

# SMC IRB NEWS

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## Welcome

*By Richard Bensinger, M.D., Chairman*

The Swedish Hospital IRB has as its duties the task of reviewing research activity at the Center and affiliated institutions to determine and certify that these projects conform to Federal Regulations concerning the health, welfare, safety, rights and privileges of human subjects enrolled in research.

There is a long historical tradition of research on humans for the advancement of knowledge and medical practice. This includes self experimentation, early studies on willing and unwilling subjects as well as a considerable body of what would now be unethical and dangerous activities. The formalization of proper conduct initially took place with the Nuremberg trials following which it was agreed that participation in research should be authorized when important questions are posed, the risks are justifiable and participation by an individual is voluntary and informed. Under the stimulus of the Tuskegee outrage, the US Government authorized the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which resulted in the publication of the Belmont Report, the cornerstone of current practice in the protection of the rights and safety of subjects in human experimentation. The definition of these rights and the means to protect them have been the subject of an ongoing process culminating in the formation of the Office for Human Research Protections (OHRP) which has the authority to provide background supervision in the protection of these rights for all research activities which might come under Federal Regulation. A recent development has also been the application of privacy rights under HIPPA regulations which expands the scope of privacy considerations by IRB covered organizations.

At Swedish Hospital, research is being conducted affecting patient care, drug and product development.

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All such studies come under the supervisory activities of the on-campus IRB. We are fortunate to have a dedicated and knowledgeable staff to carry out these Federally mandated reviews. It is important to realize that research studies require conformity with the regulations set forth and while the IRB feels the pressure to keep these rules in mind, the members are mindful of the need for medical progress and advancement. With this in mind, the IRB has the task of enforcing the regulations but encouraging research so those uncomfortable barriers to the conduct of research are not placed in the path of researchers.

The IRB is composed by law of a mix of on campus physicians, persons with technical and psychological knowledge and community members preferably without a strong medical background to provide alternate insights into patient protection. I have been privileged to be a member of this committee for over 20 years and have been impressed with the dedication of its members in the face of progressively increasing regulations that we are asked to follow. We meet once per month on a formal, voting basis to consider new studies, review ongoing studies and consider the impact of accumulating data on the safety of subjects here at Swedish Hospital. Extensive work is done behind the scenes to prepare the committee for these evaluations and to help the investigators with meeting the requirements for review. We are proud of our record of being of assistance to Swedish Hospital investigators while at the same time being viewed as advocates for research.

## IMedRIS

### SWEDISH IRO BEGINS TRANSITION TO ELECTRONIC SUBMISSIONS & REVIEW

The Swedish Medical Center Institutional Review Office (IRO) has initiated the transition from its current IRB system to iRIS™ (integrated Research Information System). iRIS™ is a web-based suite of applications designed to help create, manage and process research studies. Research study documents will be submitted, reviewed and stored electronically in iRIS™. The goal is for iRIS™ to automate submission and review processes and provide a system to compile data and monitor research studies.

#### When will it happen?

Beginning in mid-2007, new study applications and study documents for existing research studies will be submitted to the IRO electronically (eSubmission). Electronic review (eReview) of expedited review submissions will also begin mid-2007. In 2008, electronic review of full review submissions will begin. At that time, SMC IRB members will view research protocol submissions and documents on a secured website, make recommendations and record comments online, and correspond with the IRO staff electronically. Until that time, full review items will be processed very similarly to the current "paper packet" process.

#### What's next?

IRB members will be asked to complete a technology survey to help the IRO determine what resources are needed to make the iRIS™ system available to Board members.

In early 2007, Board members will begin receiving a CD with their monthly packets that will contain large documents that require Board review, such as study protocols and Investigator Brochures. Under the current process, primary reviewers receive protocols and Investigator Brochure. The Swedish Research

applications and consent forms will continue to be provided in paper format. The goal for providing the CDs is to reduce the size of the monthly paper packets and to get the Board comfortable with reviewing documents in a non-paper format.

More information about the transition to iRIS™ will be provided in the next Newsletter. Please contact the IRO if you have any questions or if you would like to preview the system.

## OHRP Frequently Asked Questions

**(October 25, 2006) – OHRP Frequently Asked Questions (and Answers) Page Now on OHRP's Website**

The Office for Human Research Protections (OHRP) has added a Frequently Asked Questions page on its website. This FAQ page includes a new set of FAQs on Investigator Responsibilities. The investigator responsibilities FAQs are in addition to FAQs on the following topics: Assurance Process; IRB Registration Process; 45 CFR part 46; and, Research with Children, that are posted on the FAQ page.

These FAQs provide guidance on OHRP's current thinking on these topics and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required.

The FAQ page can be accessed at:

<http://www.hhs.gov/ohrp/> by clicking the [Frequently Asked Questions \(FAQ\)](#) tab (5th) in the left margin.

## Swedish Medical Research Center Welcomes the State Food and Drug (SFDA) Administration Delegation from China

The Swedish Research Center will be hosting the State Food and Drug Administration (SFDA) from China January 12, 2007. This visit is conducted in partnership with WIRB's International Fellows Program as part of its collaboration with the World Health Organization (WHO), the National Institutes of Health (NIH), and the University of Washington.

The WIRB International Fellows Program is a six-month long training program for foreign health care professionals who desire to learn how to establish or improve IRBs in their regions. It is an intensive program designed to help participants develop the skills necessary to create and/or manage and administer international review boards that will protect the rights and welfare of human research subjects.

As part of this program, the Chinese delegation is interested in how researchers in the United States conduct FDA regulated research.

The intent of this visit is to provide the visitors an overview

of research at Swedish which will include open discussions and a tour of the Cancer Institute, IDS Pharmacy, Cardiovascular Research, and the Seattle Neuroscience Institute.

The visiting delegation from the SFDA includes the Deputy Director General of Drug Safety and Inspection Dept., the Division Director of Clinical Trial Inspection for Drug Safety and Inspection Dept., the Senior Staff of Chemical Drug Division of Drug Registration Dept., the Deputy Director General of GCP Certification Center, the Official of National Institute for the Control of Pharmaceutical & Biological Products, and the Director of Drug Regulatory and Medical Affairs, R&D-based Pharmaceutical Association of China.

## Compliance Initiative Success from the Research Center

In 1966 [Dr. Henry K. Beecher](#), an anesthesiologist, wrote an article (Beecher HK. "[Ethics and Clinical Research](#)" NEJM June 16, 1966) describing 22 examples of research studies with controversial ethics that had been conducted by reputable researchers and published in major journals. Beecher wrote, "Medicine is sound, and most progress is soundly attained;" however, if unethical research is not prohibited it will "do great harm to medicine." Beecher provided estimates of the number of unethical studies and concluded "unethical or questionably ethical procedures are not uncommon."

Dr. Beecher's article played an important role in heightening the awareness of researchers, the public, and the press to the problem of unethical human subject's research.

At Swedish Hospital, we are also concerned with ethical conduct of studies as part of our environment of excellence. To that end, the Swedish Research Center created the goal of achieving 100% compliance with the Office of the Human Research Protections (OHRP)

requirement that each Investigator or Research staff member complete educational modules in the appropriate protections of human subjects. Since April of 2006, we have contacted nearly 300 researchers and their research staff members to request documentation of their training in this important area. The Swedish Research Center accepts training completed through the University of Washington Institutional Review Office, the Fred Hutchinson Institutional Review Office, Children's Hospital and Medical Center or through the CITI course at the University of Miami. For those researchers who completed equivalent training elsewhere, we were pleased to document their credentials as well.

## Swedish IRB Chair Alternates

The Swedish IRB was previously fortunate in having Dr. Rayburn Lewis as an Alternate Chair in case Dr. Bensinger was not able to attend an IRB meeting. Due to the many responsibilities of both Dr. Bensinger and Dr. Lewis, we now have 2 additional board members who have graciously volunteered to step in as Alternate Chair when needed. Please welcome Dr. Lisa Florence and Mary Ersek, PhD, RN as Alternate Chairs for 2007.



*All IRB members  
need to complete  
the CITI course  
through the  
University of  
Miami once every  
three years!*

## Board Member Training Opportunities

As a reminder, it was approved by Dr. Nancy Auer, Institutional Official, to have all IRB members complete the CITI course through the University of Miami once every three years, attend a yearly continuing education event, and participate in continuing education activities as new regulations or policies are set in place.

As of today, 5 IRB members have completed the CITI course. Please take the time to complete the course as an ongoing effort of excellence in the protection of human subjects. While the approximate time for completion is stated to be about 4 hours, you may stop at any time and pick up later to complete the course without having to go all over it again.

To complete the CITI course, please go to <https://www.citiprogram.org/>, register, and complete the Biomedical Research Investigators and Key Personnel course. Upon completion, the IRO will receive information that you have completed the course. You may be eligible for CME/CEU credits upon completion of the course, so please see this information as documented on the CITI program website. If you have any questions or difficulties accessing the program, please contact the IRO office at 206-215-2536 or by email at [helen.goodman@swedish.org](mailto:helen.goodman@swedish.org).

### Local Education Opportunities

If you would like to attend an in-person education activity, the Fred Hutchinson Cancer Research Center is sponsoring the following courses in 2007.

**Description:** Training in the conduct of research that involves human subjects for all key personnel. The course is taught by Erik Schwab, Consent Editor of [FHCR Institutional Review Office](#).

**Location:** Pelton Auditorium, first floor of Thomas Building on the Day Campus of the Fred Hutchinson Cancer Research Center, 1100 Fairview Ave. N.

**Date/s:**

Monday, January 22, 2007, 1:30–4:30pm  
Monday, March 19, 2007, 1:30–4:30pm  
Monday, July 23, 2007, 1:30–4:30pm  
Monday, September 24, 2007, 1:30–4:30pm  
Monday, November 5, 2007, 1:30–4:30pm

**Registration:** RSVP by e-mail to [Noel Cebrian](mailto:Noel.Cebrian@fhcrc.org) at [ncebrian@fhcrc.org](mailto:ncebrian@fhcrc.org) (formal registration occurs at the session).

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**Motto**

*To improve the health and  
well-being of each person  
we serve*

2007 IRB Meeting Schedule

Tuesday, January 23, 2007

Tuesday, February, 27, 2007

Tuesday, March 27, 2007

Tuesday, April 24, 2007

Tuesday, May 22, 2007

Tuesday, June 26, 2007

Tuesday, July 24, 2007

Tuesday, August 28, 2007

Tuesday, September 25, 2007

Tuesday, October 23, 2007

Tuesday, November 13, 2007\*

Tuesday, December 18, 2007\*

*\*Note: These Meetings are a week earlier  
than usual to accommodate holidays*

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*We're on the Web!*

*Visit us at:*

[www.swedishmedical.org](http://www.swedishmedical.org)