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ACRP Conference

Last April Ariana, IRO Coordinator, attended the Association of Clinical Research Professionals (ACRP) Global Conference & Exhibition in Seattle. At this conference, Ariana went to a session presented by J. Mark Waxman, Esq. of Foley & Lardner LLP titled, "Who Owns My Tissue - The Biorepository Challenge." Here is a recap of key points:

Who "Owns" Donated Tissue?

Washington University v. Catalona:

<http://prostatecure.wustl.edu/>

An investigator resigns from a position at Washington University but wants the tissue that was collected from subjects under his research at the University to go with him to his new position at Northwestern University. The investigator re-contacts subjects asking them to transfer their samples to him at Northwestern. The court ruling found that subjects made a voluntary gift to Washington University when they donated their tissue and therefore the tissue belongs to Washington University. According to the article from the above web link, "The decision protects the rights of research participants by ensuring they are not exposed to misleading and potentially competing solicitations for their previously donated tissues from scientists, physicians or commercial research companies who want control over the samples."

The following recommendations were outlined during the session:

- Institutions should discuss with investigators who the tissue belongs to (the institution or the investigator) and document and/or have an agreement between the institution and the investigator outlining ownership. This way, if an investigator leaves the institution, it's clear where the tissue goes and who it belongs to.
- The consent form should state who the tissue belongs to.
- If the tissue is considered a donation, the consent form should specify what donation means. Generally donation means:
 - a) Tissue that is stored indefinitely
 - b) Subjects can not get the tissue back
 - c) Subjects can not have the tissue destroyed

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- d) In the case of intellectual property rights, the tissue belongs to the entity to which it was donated.
- e) Samples are de-identified.

Other recommendations made during the session are as follows:

- Researchers should not misrepresent what they're doing with their research/tissue samples. The consent form has to match the protocol/study plan.
- If the focus of the research changes, investigators have to go back and consent subject to the new purpose/focus. The IRB also needs to approve the new research focus.

If pertinent health information is discovered about a subject from tests done on their tissue, should the researchers go back to the subject and tell the subject about the information discovered about them? This is a question that comes up quite often and is difficult to answer because some subjects may want to know the information while others may not. In addition, what are the risks of notifying the subject and what are the risks of not notifying the subject? J. Mark Waxman, Esq. noted that the safest course of action is to avoid telling subjects the information discovered about them from tests done on their samples. If subjects are going to be notified of the information discovered, Mr. Waxman recommended that researchers work with the subject's physician rather than directly with the subject.

IRB Regulations

Did you know that if IRB regulations are not followed, some of the consequences below could be imposed?

- Suspension of research project.
- Suspension of all of an investigator's research projects.
- Inability to use data or publish results.
- Notification of sponsors, regulatory agencies and funding agencies of noncompliance.
- Debarment by FDA from using investigational products.
- Inability to receive funding from federal grants.
- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities.
- Termination of employment.
- Loss of licenses.
- Immediate shut-down of ALL research at an organization.

These examples were taken from the University of Miami CITI course.

New Parking Rates

New visitor parking rates went into effect July 1, 2007. The IRO has parking stickers so please let the IRO staff know if you need more parking stickers on meeting days. Thank you!!

Parking Rates (First Hill)

Under 30 min	Free
30 mins - 1 hr	\$4.00
1 - 2 hr	\$5.00
2 - 3 hr	\$6.00
3 - 4 hr	\$7.00
4 - 5 hr	\$10.00
5 - 6 hr	\$12.00
6 - 24 hr	\$15.00
Special Patient Rate*	\$10.00

Visitors to Attend the July IRB Meeting

The IRO has been contacted by WIRB to host another set of visitors to the IRB meeting scheduled for this July. As part of the Fellows International Program, they also have visitors from the Republic of Korea attending a two-month training program.

This two-month training program conducted by the WIRB in Olympia, WA is for foreign health care professionals who desire to learn how to establish or improve review boards in their region. 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. In addition to attending classes, the participants attend IRB meetings where they see first hand the intricacies of conducting research reviews and learn about concepts such as vulnerability and confidentiality. The names of the six Trainees are:

Dr. Shinik Kang

Dr. Byung Soo Kim

Dr. Cheol Ho Kim

Dr. Jeong Sang Lee

Dr. Hong-Ji Song

Dr. Sun Uk Song

Congratulations to Mary Ersek

For those of you that do not already know Mary Ersek, Alternate Chair, has been accepted into the American Academy of Nursing (FAAN). FAAN membership is awarded by invitation as recognition of outstanding accomplishments within the nursing profession and to health care. Individuals are selected by evidence of outstanding contributions to nursing over and above those which are required in one's position of employment.

Mary will be inducted this fall in a very formal ceremony in Philadelphia. This is an unbelievably prestigious honor and really the ultimate feather in her cap and a big, honor for the Swedish IRB and for Swedish as a whole.

Please congratulate her next time you see her!!!!!!!

IMedRIS Update

The IRO has had to delay the implementation of the electronic IRB system.

The reason for the delay was to work out some issues with the vendor. The "Go Live" date was scheduled for July 2 of this year but has been postponed. The issues with the vendor have been resolved and we expect to "Go Live" the first part of October.

So what does this mean for the IRB? At this point, as IRB members, you will still continue to review research as you do now with some minor changes. For example, the applications you will see may look a little different. You will still receive CDs with the additional information in addition to the paper version. Primarily, the ones affected will be researchers submitting research to the IRO, IRO staff, and the Chair and alternate Chairs.

Where are we in the process?

The IRO is in the midst of planning on the transition of the current database to the new system. We have exported some data and the export was a success. Another test is scheduled for later this month.

We are also designing the training material we will need to provide a training module for all users so they are able to submit their research documents to the IRO electronically. We expect to provide training in August and September.

We are still checking the flow of information within the system to ensure the user is "branched" (directed) to the correct sections of the system depending on the research they are submitting.

What's next?

We will continue providing Board members with CDs with the monthly packets that will contain large documents that require Board review, such as study protocols and Investigator Brochures. Study applications and consent forms will continue to be provided in 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.

Great feedback continues to be received from research staff during the initial orientation of the system in that the process will be less time consuming and more efficient.

Possible Changes to the Swedish Process in Reviewing Potential Conflicts of Interest

Swedish currently considers the disclosure of investigators and IRB members when they have disclosed potential conflicts of interest such as an equity interest, including stock options or warrants above the reportable threshold of \$10,000. (This does not include diversified mutual funds or similar instruments in which the shareholder has no control over the equities held by the fund.) Consulting and speaking fees that are considered on the basis of the amount earned per year when more than \$10,000 in that given year constitutes a reportable conflict of interest.

As the climate for conflicts of interest continues to become more of an issue and more prevalent, Swedish Medical Center, as an institution, is considering changing the current reportable threshold as stated above to implementing a "zero" reporting threshold. This means all potential conflicts of interest are to be reported and to be considered by the IRB.

This has not been finalized and is currently being discussed. If you would like to provide comment or would like to be a part in the discussions, please inform any IRO staff of your interest.

Remaining IRB Meetings for 2007

August 28, 2007

September 25, 2007

October 23, 2007

November 13, 2007*

December 18, 2007*

**Note: these meetings are a week earlier than usual to accommodate holidays*

IRB Member Educational Requirement Reminder

Can you believe a year has already passed since the first notification for completing the CITI course through the University of Miami was sent?

If you recall, the educational requirement for IRB members as approved by Dr. Nancy Auer, Institutional Official, is to have all IRB members complete the CITI course through the University of Miami once every three years. In addition, IRB members must attend a yearly continuing education event, and participate in continuing education activities as new regulations or policies are set in place.

This educational requirement was made based on the regulations on IRB membership 45 CFR 46.107 IRB.

(a) ... "The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. "

As of today, 6 IRB members out of 14 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.

If you have completed any other educational opportunities that you think might qualify as an alternative such as attendance of Human Subject's Protection courses at the Fred Hutchinson Cancer Research Center or University of Washington, please submit your certificate of completion to the IRO for consideration by Dr. Auer

Records Security

Federal regulations require that IRBs approve only research projects that are designed to minimize risks. Therefore, following the institution's procedures, the IRB will review data security procedures in order to assess the following:

- What kind of identifying information will be collected?
- Who will have access to the identifying information and the research data?
- What kinds of codes or encryption will be used to separate research data from subject identifiers?
- How will limitations on access be ensured?
- How will research staff persons be trained about privacy and confidentiality?
- Will research staff be required to sign an oath of confidentiality?
- How long will identifiable information or linkages to personal identifiers be kept?
- For data being transmitted physically and/or electronically, what encryption methods will be used?
- What procedures will be used for disposal/destruction of documents?

Although IRBs assess these same protections as part of their review of all research studies, records-based studies often present a particular challenge because of the possibilities of utilizing and linking various data sources.