



Research Quarterly

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

IRB NEWS

by
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Chairman, IRB

FDA Audit of the IRB a Resounding Success

The Food and Drug Administration (FDA) recently completed an audit of the St. John Hospital and Medical Center (SJHMC) Institutional Review Board (IRB). The FDA auditor commended the SJHMC IRB on the implementation of new programs and processes instituted over the past 17 months to enhance the protection of human subjects in research.

Congratulations to the IRB Administrative Staff for job well done. Your hard work and dedication have made a difference!

New Forms

The IRB application, continuing review form, revision application, and serious adverse event reporting forms have been revised, and the consent form skeleton has been updated. Please contact our office if you need the new versions.

We also want to encourage electronic submission of application materials. If electronically submitted, a signed copy of the application form still needs to reach us in a timely fashion.

Outdated and/or unsigned forms received by the IRB will be returned which may delay your project.

IRB Standard Operating Procedures (SOPS)

The IRB SOPs are printed and available as a resource document. If you have not received a copy please call 3-8314 or 3-3863.

REMINDERS

The IRB’s responsibility is to protect the rights and welfare of human subjects. The IRB reviews and oversees research to ensure that it complies with federal regulations that pertain to human subject protection, as well as good clinical practice (GCP) guidelines of the International Conference on Harmonization. No interaction with human subjects in research may begin until the IRB has reviewed and approved the protocol.

NEW STUDIES - Four (4) copies of the protocol and of the Investigator Brochure, plus two (2) copies of the application and all other materials are required.

ALL OTHER SUBMISSIONS – Two copies of all other submissions, (Continuing Review, adverse events, amendments, updated Investigator Brochures, memorandums, etc), are required.

Please use the IRB # (e.g. SJ 1010-01) when referring to your Protocol. The IRB # will assist us in locating the file and answering your questions quickly.

The IRB office is your resource center and will always be available to provide information or assistance.

IRB OFFICE CLOSURE

The IRB office will be **closed November 15-18, 2006** while the IRB staff attends the national convention in Washington D.C.

THE NOVEMBER IRB MEETING WILL BE ONE WEEK EARLIER: NOVEMBER 9, 2006.

To learn more about clinical trials available at SJHMC, please 313-343-8314 or visit <http://sjnet.sjhs.com/med-ed/IRBindex.htm>.



IRB 2007 Meeting Dates

All meetings are scheduled on the third Thursday of each month at 7:30 AM in the Mack Office Building, Suite 390.

- January 18, 2007
- February 15, 2007
- March 15, 2007
- April 19, 2007
- May 17, 2007
- June 21, 2007
- July 19, 2007
- August 16, 2007
- September 20, 2007
- October 16, 2007
- November 15, 2007
- December 20, 2007

IRB Administrative FEE Increases in 2007

Effective January 2, 2007, the one-time IRB Administrative Fee to review externally sponsored projects will be raised from \$1500.00 to \$2000.00.

Please alert all sponsors to this increase and make sure the new fee is included in all contracts. For further information, please feel free to contact the IRB office at 313-343-8314 or 313-343-3863.

Congratulations

Mary Barnhart, IRB Coordinator, will present a poster titled "Developing a Research Continuing Education Program from the Ground Up" at the Public Responsibility in Medical Research (PRIM&R) annual meeting in Washington DC, November 15-18, 2006. Well done!

SJHMC IRB recognized as a Top Ten Program!

The National Association of IRB Managers in Atlanta, Georgia has named St. John Hospital & Medical Center (SJHMC) as one of this year's top ten programs for continuing education in human research management. The award is given



to those institutions demonstrating a drive and commitment to providing quality continuing education in

research. Our IRB will be honored at the Association' May 2007 Convention in Atlanta.

"As a peer selected top ten institution, we are honored by our selection and by the acknowledgement of our hard work and effort to be a role model IRB," said Mary Barnhart, IRB Coordinator. "We thank the hospital leadership for its commitment to research excellence at our institution. This award belongs to all of us."

The National Association of IRB Managers, Inc. (NAIM) is an independent human research management organization based in Atlanta, Georgia. It developed back in early 1994, when the FDA and other regulatory authorities made a number of visits to institutions in the Atlanta area. In the process, skills an IRB should have were defined, and a study committee formed to increase the skill level of local IRB managers. That committee spawned a state, then a national convention. The Association was formed in response to a need for consistent training of IRB managers throughout the US.

Congratulations to the IRB for this honor. Well done!



To learn more about clinical trials available at SJHMC, please 313-343-8314 or visit <http://sjnet.sjhs.com/med-ed/IRBindex.htm>.

INVESTIGATORS: Anyone working on your research study must complete the NIH computer-based training modules found at:

<http://cme.nci.nih.gov>

Anyone consenting subjects or collecting data in a research trial **must** be detailed to the IRB. Research coordinators often change projects, and the IRB Office needs to be informed.

EDUCATIONAL PROGRAMS FOR INVESTIGATORS AND RESEARCH STAFF

Wednesday, October 25, 2006, Denise Cunningham, R.N. gave a presentation titled "Good Clinical Practice: Tips and Insights for Research

Coordinators". The Program was well attended, and the information provided informative and useful. Thanks Denise!

Save the date! Our next program on **January 24, 2007** will be presented by Patti Webber, RN, BSN, Education Coordinator for Wayne State University. Her topic is "The Informed Consent Process."

If you have ideas for topics or speakers, please call the IRB office at 313-343-8314 or 313-343-3863.

IRB INFORMATION CORNER



Government Guidance on Lapse of Continuing Review

WHAT IF THERE IS A LAPSE IN CONTINUING REVIEW?

There is no regulation that allows the IRB to retrospectively approve a research study. IRB approval must be obtained prior to lapse in previous IRB approval.

The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop. While the IRB *may* determine that it is in the best interests of individual subjects to continue participating in the research, that decision is not in the hands of the investigator or sponsor. New subjects cannot be enrolled if IRB approval lapses.

When a research protocol has not undergone continuing review prior to the end of the IRB-specified approval period, IRB approval expires automatically.

FDA Guidance: The Informed Consent Process

Is getting the subject to sign a consent document all that is required by the regulations?

No. The consent document is a written summary of the information that should be provided to the

subject. Many clinical investigators use the consent document as a guide for the verbal explanation of the study. The subject's signature provides documentation of agreement to participate in a study, but is only one part of the consent process.

The entire informed consent process involves:

- giving a subject adequate information concerning the study
- providing adequate opportunity for the subject to consider all options
- responding to the subject's questions,
- ensuring that the subject has comprehended this information
- obtaining the subject's voluntary agreement to participate
- continuing to provide information as the subject or situation requires.

To be effective, the process should provide ample opportunity for the investigator and the subject to exchange information and ask questions.

May informed consent be obtained by telephone from a legally authorized representative?

A verbal approval does not satisfy the 21 CFR 56.109(c) requirement for a signed consent document, as outlined in 21 CFR 50.27(a). However, it is acceptable to send the informed consent document to the legally authorized representative (LAR) by facsimile and conduct the consent interview by telephone when the LAR can read the consent as it is discussed. If the LAR agrees, he/she can sign the consent and FAX the signed document to the clinical investigator.

Are there alternatives to obtaining informed consent from a subject?

The regulations generally require that the investigator obtain informed consent from subjects. Investigators also may obtain informed consent from a legally authorized representative of the subject. FDA recognizes that a durable power of attorney might suffice as identifying a legally authorized representative under some state and local laws. For example, a subject might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research. FDA defers to state and local laws regarding who is a legally authorized representative. Therefore, the IRB should assure that the consent procedures comply with state and

local laws, including assurance that the law applies to obtaining informed consent for subjects participating in research as well as for patients who require health care decisions."

Alternatives 1 and 2 are provided for in the regulations and are appropriate. Alternative 3 allows a designated individual to provide consent for a patient with regard to health care decisions and is appropriate when it specifically includes entry into research. FDA defers to state and local laws regarding substituted consent. Therefore, the IRB must assure itself that the substituted consent procedures comply with state and local law, including assurance the law applies to obtaining informed consent for subjects participating in research as well as for patients who require health care decisions.

When should study subjects be informed of changes in the study?

Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects (21 CFR 56.108 (a)(4)). Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). FDA does not require reconsenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

QA/QI PROJECTS AND PUBLICATION

Excerpt from Robert Amdur and Elizabeth Bartlett Institutional Review Board: Management and Function. Jones & Bartlett Publ., 2006. pp 102-103.

Publication of results does not define a project as Research:

The assumption that academic publication or presentation equals research is incorrect. Publications and presentation of results is clearly the goal of all research activity, but there are situations in which academic forums are used to share the results of non-research activity with interested colleagues in the hope that they will benefit from the information. Medical Journals often contain articles that discuss information that is not the result of research activity, and the same holds true with medical meeting agendas.

Education not research is the most accurate term for these kinds of activities. **It is appropriate to inform researchers that non-research activities can be published, but it is necessary to remind them that the word research cannot be contained within the publication.**

If *research* is used to describe the project, IRB review is required, and journal editors may inquire about the status of IRB review

QUALITY ASSURANCE CHECKLIST FOR INVESTIGATORS

Conditions for Determination of QA/QI status:

1. The primary intent of the project is not peer-reviewed publication, and if publication of the results were prohibited, the project would still have merit as a QA/QI effort.
2. There is documented commitment, in advance of data collection to a corrective plan given any of a number of study outcomes.
3. The responsible staff member has both clinical supervisory responsibility and the authority to impose a corrective plan based on the outcomes of the project.
4. The project does not involve prospective assignment of patients to different procedures or therapies based on a predetermined plan such as randomization.
5. The project does not involve a "control group" in whom therapeutic or study intervention is intentionally withheld to allow an assessment of its efficacy.
6. The project does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including off-label indications).
7. Human participants will not be exposed to additional physical, psychological, social or economic risks or burdens (beyond patient satisfaction surveys) in order to make the results of the project generalizable.
8. Adequate protections are in place to maintain confidentiality of the data to be collected and there is a plan for who can access any data containing participant identifiers.
9. The project is likely to improve patient care activities and/or outcomes at SJHMC alone or as part of Ascension Health.

For the project to be classified as a QA/QI initiative, the answers to all the above questions must be "Yes". If one or more answers is "No", the project requires IRB review and approval.

ELECTROPHYSIOLOGY LAB NEWS



Dr. Luis Pires, Director of the Heart Rhythm Center and Vice Chief of Cardiology at SJHMC, is an investigator in, among others, two landmark multi-center clinical trials. The first is titled RethinQ (Resynchronization Therapy in Narrow QRS), and uses specialized echocardiographic

studies to identify patients who may benefit from biventricular pacing therapy when the QRS interval is narrow. Depending on results of this clinical trial, this may become a novel method of selecting patients for this useful form of heart failure therapy. Currently patients are selected based on a QRS interval greater than 130 ms. Dr. Pires is a steering committee member for this clinical trial.

The second study is titled the MADIT CRT (Multi-center Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy), and it aims to determine if prophylactic biventricular pacing therapy (also known as cardiac resynchronization therapy, CRT) can inhibit the progression of heart failure symptoms and possibly improve survival in patients with mild (NYHA Class I or II) heart failure. Currently, only patients with NYHA Class III or IV heart failure are eligible for CRT.

For information regarding these and other clinical trials being conducted in the Heart Research Center at SJHMC, please contact Dr. Luis Pires, MD, Director of the Heart Rhythm Center at 313-343-7327 or Rosemarie Henschel, RN, Electrophysiology Research Coordinator at 313-343-4714.

UPDATE FROM EMERGENCY MEDICINE

The fall has been busy in the Emergency Medicine Department with 4 presentations at the Mid-West SAEM Regional meeting, on September 25, 2006, including one that won best poster presentation titled: "Hospital Personnel Response during a hypothetical Influenza." Other presentations included:



"Pandemic-Will they come to work?", authored by Dr. Charlene Irvin, William Patterson, and Lauren Cindrich. This project was presented by William Patterson, a University of Michigan premedical student who worked with

Dr. Irvin during the summer on this research project. This presentation was actually an abbreviated oral, and William did an outstanding job in his first oral research presentation.

- Other presenters included Dr. Patricia Nouhan who presented her project titled: "Demographics of Patients Returning to an Urban Emergency Department within 48 hours of Their Initial Visit" and
- Dr. Elizabeth Bascom, who had an extended



oral presentation titled: "Building Bridges: Breast Cancer Prevention in Emergency Departments by Connecting At Risk Women to Mammography."

Dr. Bascom also presented a poster (shown below) describing her study at the National American College of Emergency Medicine Research Forum in New Orleans in October. The Society issued a national press release about the study that quoted Dr. Bascom.



Four other presentations were given at the National Research Forum, including three by Dr. Benjamin Flagel. Ben has been very active in research since he joined the Emergency Medicine residency at SJHMC. His presentations were titled:

- Delta GS in Head-Injured Patients
- Trauma Center Designation: Time to Operating Room and Outcome
- Delta GCS: A New Predictor of Outcome in Blunt Trauma

His work, co-authored with Dr. Irvin, has resulted in a quick and easily applied method to identify

trauma patients at increased risk for mortality and morbidity. If the calculated change in Glasgow Coma Scale (GCS) score (EMS GCS minus the ED arrival GCS), is more than -2 to -3, even if the initial GCS is 13-15, it can reveal a patient at risk for increased mortality and morbidity.

Nate Minnick, former pre-med student at the University of Michigan, presented his work with Dr. Wimmer "Non-Invasive Cardiac Output and Cerebral Oximetry Compared with Traditional Measures". Nate is now a first year medical student at Virginia College of Osteopathic Medicine.

In addition, SJHMC and St. John Oakland have 9 presentations accepted at the Society of Emergency Medicine Mid-Atlantic Regional Meeting at Georgetown University in Washington, DC on November 3, 2006. As EM research directors from SJHMC and St. John Oakland respectively, Drs. Charlene Irvin and Elizabeth Bascom are intensively involved with these projects. Unfortunately, both will be out of the country on a medical mission trip to remote areas in Brazil, and unable to attend the meeting. Supporting the residents and students, and as co-author on 2 of these projects, Dr. Marson MA II will be attending.

Internal Medicine Update

Our Internal Medicine residents have also done well recently.

- Dr. Navkiranjot Brar took third place for her poster "The Impact of Avoiding Both Steroids and Calcineurin Inhibitors on Polyomavirus-associated Nephropathy in Kidney Transplantation" at the Michigan Association of Physicians from India (MAPI) May meeting. Drs. Butcher, El-Ghoroury and Provenzano from Nephrology were her advisors.
- With Dr. Desi Kamalakannan, Dr. John Frank won Second Place for their Poster titled "Retroperitoneal Hematoma in Patients Undergoing Cardiac Catheterization." at the state American College of Physicians meeting in September. Dr. Howard Rosman was mentor for the project. Dr. Frank has placed every year he has attended this meeting – a remarkable achievement!
- Dr. Manreet Kanwar (Manpreet Kanwar's sister) won third place for her oral presentation "An Unusual Presentation for Small Cell

Cancer" at the state American College of Physicians meeting in September. Dr. Robert Leonard was her advisor.

- With Navkiranjot Brar, Manreet also won the KASS award at the 2006 Annual Meeting of the Infectious Disease Society of America (IDSA) for their poster titled "Overdiagnosis of Community Acquired Pneumonia and Inappropriate Utilization of Antibiotics: Side Effects of the 4-hour Antibiotic Administration Rule" under the guidance of Drs. Riad Khatib and Mohamad G. Fakh.

Wayne State Receives CTSA Planning Grant

Wayne State University recently was awarded a \$150,000 planning grant for a Clinical and Translational Science Award (CTSA). The NIH is following a Congressional mandate to deliver cutting-edge research to the community faster and more efficiently than currently occurs. Community hospital-university partnerships are envisioned as the best way to make more rapid strides in moving research findings from bench to bedside. Led by the National Center for Research Resources (NCRR), this new consortium, funded through CTSA's, has begun with 12 academic health centers (AHCs) throughout the nation. An additional 52 AHCs received planning grants to help them prepare applications to join the consortium. At full implementation in 2012, this clinical and translational science endeavor will link about 60 institutions. This link gives more information on the consortium:

<https://www.ctnbestpractices.org/networks/nih-ctsa-awardees/>

SJ Health's hospitals are well positioned to join with WSU in this important endeavor!

IRB Office Information

Hours of Operation:

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

313-343-8314 – Mary Barnhart

313-343-3863 – Lee Booze-Battle

313-343-7813 – Denise Cunningham

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.