

## Human Subjects Research in the News:

**Drug Testing Rules Broken by Canadian Researchers**  
The Star.com Canada  
November 10, 2014

**Detergent Pods Pose Risk to Children, Study Finds**  
Catherine Saint Louis  
NY Times  
November 10, 2014

**Lucid Dreams Could Help People with Odd Sleep Disorder**  
LiveScience  
November 4, 2014

**A Face to Remember**  
Kerry Grens  
The Scientist  
November 1, 2014



## Upcoming Training Sessions

### After IRB Approval...

December 8, 2014 2-3:30PM  
HP Smith Conference Room  
(W256 GH)

### HSO Office Hours

Wednesdays 2-4PM  
and

Thursdays 10-12PM  
101 Hardin Library

Mondays 2-4 PM  
N186 Lindquist Center

No appointment necessary

Office hours will be held until December 18, 2014. Check the [HSO website](#) for the Spring schedule and locations

## External IRBs incorporated into HawkIRB!

The HSO has exciting news! WIRB is being integrated into the HawkIRB system! Along with WIRB, we are onboarding four new external (or centralized) IRB models -- Quorum, PCORI, NCI-CIRB and StrokeNet.

WIRB is a commercial IRB that has been used by the University of Iowa since 2006. Studies with Department of Defense Navy funding are currently the only type of study required to be submitted to WIRB for review. Researchers have the *option* to submit to WIRB if a project is industry funded/initiated and meet a specific set of criteria.



This criteria is currently vetted via "WIRB's Form A" process, which will be incorporated into the HawkIRB application in mid December. Selecting the "WIRB" link on the Project Introduction page will route you to preliminary eligibility questions granting permission to use WIRB instead of the institutional IRB. The eligibility criteria can be found on our website [here](#). You will then be re-routed back to the Project Introduction page to finish the application, which incorporates questions necessary to notify other Human

Research Protection Program (HRPP) Committee(s). Other HRPP Committee review requirements can be found [here](#).

A protocol and a draft external IRB application are required as part of the initial submission to the HSO. Once all institutional and applicable HRPP committee reviews are complete, you will be approved to submit to WIRB. If you currently have an open WIRB application, or are in the process of applying for one, you will continue to submit the forms via email. Only new projects that are submitted after the release date will be integrated into HawkIRB.

When utilizing an external or centralized IRB, the Principal Investigator is responsible for adhering to:

- the policies and procedures of the residing IRB of record
- all University of Iowa institutional policies
- state and local laws related to human subjects research

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## Financial Interest Disclosure Reporting

University of Iowa researchers should submit financial interest disclosures annually through the electronic Conflict of Interest system (eCOI). The annual disclosure period is between January 1 and April 30. Financial interest disclosures can and should be updated at any time throughout the year when a new financial interest arises.

The disclosure procedure is a two part process that includes an Annual Certification, completed yearly, and an individual Disclosure Report. Individual Disclosure Reports should be submitted at least annually, and within 30 days of any changes, including reporting new financial interests.

Annual Certifications must be completed by all UI researchers, even if he or she has no financial interest to disclose. In this case, the researcher will certify that he or she has no financial interests to disclose.

The individual Disclosure Report is the form used to disclose specific financial interests. The types of financial interests that need to be disclosed must first and foremost be related to the researcher's area of expertise. Outside professional activities to be included are consulting, employment, serving on an advisory board, providing or receiving training, serving as an expert witness, product development/evaluation, service on a Board of Directors, etc. Activities with both non-profit organizations and corporate entities must be reported.

Types of financial interests to be reported include remuneration, family member compensation, licensing or royalty income, stock in a publicly traded company, and equity interest (aka ownership) in a non-publicly traded company, such as a start-up company. If the researcher is part of UI Health Care, then he or she must also disclose stock dividends.

Once the disclosure report is submitted in eCOI, it is reviewed by the staff of the Conflict of Interest in Research Office. Depending on the person disclosing, it may also be reviewed by the UI Health Care Joint Office for Compliance, the Office of the Provost, and Human Resources. In the next issue, we will discuss how financial interests may overlap with research.



Quorum Review IRB is a commercial IRB like WIRB. However, submission to Quorum is limited to specialized trials from Novartis. The PI will be required to have all institutional and HRPP committee reviews completed prior to receiving approval to submit to Quorum for IRB review.

Occasionally, industry sponsors require an IRB ID number before protocols are completed. Because of this, we have added a new feature -- after question III.5, a prompt will generate asking, "Do you have the protocol consent document and other materials for HRPP committee review?" If you select "NO" for this question, you will be routed ahead to the Attachments section. Attach the Assurance Document and submit your project. You will then be given an IRB ID number. **Please note** this does not get your application processed faster. You will still be required to complete the remaining questions and return the submission to the HSO for further processing, but now you will have the ID number when the sponsor requires it.



The NCI CIRB is an IRB reviewing federally funded oncology research under the purview of the National Cancer Institute (NCI.) Only approved clinical trials listed on the CTSU (Clinical Trials Support Unit) website can be submitted to the NCI CIRB for review. The Human Subjects Office will reserve the right to retain any project that would have research components requiring institutional IRB review.



StrokeNet is a fourth option added to the HawkIRB research application. The NIH created the StrokeNet trials network to conduct small and large clinical trials and research that studies stroke treatment, prevention, recovery and rehabilitation. The University of Iowa is a Regional Center within this network. The University of Cincinnati has been named as the IRB of record for all studies submitted under the StrokeNet network.

The Human Subjects Office will facilitate the collection of research related materials in HawkIRB to ensure all applicable HRPP committee reviews are in place prior to submitting to the University of Cincinnati for IRB review.



PCORI is the final option added in the HawkIRB application. PCORI is an acronym for "Patient Centered Outcomes Research Institute." Projects funded under this initiative are designed to improve patient care and outcomes through patient-centered comparative clinical research. The University of Iowa is part of a PCORI Greater Plains Consortium (GPC) focusing on three primary areas of patient centered outcomes research. If you are applying for a PCORI funded study, first verify whether or not the grant requires the use of a centralized IRB model. If it does, it is critical to contact the Human Subjects Office prior to seeking or submitting a grant request for a PCORI award. The Human Subjects Office will work with you to determine what centralized IRB model may work best for your research. PCORI awarded projects may have the University of Iowa as the primary IRB of record or use an alternative IRB based on the grant structure and the award requirements. If the University of Iowa is named as the IRB of record under a GPC endorsed study, the University of Iowa researcher will submit the project through the IRB-01 option in HawkIRB. The University of Iowa Principal Investigator will be responsible for ensuring all sites involved in the project follow the University of Iowa IRB policies and procedures as well as their local institutional requirements. The University of Iowa PI is responsible for the overall conduct of the study at all participating sites. In the event the University of Iowa is not the named IRB of record for a PCORI award, the HawkIRB application should reflect the "PCORI" option. When selecting this option, an executed reliance agreement with the named IRB of record must be in place prior to your HawkIRB submission.

For WIRB studies, contact Kathy Beck at [uiwirb@uiowa.edu](mailto:uiwirb@uiowa.edu). For other external IRB processing, contact Rachel Bullis at [uirb-external@uiowa.edu](mailto:uirb-external@uiowa.edu). We look forward to working with you!



The Human Subjects Office is excited to announce that Patricia Katopol and Leona Ryan have joined our staff as IRB Education and Compliance Specialists. Both have first-hand experience conducting research and many other strengths that will benefit the UI research community. Please join us in welcoming Patricia and Leona to the HSO!

## Human Subjects

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