The Quality Improvement Program is a part of the UICOM-P HRPP. The goal of the program is to assess, maintain, and improve compliance with local, state, and federal regulations as well as UICOM-P Policies and Procedures through **IRB-Directed Monitoring** and **Post-Approval Monitoring**.

**IRB-Directed Monitoring** - Monitoring of external studies (research performed at an affiliated community institution or research performed by their staff) for which the PIRB 1 or PIRB 2 serves as the IRB of record. These visits are limited to compliance concerns identified either during IRB meetings or resulting from complaints or concerns reported to the IRB or IRB Office by subjects, research team members, or members of the community.

**Post-Approval Monitoring** - A not for cause, post approval monitoring event. The purpose of the visit will be to determine whether or not the study is being conducted in the manner in which it was approved by the IRB. A list of open studies will be consulted to identify studies for monitoring. Only studies being conducted by a UICOM-P employed PI will be subject to post approval monitoring.

Of the nine monitoring events conducted to date, the following recurring events have been identified:

**The consent form:**
- Subject signed non-IRB approved version of consent (no approval stamp)
- Subject signed incorrect version of consent (not most current at time of consent process)
- Whole consent not maintained as part of the research record (only signature page filed)

**The consent process:**
- No source documentation that subject was provided a copy of consent
- Missing forms/document retention (no documentation of informed consent)
- Form signed by unapproved study personnel
- Did not solicit assent from age-appropriate subjects
Protocol Adherence Issues:

- Enrolled more subjects than specified in the IRB-approved protocol
- Withdrew too much sample
- Performed minor procedure at non-indicated site
- Did not maintain research records according to the IRB-approved protocol specifications

Many of these issues are corrected by re-consenting subjects and process changes by the site. Failure to document consent, however, may be reportable to a federal agency depending on the funding source of the research project. Investigators are expected to submit a corrective action preventative action (CAPA) plan to the IRB Chair of record in response to deficiencies identified during a monitoring event. Additionally, education will be offered both at the time of discovery and if necessary, at a separately scheduled visit in order to ensure the nature of the deficiency is understood and can be effectively corrected (if possible) and prevented from occurring again.

If details of possible serious or continuing noncompliance are contained in the report, the IRB Chair will refer the report to the convened IRB.

The GCP series includes three distinct basic courses tailored to the different types of clinical research:

- Good Clinical Practice Course, US FDA Focus
- Good Clinical Practice Course for Clinical Trials Involving Medical Devices
- Good Clinical Practice Course for Clinical Trials Involving Investigational Drugs and Biologics (ICH focus)

“GCP content is suitable for research teams involved in clinical trials of drugs, biologics, and devices.

The RCR series covers core norms, principles, regulations, and rules governing the practice of research. The National Institutes of Health (NIH), the National Science Foundation (NSF), and the U.S. Department of Agriculture (USDA) require certain categories of researchers to receive RCR training. RCR is increasingly viewed as an essential component of training, regardless of a researcher's source of funding.

The RCR series consists of a basic course, complemented with a set of additional modules of interest.

RCR content is suitable for any person involved in research, ranging from upper-level undergraduates to established faculty. Particular emphasis is given to the educational needs of graduate students and postdoctoral researchers.”

The link to both programs is www.citiprogram.org. You will begin by registering and selecting the participating institution as University of Illinois College of Medicine at Peoria if you are new to CITI. Otherwise, please login to your existing account and “add a course or update learner groups.” For the CITI Course Enrollment Questions, please scroll down the page to Good Clinical Practice and choose
the most appropriate course for yourself. If you are adding Responsible Conduct of Research, please scroll down the page and choose “Responsible Conduct of Research.”


Policy Reminder: 2.5.2, Description of the Purposes for the Two Panels

PIRB #1 oversees research that may engage any one or more of the following institutions: University of Illinois College of Medicine at Peoria (UICOM-P), UnityPoint Methodist, UnityPoint Proctor, Saint Francis Medical Center, Illinois CancerCare, St. Jude Midwest Affiliate, Galesburg Cottage Hospital, or OSF Saint Joseph’s in Bloomington. PIRB #2 is established to review research that might engage UnityPoint Methodist, UnityPoint Proctor, Illinois CancerCare, St. Jude Midwest Affiliate, Galesburg Cottage Hospital and UICOM-P, but would not be acceptable for approval at OSF Saint Francis Medical Center or OSF Saint Joseph’s in Bloomington due to their Ethical and Religious Directives.

Because the UICOM-P IRB serves as the IRB of record for multiple Catholic institutions, IRB #1 consent forms must include abstinence as an acceptable means to avoid pregnancy. However, in some studies, the harmful effects of a research study drug (e.g., thalidomide, or drugs labeled as Category X) on a fetus can be quite severe. In such cases, the study sponsor (via the protocol) may declare that abstinence is not an acceptable means to avoid pregnancy and specific measures must be listed. In this case, the study should be submitted to PIRB #2 for review.

Studies involving the following should also be submitted to IRB #2:

• Studies involving the use of contraceptives (chart reviews, surveys, focus groups, clinical trial)
• Studies involving abortion (chart reviews, surveys, focus groups)

If you have any questions regarding what IRB your study should be submitted to, please contact the IRB staff at 309-680-8630.

Stories from the Frontline

Recently, PIRB was contacted by a study site requesting an emergency IRB review of a research protocol for a subject.

The PIRB team was able to accommodate the site’s request through the emergency use process outlined in Section 14.8 of the UICOMP-P IRB Policy & Procedure Manual, Version 3.3.3.

Unfortunately, the study sponsor would not allow the subject to be enrolled under an emergency
use acknowledgement and an emergency meeting of the IRB was able to be conducted within just a few hours on a Monday morning to accommodate the sponsor requirement.

This is just another striking example of the teamwork demonstrated by our research community through our staff, research leaders, study personnel, IRB members and IRB Chairs! Thank you all!!
Thursday, July 14, 2016
12:00-1:30 pm
“Understanding FDA Regulatory Requirements for Investigational New Drug (IND) Applications & Investigational Device Exemptions (IDE)”
OSF Coordinator Group Meeting
Presented by Heather Hermann
OSF Saint Francis 7th Floor Conference Room

Please RSVP to OSF.ClinicalResearch@osfhealthcare.org if you plan to attend to ensure adequate meeting space.

Upcoming PIRB Meeting Dates

Thursday, July 14, 2016 – 12:30 PM
Thursday, August 11, 2016 – 12:30 PM
Thursday, September 8, 2016 – 12:30 PM

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.