

Research Quarterly

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



IRB NEWS

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

New Forms

The IRB application and serious adverse event reporting forms have 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. If electronically submitted, a signed copy of the application form still needs to reach us in a timely fashion. *Outdated forms received by the IRB will be returned which may delay your project.*

REMINDERS

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

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

Remember: For timely service, please use the IRB # (e.g. SJ 1010-01) when referring to any number of protocols and using the IRB # will assist us in locating the file and answering your questions quickly.

The IRB Monitoring Program BEGINS in June!

by
Denise Cunningham, R.N., MSN, CCRC, CIP
Research Nurse Monitor



I would like to introduce myself. I transferred to St. John in March from Providence Hospital after 35 years of service with 27 of those years spent in the Research Department. I have experience as a study coordinator and a clinical trials manager. I have been a member of the Providence Hospital Research Committee and IRB for many years and continue to serve on these committees. I also have experience as an independent site reviewer for a central IRB. I am grateful for the opportunity to implement the IRB Monitoring Program at St John as your Research Nurse Monitor. I am inviting you to join me in this exciting partnership.

The purpose of the IRB Monitoring Program is to ensure the institution is compliant with Federal and State regulations governing clinical research. The ultimate goal of the program is to achieve a high quality clinical research operation. The focus of the program is ongoing monitoring of clinical research studies and the education of investigators and research staff.

The IRB Monitoring Program is responsible for and has the authority to:

1. Perform routine audits on randomly selected studies that have been approved by the IRB.
2. Conduct directed audits referred by the IRB, for example high-risk studies or those

triggered by noncompliance (e.g. late continuing review, failure to report SAEs in a timely fashion, etc.).

- 3. Perform directed audits requested by others, such as a family member, an associate, a physician, or a study site in preparation for an external audit.

Once a study is selected for audit, the principal investigator and the study coordinator will be notified of the audit by telephone, and receive a written confirmation at least 10 working days prior to the site visit. The site will be asked to submit a list of all enrolled study participants. At least 20% of subject files will be examined; all informed consent documents will be reviewed.

Prior to the audit, the IRB study file for the selected protocol will be reviewed, including the protocol, IRB submissions and correspondence. During the audit, all study documents will be reviewed for completeness, accuracy and compliance with regulatory requirements. At completion of the audit, an exit interview will be scheduled with the investigator and the study coordinator to review the findings. Then a written report will be drafted itemizing and describing the findings. The principal investigator will be asked to respond to this report within 30 days. The IRB will review the audit report and investigator response, and decide on the action to be taken.

The first audit will be conducted in June 2006. One to two audits will be conducted each month. In June 2007, the first annual report will be published. This report will contain useful information for all of us regarding the strengths and weaknesses of our clinical research operation.

If you have any questions regarding the program, please contact me at (313) 343-7813 or by email at Denise.Cunningham@stjohn.org. I am available as a resource and with any help you may need in navigating the IRB system.

IRB Standard Operating Procedures (SOPS):

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

INTRODUCING THE CREDIT RESEARCH SOFTWARE SYSTEM

by
Chris Palazolo
CFO, SJH&MC



St. John Health System has purchased research management software (Clinical Research Environmental Data Information Tracking – CREDIT, a product of DDOTS, INC.) that will support the efficient management of research studies and subject follow-up as well as facilitate improved financial compliance and monitoring of research study activity and billing services. The health system has purchased this software for St. John Hospital & Medical Center (SJH&MC) employed researchers and will supply the software to private physicians who perform research approved through the hospital’s IRB.

You must be trained on and use the Credit Research Software if any of the following are true:

- 1. The researcher, research coordinator, nurses, or any research staff are employed by SJH&MC.
- 2. The research protocol involves **billable events** (those events that will be billed or performed through SJH&MC such as overnight hospital stays for research, laboratory specimen processing, researcher physician visits, device implantation procedures, operating room or procedure room usage, etc.)
- 3. SJH&MC inpatients will be used as subjects for research usage.

NOTE: The software was designed to manage research activities and the institution encourages its use by private physician research offices.

IRB UPDATES

by
IRB Administrative Office



IRB 101 An Outstanding Success

The Public Responsibility in Medicine and Research (PRIM&R) sent two outstanding educators, Daniel Nelson (above) and Moira Keane, to present an overview of Federal Regulations Governing IRB Operations on April 12th at the Grosse Pointe War Memorial. All participants agreed that it was an excellent educational experience.

Congratulations

Mary Barnhart, IRB Coordinator, presented a workshop titled "IRB Reports and Activities" at the National Association of IRB Managers (NAIM) Convention in Atlanta May 4-5, 2006. Well done!

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.

UPCOMING EDUCATIONAL PROGRAMS FOR INVESTIGATORS AND RESEARCH STAFF

Credit Research Management Software Training:
July 27, 28, 2006 at CSB – South.
Spots still available! Call the IRB Office to sign up.

INFORMATION CORNER

Guidance from:

***Office for Protection from Research Risks
(OHRP)***

"Exculpatory Language" in Informed Consent

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. --- [45 CFR 46.116](#)

Examples of Exculpatory Language:

- By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Acceptable Language Examples

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

SURGERY CENTER NEWS



Surgery Center Looks at Exercise and Breast Cancer

Surgeon Cheryl Wesen, M.D. has teamed up with physical therapist Michelle Doan to study the effects of exercise on patients who have undergone sentinel lymph node biopsy (used to determine the presence of breast cancer) compared to patients who do not exercise. Subject participation is taking place at the St. John Outpatient Therapy Clinic in St. Clair Shores.

In collaboration with Oakland University and SJH&MC Physical Therapist Rebecal Mucha, the study demonstrates SJH&MC's on-going commitment to service excellence and research-supported techniques that will best serve this patient population. For more information regarding this study, please call 586-489-3500.

NEWS FROM FAMILY MEDICINE



Seasonal Variation of Postpartum Depression by Patti Mackin, Research Assistant

Since July 2004, Family Medicine (FM) resident physicians Manjeet Geeta and Veena Panthangi have been working on a study investigating seasonal variation of postpartum depression (PPD). Seasonal variation of depression has been a popular topic for researchers for some time. Similarly, PPD has been widely investigated. Between 15% and 20% of women experience depression (as opposed to "baby blues") after giving birth. Women who have given birth during the winter months may be more likely to experience symptoms of depression. However, only a single publication suggests that there may be seasonal variation in PPD. The FM residents designed a study to evaluate this possibility.

For the past two years, data collection has been carried out at the Family Medical Center, Masonic Medical Center, and St. John OB/GYN clinic. Women returning for their six-week postnatal visit were approached (while waiting to see their doctor) by a research assistant, who explained the study. After consenting to participate, the patient was asked to fill out a questionnaire. This questionnaire included demographic information as well as the Edinburgh Postpartum Depression Scale, a tool found to be valid in women around the world. Scores on the 10-item questionnaire were used to determine whether the patient was depressed. The research assistant notified the physician of any patient with a score indicative of depression.

Overall incidence of postpartum depression was 18.4%, consistent with national rates. However, no statistically significant seasonal variation was detected except when comparing incidence of depression during the summer to non-summer months. Women who delivered during June-August were less likely to experience depression than women who delivered at other times (13.4% vs. 20.6%).

Although seasonal variation was less significant than expected, other findings confirmed prior reports of factors influencing PPD. Women who reported having excellent or very good support at home had lower rates of depression than those who with less support. Also, women were more likely to experience depression if they had higher gravidity or parity, and if they had a history of personal depression. These findings are relevant to clinical practice, as clinicians can use this information to more effectively screen their postpartum patients for depression.

The continued success of this endeavor can be attributed to the hard work and dedication of Dr. Panthangi, the current principal investigator. For her presentation on PPD, she placed First among the Family Medicine graduating residents. She went on to win First Place for her oral presentation at SJH&MC Resident Research Day and "Best Paper by a Resident" at the Michigan Family Medicine Research Day, where she competed with Family Medicine residents throughout the state.



Last year graduating resident Sharon Cabansag won First Place for her poster "Infant and Toddler Feeding Patterns and Obesity" at the Michigan Family Medicine Research Day and Juanito Joel took First at SJH&MC Resident Research Day for oral presentation "Screening for Dementia in Primary Care using the Clock Drawing and Six-Item Tool."

CANCER CENTER NEWS



Congratulations to Dr. Hadi Sawaf and the Pediatric Oncology Staff for their dedication and hard work in children's oncology!

The Pediatric Hematology Oncology Service at Van Elslander Cancer Center has been acknowledged in 4 peer reviewed journal publications and 2 national presentations within the past 6 months. If you would like reprints of these publications, please contact the Van Elslander Cancer Center.

The journal articles are:

1. **Prospective phase 1/2 study of rituximab in childhood and adolescent chronic immune thrombocytopenic purpura.** Blood 2006; 107: 2639-42.

Carolyn M. Bennett, Zora R. Rogers, Daniel D. Kinnamon, James B. Bussel, Donald H. Mahoney, Thomas C. Abshire, Hadi Sawaf, Theodore B. Moore, Mignon L. Loh, Bertil E. Glader, Maggie C. McCarthy, Brigitta U. Mueller, Thomas A. Olson, Adonis N. Lorenzana, William C. Mentzer, George R. Buchanan, Henry A. Feldman, and Ellis J. Neufeld, for the Pediatric Rituximab/ITP Study Group and the Glaser Pediatric Research Network.

From the Division of Hematology/Oncology and the Clinical Research Program, Children's Hospital Boston, Dana-Farber Cancer Institute and Harvard Medical School, MA; the Department of Pediatrics, University of Texas Southwestern Medical Center, Dallas; Weill Medical College at Cornell University, New York, NY; Baylor College of Medicine, Houston, TX; Emory University School of Medicine, Atlanta, GA; Van Elslander Cancer Center, St John Hospital, Detroit, MI; University of California, Los Angeles (UCLA)/Mattel Children's Hospital at UCLA; University of California, San Francisco; and Stanford University, CA.

2. **Childhood cancer among Arab Americans in southeast Michigan.** Ethnicity & Disease. 15(1 Suppl 1):S1-13-4, 2005

Sawaf H. Lorenzana A. Dombi G. Hamre M. Schwartz K.

VanElslander Cancer Center St John hospital; Children Hospital of Michigan; Dept of Public Health, Wayne State University

3. **Health-Related Quality of Life in Young Survivors of Childhood Cancer Using the Minneapolis-Manchester Quality of Life-Youth Form.** Pediatrics 2005; 115: 435 - 442.

Sadhna Shankar, Leslie Robison, Meriel E.M. Jenney, Todd H. Rockwood, Eric Wu, James Feusner, Debra Friedman, Robert L. Kane, and Smita Bhatia

Cited as participating institution:Childrens Hospital at North Shore, Manhasset, NY (Arlene Redner); St Johns Hospital and Medical Center, Detroit, MI (Hadi Sawaf); University of Mississippi Medical Center Childrens Hospital, Jackson, MS.....

4. **Childhood ITP: 12 Months Follow-Up Data From the Prospective Registry I of the Intercontinental Childhood ITP Study Group (ICIS).** Pediatr Blood Cancer 2006;46:351-356

P Imbach, T Kuhne, D Muller, W Berchtold, S Zimmerman, M Elalfy, and GR Buchanan

Cited as participating ICIS Registry I member: ...Merlin Hamre, Adonis Lorenzana, Jeanne Lusher, Yaddanapudi Ravindranath, Hadi Sawaf, Indira Warriar, Detroit...

Poster Presentations include:

1. **Pharmacokinetics (PK) Substudy of Rituximab in a Prospective Clinical Trial for Pediatric Chronic Immune Thrombocytopenic Purpura (cITP).** Blood (ASH Annual Meeting Abstracts) 2005 106: Abstract 1243

Carolyn M. Bennett, James B. Bussel, Brigitta U. Mueller, Thomas C. Abshire, Hadi Sawaf, Theodore B. Moore, Mignon L. Loh, Zora R. Rogers, Henry A. Feldman, Ellis J. Neufeld The Glaser Pediatric Research Network for the Pediatric ITP/Rituximab Study Group

- 1 Hematology/Oncology, Children's Hospital, Boston;
- 2 Pediatrics, NYPH-Weill Medical College, New York;
- 3 Pediatrics, Baylor College of Medicine, Houston;
- 4 Pediatrics, Emory University, Atlanta;
- 5 Pediatrics, St. John Hospital, Detroit;
- 6 Pediatrics, University of California, Los Angeles;
- 7 Pediatrics, University of California, San Francisco and
- 8 Pediatrics, UT Southwestern Medical Center, Dallas.

Poster Presentations (cont.):

2. The Impact of Rituxamab on Health Related-Quality of Life in Children with Severe, Chronic Immune Thrombocytopenia over 52 weeks. American Society of Pediatric Hematology Oncology. San Francisco, CA May 2, 2006. Abstract 3507.53

S.K. Parsons, C. Bennett, D. Mahoney, T. Olson, **H. Sawaf**, T. Moore, M. Loh, G. Buchanan, and E. Neufeld

Abstract published, not selected for presentation:

Health-Related Quality of Life (HRQL) in Children with Severe, Chronic Immune Thrombocytopenia (cITP) Treated with Rituximab. Blood (ASH Annual Meeting Abstracts) 2005 106: Abstract 5575

Susan Parsons, Carolyn Bennett, Donald Mahoney, Thomas Olson, **Hadi Sawaf**, Theodore Moore, Mignon Loh, George Buchanan, and Ellis Neufeld

Institute of Clinical Research and Health Policy Studies, Tufts-New England Medical Center, Boston, MA, USA; ²Children’s Hospital of Boston, Boston, MA, USA; ³Baylor College of Medicine, Houston, TX, USA; ⁴Emory University, Atlanta, GA, USA; ⁵St. John’s Hospital, Detroit, MI, USA; ⁶UCLA, Los Angeles, CA, USA; ⁷UCSF, San Francisco, CA, USA; ⁸UT-Southwestern, Dallas, TX, USA and ⁹Glaser Pediatric Research Network/Pediatric ITP/Rituximab Study Group, Children’s Hospital of Boston, Boston, MA, USA

Pediatric Assent

by
Lee Booze-Battle, B.S., CIM

Because children cannot legally give consent, federal regulations require the permission of their parents and, with the exception of very young children in some treatment protocols, the assent (affirmation agreement) of the child-subject.

Assent has generally been divided into three categories depending upon the age of the child-subject. The commonly accepted rule of thumb is that children under the age of 7 are too young to assent; those children between 7 to 12 should be capable of assenting; and children over the age of 12 should be able to participate fully in the consent process (i.e., giving assent and documenting that

decision in writing). Parents or guardians, however, may provide permission for their child to participate in a research study. For research with very young children (preschool and under), only the parent’s permission is typically needed.

For teenagers, a single form that both the minor and the parent(s) sign may be adequate. For children in between (7-12), two forms are generally advisable; one consent that is written at a basic level for the child (as a script for oral presentation or for reading), and a more detailed form for the parent’s understanding and signature. Furthermore, to the extent that they are able, children should be asked about their willingness to participate. Information about the research study must be presented to children at their developmental level, so they can understand what is being asked of them. The combination of assent (agreement) of the minor subject and permission of the parent or legal guardian is recognized by the federal regulations as an adequate substitute for consent.

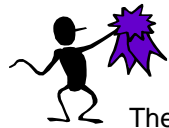
Notes from Emergency Medicine

The Department of Emergency Medicine has 4 abstracts accepted for presentation at the National American College of Emergency Medicine Research Forum to be held in New Orleans this October. Additionally, Greg Neyman (PGYIII) is the first author on a manuscript to be published in the November Academic Emergency Medicine journal titled: “A single Ventilator for Multiple Simulated Patients to Meet Disaster Surge” .

Dr. Elizabeth Bascom was named best young investigator at the New York Regional Society of Academic Emergency Medicine meeting. She graduated from St. John Department of Emergency Medicine and is an attending physician at SJH&MC and SJ Oakland.



This summer our department is investigating the use of impedance cardiography (IC), a non-invasive method to estimate cardiac output and systemic vascular resistance. Via electrodes applied to the skin of the chest, changes in impedance indicate hemodynamic alterations, making it possible to determine cardiac index and systemic vascular resistance index (SVRI). IC estimates of cardiac output are highly correlated with estimates by traditional thermodilution methods. IC utility in the emergency department has yet to be determined. Untreated hypertensive patients may present with blood pressures in the normal range if suffering from such conditions as sepsis, internal bleeding or trauma. However, this blood pressure may be a relative hypotensive state for the patient, if their blood pressure would otherwise be elevated. Information on cardiac output and SVRI may reveal a low perfusion state and help maximize clinician care. Drs. Flagel and Corwin are heading up studies to evaluate IC impact in the Emergency Department.



Presentation Awards

The Research Office is pleased to congratulate Drs. Panthangi and Bascom on their well-deserved awards.

We'd also like to share that Manpreet Kanwar, Cardiology fellow, won first place for her presentation at the Michigan American College of Cardiology 2005 meeting for her poster "Usefulness of Clinical Evaluation, Troponins and C-Reactive Protein in Predicting Mortality among Stable Hemodialysis Patients". Her manuscript has been accepted and will appear in the November issue of the American Journal of Cardiology.

Our Internal Medicine residents have done well recently with their case reports. Manreet Kanwar (Manpreet's sister) won third place for her poster "Carcinoma Associated Retinopathy – An Unusual Presentation for Small Cell Cancer" at the local American College of Physicians meeting in May. 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), also in May. John Frank won First Place for his Case Report Poster titled "Uncommon Cause for Recurrent Strokes in the Young" at the 2005 Michigan American College of Physicians meeting.

IRB Office Information:

Hours of Operation:

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

Telephone Numbers:

313-343-8314 – Mary Barnhart,
313-343-3863 – Lee Booze-Battle or
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.

The St. John Hospital & Medical Center Institutional Review Board (IRB) feels that the distribution of pertinent information to research professionals is key to good clinical practice (GCP), and to effective research within our organization. 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.

All researchers, investigators, coordinators, and other research personnel are encouraged 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.