HawkIRB

Upcoming Training Sessions

After IRB Approval...
December 13, 2013: 2:30-4PM
HP Smith Conference Room
(W256 GH)

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HSO Office Hours
Wednesdays 2-4PM and Thursdays 10-12PM in 101 Hardin Library

Fridays 10-12pm in N186 Lindquist Center

No appointment necessary

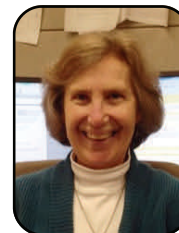Office hours will be held until December 20, 2013. Check the HSO website for the Spring schedule and locations

Why is my study going to the Full Board?

Hello from the IRB Biomedical group! I'm Becka Simpson, HSO staff member who works on studies that receive full board IRB-01 or IRB-03 review. After working in psychiatry research for 15 years, I came to the Human Subjects Office 4 years ago. I mainly review IRB-01 (biomedical research) and IRB-03 studies (research conducted at the VAHCS), although I also process mass email requests and sometimes help with IRB-02 (social, behavioral, and education research) projects. I will be writing occasional articles geared to answering the questions I commonly get. My question this month: *Why is my new study going "full board," and what does this entail?* Full board review means that the study is reviewed by a group of IRB members at a designated meeting, rather than a single IRB Chair. Full board review is required when the study is considered to have more than minimal risk to subjects, when there is a controversial aspect to the study that an IRB Chair does not feel should be considered by only one reviewer, or if the study does not meet one of the categories of expedited review put forth by OHRP. Studies involving new medical procedures, investigational drugs or devices, will always have full board review. All applications receive several levels of review:

1) First, pre-screening for completeness

2) Followed by full HSO Staff screening prior to review by an IRB Chair or full board review

3) The application and attachments are then reviewed and issues identified for the research team to address

4) Workflow correspondence may go back and forth several times to clarify responses before the application is ready for IRB review

There is usually about a 2 week span between when a study is scheduled and the IRB meeting, to allow time to assign reviewers and prepare meeting materials. After the meeting, minutes are written, approved by the IRB Chair and the research team is usually notified of the IRB's determinations within a week of the meeting. Investigators should plan for IRB review to take approximately 6-8 weeks for a new study, regardless of whether it receives expedited or full board review. We encourage you to call us with questions when preparing an IRB submission, or if you don't understand an issue noted in workflow correspondence. We like hearing from you!

- Becka Simpson
Senior IRB Application Analyst

Come to the *Dark Side*, we have cookies!

Like the majority of staff in the Human Subjects Office, I started on the other side: conducting research with people. Working with patients (we never used the term "subjects") was the best and the hardest part of the work. (Does anyone enjoy recruiting participants? I have yet to meet someone who cites that as the best part of the job). My previous work involved treatment comparisons, clinical trials, and pure investigational research. I was fortunate enough to be in a position to see some patients benefit from our work—it was fantastic. Leaving patients and joining the regulatory world was a major shift in my thinking, and yes, my research colleague-friends really did affectionately warn me about the dangers of going to the *Dark Side*. But... I haven't seen Darth Vader running around the office yet, and I've been here a while now. What I do see is people who are equally invested in furthering the goals of research. IRBs and federal regulations exist because of past abuses and tragedies; transparent research cannot occur without the protection provided by these regulations (not in the modern ethical world, anyway). I adamantly want the aims of research to advance, but I also want that research to be ethical. For example, I may ask you to justify a waiver of consent request for a retrospective review in your HawkIRB application, not because a retrospective chart review involves more than minimal risk, or because I think you'll abuse that access, but because protecting medical privacy is just one block in the overall foundation of human subjects protections. So fear not, the *Dark Side* is not so dark. And despite Admiral Ackbar's concerns, it is NOT a trap because I know researchers and regulators alike share in the goal of protecting research participants.

- Sarah Heady
IRB Education and Compliance Specialist

What's that Mean?: Human Subjects Research Acronyms
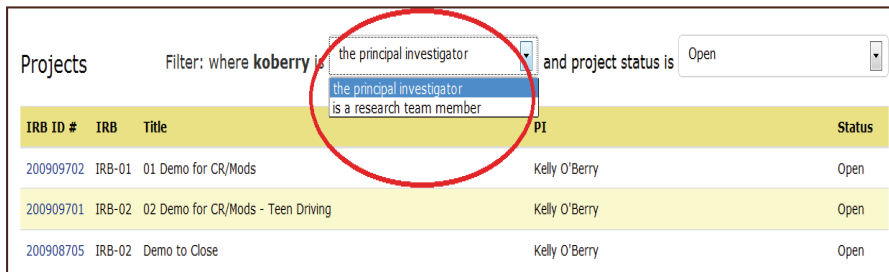
Have you heard acronyms thrown around when attending an educational presentation, sitting in on an Education and Compliance monitoring visit, or when speaking with colleagues and were not sure what they meant? The table below provides the full title and a brief description of some common acronyms that apply to the conduct of human subjects research.

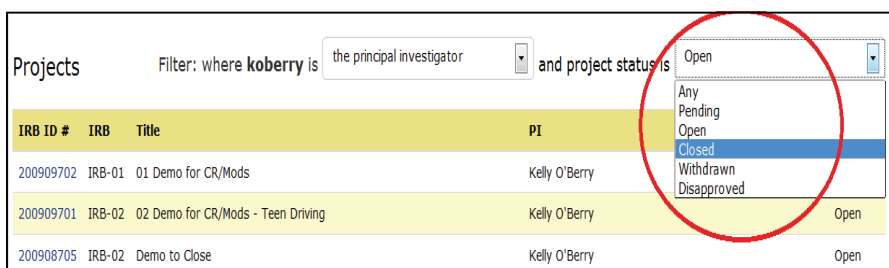| Who	What	What else you should know….
FDA	U.S. Food and Drug Administration	An agency of the U.S. Department and Health and Human Services, the FDA is responsible for the regulation and supervision of drugs and medical devices among several other products related to public health safety. Investigators working with FDA-regulated products or who plan to submit their data to the FDA must comply with 21 CFR 50 (protection of human subjects) and 56 (IRB review). Compliance with 21 CFR 312 for drug studies and 21 CFR 812 and 814 for device studies is also required.
HHS	U.S. Department of Health and Human Services	The HHS is a cabinet-level department of the U.S. federal government with the goal of protecting the health of all Americans and providing essential human services. Investigators receiving funds from HHS are required to comply with 45 CFR 46. HHS and FDA regulations dealing with human subjects protections (21 CFR 50 and 45 CFR 46) are not identical, but were harmonized in 1991.
OHRP	Office for Human Research Protections	An office within HHS, OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by HHS. OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. An institution (such as the UI) receiving HHS support must register their Institutional Review Board (IRB) and obtain a Federalwide Assurance (FWA) with OHRP . Through the FWA, the institution commits to HHS that it will comply with the 45 CFR 46 for the protection of human subjects.
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use	In 1990, representatives of regulatory agencies and the pharmaceutical industry from the U.S., Japan, and Europe held a meet in Belgium that grew to become the ICH. Since then, the ICH has used the ethical principles found in the Declaration of Helsinki to generate guidelines for clinical researchers. The objective of ICH is to increase international harmonization of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost-effective manner. One of the topics covered in its efficacy guidelines is Good Clinical Practice (GCP). The GCP guidelines cover expectations for everyone who participates in the conduct of a clinical trial. This includes investigators, monitors, sponsors, and IRBs. The UI IRB-01 and IRB-03 offers investigators the option to have their projects reviewed using the GCP guidelines.
AAHRPP	Association for the Accreditation of Human Research Protections Programs	An independent, non-profit accrediting body, AAHRPP promotes high-quality research through an accreditation process that helps organizations (such as the UI) strengthen their human research protection programs (HRPPs). AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement. The UI received full AAHRPP accreditation in 2003.

HawkIRB: How Do I…..

Use the Inbox Filter?

HawkIRB users can change the filter located in their HawkIRB inbox to view pending, open, closed, withdrawn, and disapproved projects for which they are the Principal Investigator (PI) or a research team member. The HawkIRB inbox default setting is "Principal Investigator" and "open" projects. However, users can easily change the filter to view projects of varying status.

Projects

Filter: where **koberry** is [the principal investigator ▼] and project status is [Open ▼]

the principal investigator
is a research team member

IRB ID #	IRB	Title	PI	Status
200909702	IRB-01	01 Demo for CR/Mods	Kelly O'Berry	Open
200909701	IRB-02	02 Demo for CR/Mods - Teen Driving	Kelly O'Berry	Open
200908705	IRB-02	Demo to Close	Kelly O'Berry	Open

Projects

Filter: where **koberry** is [the principal investigator ▼] and project status is [Open ▼]

Any
Pending
Open
Closed
Withdrawn
Disapproved

IRB ID #	IRB	Title	PI	
200909702	IRB-01	01 Demo for CR/Mods	Kelly O'Berry	
200909701	IRB-02	02 Demo for CR/Mods - Teen Driving	Kelly O'Berry	Open
200908705	IRB-02	Demo to Close	Kelly O'Berry	Open

Human Subjects Office

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