Welcome to the first edition of the Peoria IRB quarterly newsletter. We are excited about this new opportunity to communicate regularly with our partners in the research community. In the days ahead, we will cover topics of interest such as new guidance from OHRP and FDA, education about trends in research, regulatory updates, and news items of local interest. This will also be a way to provide education in these areas, and notify you of changes in IRBNet, as well as other updates that will help make the IRB process easier and more engaging. As our local IRB continues to evolve and improve, we are also excited about the work that is being done to gain AAHRPP accreditation, and expand our boundaries as we assist the regional research effort.

We are expanding our educational activities in the area of human subject
protections; and, we are developing systematic programs for helping our constituents with compliance and negotiating the regulatory environment. In the “Chairs’ Corner,” we hope to be able to keep you updated on the progress that we are making, and on highlighting new ways that we hope to take the Board to the next level in terms of providing efficient, comprehensive services. We hope to be able to describe involvement in our own research on regulatory and related issues, such as informed consent processes, benchmarking, and evaluating novel research. We also hope to be able to tell you about the accomplishments of some of the people in our community who have taken research seriously, and have by so-doing enhanced our communities at-large.

So, welcome to the newsletter! We invite your comments and feedback, and your interest and contributions

The Final PIRB FDA Audit Report is in!


The inspector sent from the FDA’s Chicago District Office was conducting the routine inspection under an FDA program to ensure the data and information contained in requests for IDE’s, Premarket Approval applications, and Premarket Notification (501(k)) are scientifically valid and accurate. Though the inspector had already shared the results with the PIRB during the close-out discussion in March 2013, the official letter from the FDA was just received by the PIRB in February 2014.
As anticipated, the PIRB received no form 483! Additionally, there is no response required by the PIRB. The PIRB works hard to ensure that the determinations required by the FDA are properly made and documented for each study reviewed. We are happy to share these positive results with our investigators!

**IRBNet Tech Tip by: Heidi Vermillion**

Q. How do I know if I have submitted my initial project or subsequent submission package successfully in IRBNet?

A. It is important to complete the last step of the submission process in IRBNet, “Submit this Package.” If your package is in “pending review” status, you have successfully submitted the package and PIRB has received it for processing. If your package is in “work in progress” status, it has not been submitted and we cannot view it until the last step is completed.

**Policy Reminder – CITI Training**

All principal investigators and key personnel listed on protocols submitted to the PIRB for review are required to complete CITI course on the Protection of Human Research Subjects prior to conducting the research. This will help assure that both investigators and UICOM-P IRB remain in compliance with all state and federal regulations regarding research involving human subjects. Investigators conducting research involving protected health information (PHI) must also complete the
HIPAA training provided in CITI. All key personnel must also complete the conflict of interest course available in CITI. Refresher training in CITI is required of all investigators and key personnel every three years.

Visit the PIRB LibGuide page at [http://researchguides.uic.edu/UICOMP-IRB](http://researchguides.uic.edu/UICOMP-IRB) and click on the “Training” tab for instructions on how to get started with your CITI training today.

**Upcoming PIRB Meeting Dates**

April: IRB 1 – 12:30 PM April 10, 2014  
May: IRB 1 – 12:30 PM May 8, 2014  
June: IRB 1 – 12:30 PM June 12, 2014

Submission Deadlines are the end of business on the last Thursday of each month.

Meetings are held in Room A100-2 at the University of Illinois College of Medicine at Peoria.

IRB 2 meets immediately after IRB 1

**Upcoming Presentations from your PIRB Education Program:**

Please feel free to join us  
Friday March 28 from 12-1  
at UICOMP Room A-100-1 (Lecture hall off the main entrance)
Do I need to report that?

Adverse Events, UPIRSOs and Noncompliance

AND

Tuesday April 29, 2014
12-1 PM
JUMP Trading Simulation & Education Center
Lecture Hall 162
Can't make it? No Problem! You can watch the presentations later by visiting the UICOMP IRB LibGuide Page at:

http://researchguides.uic.edu/UICOMP-IRB

All Presentations given by the Education Program will be available to listen to and watch within a few days of the event.