nickles, M.D.

Chairman, Institutional Review Board



IRB NEWS

By

Peter A. Nickles, M.D.
Chairman, IRB

COMPUTER BASED RESEARCH TRAINING REQUIRED PRIOR TO PROTOCOL APPROVAL

The Institutional Review Board of St. John Hospital & Medical Center (SJHMC) requires that all key personnel participating in human subjects research complete educational training in the protection of human research subjects. All investigators, co-investigators and study coordinators are considered key personnel. Others may also be included.

This initial requirement may be fulfilled by one of the following:

- 1) completion of the computer based training

<http://ohsr.od.nih.gov/cbt> IRB Members section, **OR**

2) completion of the computer based training at <http://cme.nci.nih.gov>

All IRB members and staff must complete the IRB Members section in (1) above.

Option (2) provides up to 2 hours of category 1 credit (accredited by the Accreditation Council for Continuing Medical Education, ACCME)

DOCUMENTATION

A copy of the "Certification of Completion" at the end of each program **must** be sent to the IRB Office, Medical Education, MOB, Suite 340, 19251 Mack Avenue, Grosse Pointe Woods, MI. 48236 for documentation.

Why is Training Necessary?

The purpose is to assure that all research investigators have had appropriate institutional training before conducting human subject research. The goals for education are (1) increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research (2) improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research (3) develop appreciation for the range of accepted scientific practices for conducting research (4) provide information about the regulations, policies, statutes, and guidelines that govern the conduct of research (5) develop positive attitudes toward life-long learning in matters involving the responsible conduct of research. Documentation of completion will be kept in file in the IRB Office.

REMEMBER! NO PROTOCOLS WILL BE APPROVED BY THE IRB WITHOUT EVIDENCE OF RESEARCH ETHICS TRAINING.

IRB UPDATE
by
IRB Administrative Office



St. John Hospital & Medical Center and the IRB would like to welcome Lee Booze-Battle, BS, CIM, as she joins our staff as the new IRB Assistant. Lee comes to us from St. Joseph's Mercy Healthcare System with extensive IRB experience and background. The IRB is pleased to welcome Lee as a member of our IRB Team.

For research and application materials, or IRB information, Lee can be contacted at 313-343-3863, by fax at 313-343-7840 or through email at lee.booze-battle@stjohn.org.

New Application Forms

The IRB application has been revised. Please contact our office if you need the new version. The consent form skeleton has also been updated. We will be happy to provide copies. We also want to encourage electronic submission of application materials. A signed copy of the application form still needs to reach us in a timely fashion.

WE HAVE MOVED!

As of May 5, 2005 the IRB Office and Medical Education have moved. We are located on the third floor of the Mack Avenue Medical Office Building.

Our new address is:
19251 Mack Avenue, Suite 340
Grosse Pointe Woods, MI. 48236

Interoffice Mail for the IRB can be sent to MOB, Suite 340.

Telephone and Fax Numbers are:

Telephone: 313-343-8314, or 313-343-3863
FAX: 313-343-7840

IRB INFORMATION CORNER



INVESTIGATOR RESPONSIBILITIES!

Researchers! Are You Aware of Your Responsibilities?

Each investigator is responsible for taking action to promote and protect the research subject's rights and safety. The investigator assumes the responsibility for compliance with Federal, state, and institutional rules and regulations related to research involving human subjects. The investigator may not initiate any research involving human subjects without Institutional Review Board (IRB) review and approval.

The promotion and protection of research subjects' rights and safety consistent with Federal and State Law and regulations is the primary responsibility of each investigator in the conduct of his/her research study.

The IRB holds the principal investigator responsible for the following aspects of research:

The Protection of Human Subjects

1. To ensure the risks to the involved research subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the subjects to risk;
2. To ensure that risks to the subjects are reasonable in relation to the anticipated benefits (if any) to the individual and the importance of the knowledge that may be expected to result;
3. To ensure the selection of subjects is equitable;
4. To ensure in the event of an adverse event, every reasonable effort is made to provide the involved subjects, as soon as possible, with adequate care to

correct or alleviate the consequences of the adverse event to the extent possible;

5. To ensure the subjects are informed of any new information that may affect their willingness to continue to participate in the study;
6. To promptly report to the IRB any information received from the study sponsor of serious or unexpected adverse events or any reported significant changes to the risk/benefit ratio.
7. To notify the IRB of any on-site serious adverse events (SAE) within 7 days of becoming aware of the SAE. An SAE is defined by the FDA as any adverse experience occurring during any study that results in any of the following outcomes:
 - a. Life-threatening
 - b. Death
 - c. Hospitalization/prolongation of hospitalization
 - d. Congenital anomaly
 - e. Persistent or significant disability/incapacity
 - f. Required intervention to prevent permanent impairment/damage

Informed Consent

1. To ensure that subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research, and that informed consent will be obtained from each subject or his/her legally authorized representative, in accordance with St. John Hospital & Medical Center IRB policy, and Federal regulations;
2. To obtain informed consent prior to research participation, to appropriately document said consent, and to provide a signed copy of the consent to the research subject in a timely manner;
3. To ensure, where appropriate, that routine monitoring of data collection is in place for the safety of subjects;
4. To ensure the privacy of subjects is protected and confidentiality is maintained as agreed by the subject

in the informed consent, and consistent with Federal and State law and regulations affecting the privacy interests of research subjects; and

5. To ensure that appropriate additional safeguards are included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (i.e., children, prisoners, pregnant women, mentally disabled persons and economically or educationally disadvantaged persons).

Investigator Interaction with the IRB

1. To ensure a prompt response is provided to all requests for information or materials solicited by the IRB Office, including the timely submission of protocols for re-approval;
2. To ensure enrollment of subjects is not begun or continued:
 - a. Until such study is approved in writing, by the IRB,
 - b. During periods wherein the IRB, sponsor/principal investigator, or FDA has suspended study activities, or
 - c. Following IRB, FDA, sponsor/principal investigator-directed termination of the study;
3. To ensure prompt reporting to the IRB, sponsor, and government agencies (if applicable), any serious or unexpected adverse event that is observed in the study or any significant changes to the risk/benefit ratio. To ensure that such reporting is consistent with IRB policy and procedure;
4. To ensure that IRB relevant recommendations and approvals are maintained with the study records.

Are You Conducting Research With Human Subjects?

Human subjects are living individuals about whom an investigator conducting research obtains (1) data through intervention or interaction with the individuals, or (2) identifiable private information. Regulatory requirements to protect human subjects (research participants) apply to a much broader range of research than many investigators realize, and researchers obtaining new data or using existing data are often unsure about how regulations apply to their research. Regulatory and ethical obligations to protect research participants apply, for example, to research that uses:

- **Data from varied research methods** including surveys, interviews, and observation;
- **Private information**, such as medical, family, or employment information, or administrative records including earnings, and treatment histories that can be readily identified with individuals, even if the information was not specifically collected for the study in question;
- **Tissue specimens**, obtained for routine medical care that would have been discarded if not used for research, or **DNA samples**, where samples or specimens can be linked to a living individual. (For detailed information, see Research on Human Specimens (Brochure) www.cdp.ims.nci.nih.gov/policy.html)

If so, you must...

Comply with SJH&MC's rules and the requirements of the IRB as well as meet the Federal requirements¹ in order to carry out your research. If you have any doubts about whether you need IRB approval, ask your IRB chair, or office staff for clarification². If you apply for an NIH grant, or respond to a Request for Proposal (RFP), failure to follow SJH&MC's procedures, or to document the use of human data in your grant application or contract proposal, may delay or prohibit funding.

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1. Title 45 Code of Federal Regulations (CFR), Part 46, Protection of Human Subjects (June 18, 1991).
 2. If your institution has no IRB, you may establish an IRB at your own institution or you may obtain approval for your plan to involve human subjects from an IRB elsewhere that satisfies all Federal requirements. For information about these options, contact the Office for Human Research Protections (OHRP).

Why is Research Important to a Healthcare System

By
Peter A. Nickles, M.D., Chairperson
Institutional Review Board



The St. John Hospital and Medical Center (SJH&MC) currently has about 300+ open research investigations underway. This includes studies by our physicians, nurses, social workers, residents and others. The number of sponsored research projects underway at SJH&MC has continued to rise steadily over the last 5 years. This trend towards increasing research activity within our systems begs the questions of “What role does research play here at St. John Hospital & Medical Center?” and “How does it contribute to the overall institutional mission and strategic plan?” Below is a partial listing of some of the benefits that a vibrant, active research program can bring to our healthcare system.

- Increased Availability of State-of-the-art Therapies: Involvement in clinical trials research allows SJH&MC to bring promising new therapies to our patients before they are made available to the general public. This gives our Clinicians wider treatment options, keeps them better informed about new

treatments and hopefully produces better outcomes of care, as well as influencing retention of existing patients & recruitment of new patients:

- Improved care and satisfaction for participating patients: Increasingly well-informed patients are seeking out institutions that offer cutting edge therapies. This is particularly true for chronic and life-threatening conditions such as cancer and severe cardiac illness.
- Encourages “critical thinking skills” in staff: Involvement in research requires and hones critical thinking skills. This allows investigators to ask relevant questions about how we deliver care and frame those questions in ways that are testable. Doing this rigorous methods, and valid data is not only critical to research in its more formal sense but equally important for functions such as Care Management and our High-Leverage Opportunity initiatives as well.
- Give SJH&MC a higher academic profile: Medical research makes news and is of great interest to the general public. Television, radio and print news almost all provide some type of specialized health reporting. This interest by the public and these venues for reporting to the public are not lost on healthcare systems including our market competition. Patients want to be treated by the experts and reporting on research activities conveys to the public greater credibility and expertise.

SJH&MC continues to evolve and adapt to a very complex healthcare market. Survival will in part depend on creative ways to set ourselves apart from our competition and to make the communities we serve aware of our excellent care. Increased research activities infuse the system with a number of benefits that ultimately translate to better care, more satisfied patient/families and staff, and is an essential part of any strategic plan for a healthcare system.

**National Association of IRB
Manager's Holds the 2005
Convention in Detroit**

The National Association of IRB Manager's (NAIM) held their 2005 National Convention at the Crowne Plaza on Merriman Rd. in Romulus, MI on May 19, and May 20, 2005. It was a great honor to host this national research convention in our city. Speakers from the Office of Human Research Protections (OHRP), Office of Research Integrity (ORI), and the Food & Drug Administration (FDA) taught sessions on FDA Regulations and Audit, OHRP Guidelines, and Scientific Misconduct.

Our own IRB Coordinator, Mary Barnhart, MA, CIM, and CIP was included on the speaker list at the convention. Mary taught a session on Certification for IRB Professionals and is the Associate Program Director for the association.

A special "thank you" should be extended to those SJH&MC associates that helped to make the NAIM, 2005 Conference, a success, Ruth Moore, Lee Booze-Battle, Mary Barnhart, and Jeff Warglo.

**Suggestions or Comments on this
Newsletter**



If you have any suggestions or comments regarding this newsletter, its design or content, please contact, Mary Barnhart, at our IRB Office 313-343-8314 or Lee Booze-Battle, at 313-343-3863.

If you would like to contribute to this newsletter and/or have suggestions for articles and information you would like included please let us know. ***The next Research Quarterly Newsletter will be distributed in***

OCTOBER 2005, and all articles are due by September 30, 2005.

The purpose of this publication is to inform, educate, and provide a forum for discussion of research related issues. So please write an article and share the exciting things happening in your area of research.

The IRB hopes that the information provided in this newsletter has given you insight and provided you with valuable information.

Reminder!!!

Protocol submissions are due the first day of each month. In order to ensure that your protocol is considered in a timely manner, please adhere to the deadline.



IRB Office Information:

Hours of Operation:

Monday through Friday, 7:30 AM – 4:30 PM

Contact Information:

Telephone Number: (313-343-8314)
or
(313-343-3863)

Fax Number: (313)-343-7840

The IRB Office is your research resource center. Please do not hesitate to call us if you need information, or assistance.