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UICOMP’s Human Research Protection Program (HRPP) is Accredited

At its March 2016 meeting, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) awarded Full Accreditation to UICOMP’s Human Research Protection Program (HRPP) for three years. AAHRPP is an accrediting entity that works with organizations involved in human subjects clinical research to establish high standards for the protection of clinical research participants. AAHRPP accredits organizations that can demonstrate they provide participant safeguards that surpass the threshold of state and federal requirements.

The accreditation program utilizes a voluntary, peer-driven review and educational model. AAHRPP accreditation indicates that our organization follows rigorous standards for ethics, quality, and protections for human research. Accredited organizations are required to renew their accreditation with AAHRPP every three to five years to demonstrate compliance with current AAHRPP criteria.

Check out the UICOMP HRPP website to view our accreditation seal at http://peoria.medicine.uic.edu/cms/One.aspx?portalId=513437&pageId=652704

In addition, please see the added “Information for Potential Research Participants” tab at http://peoria.medicine.uic.edu/departments__programs/institutional_review_board/for_potential_research_participants/
Passing the Torch

In February of 2015, UICOMP welcomed Dr. Bento Soares as the new Senior Associate Dean for Research, along with his role as the head of Cancer Biology and Pharmacology. On May 1st of 2016, Dr. Soares will add serving as the Institutional Official (IO) to his responsibilities. He will replace Regional Dean, Dr. Sara Rusch in that role.

Dr. Soares is no stranger to human subjects protection. He is known for his work on the Human Genome Project and as the director of the Cancer Biology and Epigenomics Program at Stanley Manne Children’s Research Institute and scientific director of Falk Brain Tumor Center at the Ann and Robert H. Lurie Children’s Hospital of Chicago.

Dr. Soares transitioned into this additional role by being an active attendee of all things IRB, including our site visit from AAHRPP. Welcome to our world, Dr. Soares. We can’t wait to work with you!

In the Spotlight: Research with Children

Children are considered by the federal regulations as being vulnerable to coercion. To safeguard their interests and protect them from harm, additional regulatory protections exist NOT ONLY for research involving children, but for children that are wards of the state.

A ward means any child who is placed in the legal custody of the state or other agency, institution, or entity, consistent with the applicable federal, state, and local laws and regulations. (21 CFR 50.3(g). In Illinois, a ward of the state includes but is not limited to a child placed by court under the guardianship of the Illinois Department of Children and Family Services. In Illinois, children placed in foster care are wards of the state.

Research projects involving wards of the state must first be approved by the DCFS “Research Review Board” before the UICOMP IRB can review the research. For research involving foster children, the UICOMP IRB must also follow the specific foster agency requirements concerning the appointment of an advocate.

Investigators are responsible for determining any changes in the legally authorized representative status for children participating in research for all cases with vulnerable populations.

The investigator must be particularly attentive with wards, since the legally authorized representative may change if the ward is adopted or if the parents regain guardianship. The investigator must perform one of the following at minimum:
1. Periodically assess with an adult accompanying the child if there has been a change in guardianship;
2. Including a statement in the informed consent form that the guardian should inform the investigator when there is a change in the guardian status; and
3. Any other methods to ensure prompt notification of a change in guardianship status.

If an enrolled subject unexpectedly becomes a ward of the state while the UICOMP research is active, the investigator has a responsibility to immediately notify the IRB.

Policy Reminder – Documentation of Informed Consent

Pursuant to 45 CFR 46.109(b) "An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116," a complete informed consent form with the subject’s original-ink signature should be retained in the Principal Investigator’s research files. In cases where photocopy equipment is unavailable, the investigator may ask the participant to sign and date two consents, one for the participant to keep and one for the research file.

Without a complete consent present in the research file, a monitor is unable to document that the informed consent process included all of the relevant information. The Peoria Institutional Review Board Policy and Procedures Manual (Version 3.3.3) addresses this issue in Sections 7.1 and 7.10.

Stories from the Frontlines

Recently, PIRB was contacted by a study site requesting a quick turnaround time for a submitted modification.

The PIRB team jumped into action to move this time-sensitive submission through the process. Fortunately, we were able to accommodate the site’s request and saved the family an eight hour drive, one way, to receive treatment. The site coordinator shared that the mother was in tears upon finding out that the drive would not be necessary.

This is a heart-warming example of the critical work the human research protection program does, and the difference that a dedicated research community can make to critically ill patients and their families.
IT’S RESEARCH DAY SEASON!

4th Annual UICOMP Student Research Day – April 13, 2016
2:00-6:00 PM
UICOMP Lobby
http://illinois.edu/calendar/detail/5492/33134589

Family Medicine Residency Research Day – May 12, 2016
12:30-4:30 PM
UICOMP Lecture Hall

OSF HealthCare Annual Research Symposium– May 18, 2016
8:00 AM-5:00 PM
Jump Trading Simulation & Education Center
http://jumpsimulation.org/calendar/event/108/

***Educational Opportunities***

Wednesday, May 4, 2016, 12:00-1:30 PM
“Minor Assent & Parental Permission”
OSF Coordinator Group Meeting
Presented by Heather Hermann & Mindy Reeter
Emerald Conference Room
Professional Office Building (POB) at Saint Francis Medical Center, G01-10
Please RSVP to OSF.ClinicalResearch@osfhealthcare.org if you plan to attend
to ensure adequate meeting space.

Wednesday, May 4, 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
7350-7th Floor Seminar Room
Saint Francis Medical Center
Please RSVP to OSF.ClinicalResearch@osfhealthcare.org if you plan to attend
to ensure adequate meeting space.

Upcoming PIRB Meeting Dates

Thursday, April 14, 2016 – 12:30 PM
Thursday, May 12, 2016 – 12:30 PM
Thursday, June 9, 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.