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## International Research

By Jennifer Hansberry

Thank you for your dedication and service to Swedish. I wanted to inform you that Swedish, as an institution, is embarking on seeking to participate in more international research and in seeking more international collaborative efforts.

Recently, the IRB reviewed a study for an investigator to be conducted outside the United States. The IRB has also participated and hosted visitors from China and Korea as part of the World Health Organization with the goal of sharing research oversight with other counterparts in other countries. We expect to continue participating and hosting more delegates in the future with the Western IRB as part of their International Fellows Program.

We are in the process of applying for several grants which will include Swedish as a collaborator with other institutions in the Seattle area and abroad. This work will continue to place Swedish at the forefront of many fields and is critical to the success not only of the individuals involved but also to the organization as a whole. As the institutes grow and develop more relationships with industry and others in their fields we are responding to more calls about how the international collaborations will work. This is anticipated to expand significantly in the years to come

These are exciting times and we will be providing you more information on these programs as they develop and will also be providing the IRB with educational opportunities on International Research.

### Inside This Issue

International Research	1
Board Packets	1
Conflict of Interest	2
iRIS Update	2
Meeting Reminder	3
Staff Changes	3

## Board Packet Reminder

As a follow up to the announcement made at the last IRB meeting in September, the following items will no longer be provided in paper but will provided to all Board Members on CD:

- Adverse Event (AE) Reports will be on the CD. IRB Members will still be assigned as reviewers for these reports. However, all reports will be on CD. In addition, the agenda will list the AEs slightly different. The AEs requiring full review will be listed with "Local AEs" first and then the "Non-Local AEs" will follow. The AEs not requiring full review will be last and are provided for informational purposes only.
- Changes to Investigator Brochures (IBs) will also be added to the Continuing Reviews if the IB has changed. The Chair will initially review the IBs when they are submitted as a change. However, the Medical Primary Reviewers will also receive the changed IB at the study's continuing review.
- Previous Minutes from the IRB meeting will be on the CD
- The "Pink" sheets will also be on the CD. Please continue using the "Pinks"

Please see *Board Packets* on page 2

*Board Packets* from page 1

as a guide but the IRO staff would greatly appreciate any notes made on the “Pinks” to be voiced in the meeting for Board discussion.

- Another change will be to the agenda itself. In order to increase efficiency, staff will no longer hand write individual IRB member names on the agenda, or highlight the specific assigned member items. This will save a great amount of time for the IRB Coordinators.

We greatly appreciate your patience as we implement process changes in preparation for going electronic. We are taking small steps so we can all be better prepared.

## Disclosing Potential Conflicts of Interest

Did you know that IRB members are also asked to disclose any potential conflicts of interest during IRB meetings just like Investigators?

Each year IRB members are asked to fill out the financial disclosure forms which are an auditable requirement. In addition, IRB members are to disclose any potential conflicts during the meeting prior to reviewing the scheduled agenda items. This disclosure will allow us to make a determination if there is a conflict of interest. If a conflict of interest exists, the IRB member would need to recuse themselves during the deliberation and not vote that particular review. While the financial conflicts may be easier to identify, there are other potential conflicts which need to be considered. For example, is there a relationship conflict? Could an IRB member have a family relationship with an investigator, or maybe work in the same department in which the IRB member's vote could potentially influence a study approval? Not all situations may be considered a conflict and an IRB member may not need to recuse themselves but disclosure is required and needs to be captured in the minutes. If a conflict determination is made, the IRB member can provide comments but would need to leave the meeting during deliberations, the voting process, and not be counted towards quorum.

## iRIS Update

**The iRIS information below was distributed throughout the Swedish system. This is good Information in case someone approaches you with any questions.**

***Do you conduct research at Swedish? If yes, this is for you!!!!***

**Swedish Medical Center IRB Office  
Transitions to iRIS™**

**WHEN:** October 8, 2007

**WHAT IS iRIS™?**

*Integrated Research Information System* – A web-based suite of applications designed to help create, manage and process research studies. The goal is to automate IRB submissions and review processes.

**WHAT DOES THIS MEAN?**

This means **ALL** research materials are to be submitted to the SMC IRB ***electronically*** starting October 8, 2007.

**WHAT WILL I NEED?**

**Must** have a **User ID and Password** to be able to access iRIS™. It is very important for you to have an **accurate email address** because this is how you will be contacted and receive notifications from the IRB Office. Call the Swedish IRB Office at (206) 215-2536 to obtain your User ID and Password.

**WHY THE CHANGE?**

iRIS™ will manage IRB files more efficiently and cut down on paper but most importantly, iRIS™ will provide an on-line system for you to fill out, track, and store all submissions to the SMC IRB Office.

**This means you can:**

- Complete all SMC IRB forms on-line anywhere, anytime
- Track the SMC IRB approval process for your submission; receive emails and updates on all stages of the process from submission to approval
- All SMC IRB submissions will be stored

Please see *iRIS* on page 3

*IRIS* from page 2

electronically so Investigators and study personnel can review all their study materials in an organized and easy to use system on-line anywhere, anytime

#### WHERE CAN I LEARN MORE?

**Training** for users is being offered by the IRB Office. Please contact the IRB Office at 206-215-2536 to schedule a training session.

## Meeting Reminder

With the holidays coming up, the IRB meetings for November and December are scheduled **earlier** in the month.

#### Dates:

**November 13<sup>th</sup>**

**December 18<sup>th</sup>**

Please mark your calendars!! If your schedule does not allow you to attend a meeting, please call (206) 215-2536 as soon as possible.

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<https://swedish.imedris.net>

#### Motto

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

## IRO Staff Changes

### We say Farewell to Helen Goodman

**Helen**, IRO Administrative Assistant, has received a promotion and will be leaving the IRB but she won't be going far. She accepted a promotion with Clinical Effectiveness which is responsible for the development of computerized clinical effectiveness databases. Her last working day was October 12. Helen did a great job of keeping the IRB office running smoothly by making sure that we had all the resources needed to get the job done. She will be missed greatly but we wish her the best with her new position. *Congratulations!*

### Welcome to Tahiroh Barr and Kelly Nguyen

**Tahiroh** was hired as an IRB Coordinator. She processes the Western IRB submissions and all changes to the Expedited review items. She has quickly integrated into the Team and was barely able to breathe before she was asked to take on the responsibilities for another staff member who left the IRB office. To top that, she actively took the role of training our newest hire. *Welcome Tahiroh!*

**Kelly** was hired as the Regulatory Affairs Coordinator. You will not have a great deal of interaction with Kelly as she works closely with study coordinators and investigators. Her primary function is to assist research staff in submitting research through Swedish to the Western IRB. *Welcome Kelly!!*