THE UNIVERSITY OF IOWA

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10/21/15

To: UI Research Community

From: Michele Countryman MC
HSO Interim Director

RE: HawkIRB enhancements live this week!

- **Launch of External\Central IRB module (including WIRB) (live on 10/22/15)**

A few weeks ago, our office rolled out the first of several phases of enhancements to the electronic research application (HawkIRB). The rollout is the highly anticipated automation of all external (or central) IRB requests in HawkIRB.

The use of WIRB and any other external (or central) IRB model will now be tracked in HawkIRB. There are several different models could be selected with the use of an External IRB. Review the Central & External IRB page on HSO Website for specific details. An External IRB SOP has also been created and can be found on the bottom of the Central and External IRB portion of the website. The HSO\IRB External IRB Standard Operating Procedures are followed regardless of the type of external (or central) IRB model requested. As a brief summary, the types of external IRB models are listed below. Please review the HSO website for specific information on each of these scenarios.

1. **Commericial IRB** The University of Iowa currently has developed a relationship with two commercial IRBs, Western IRB (WIRB) and Quorum.
    a. **WIRB:** Minor changes to the existing relationship with WIRB have been made with the transition of the submission process to HawkIRB.
        i. Any study with Department of Defense (DoD) Navy (ONR) research requires review by WIRB.
        ii. The Principal Investigator has the option to select WIRB for any industry initiated, industry funded clinical trial involving drugs.
            1. Device trials now require review by the IRB-01 (UI Biomedical IRB)

    b. **Quorum:** The University of Iowa has a single protocol reliance agreement for a specialized signature clinical trials series. If a researcher elects to use Quorum, a per protocol reliance agreement will be required prior to final institutional signoff. For more information on the Commercial IRB options, review the HSO website under either WIRB or Quorum.

2. **Established multi site external (or central) IRB models**
    a. **Great Plains Collaborative:** This is a Patient Centered Outcomes Research Initiative funded model with a fully executed IRB Reliance Agreement and specific set of Standard Operating Procedures. For more information, review the Great Plains Collaborative page on HSO website and GPC Standard Operating Procedures located at the bottom of this webpage.

    b. **StrokeNet:** This is a NIH funded network to conduct small and large clinical trials that study stroke treatment, prevention, recovery, and rehabilitation. The StrokeNet model has a fully executed IRB Reliance Agreement and specific set of Standard Operating Procedures. For more information, review the StrokeNet page on the HSO website and the StrokeNet Standard Operating Procedures located at the bottom of this webpage.

    c. **NCI CIRB:** The NCI CIRB is sponsored by the National Cancer Institute (NCI) and reviews select NCI sponsored clinical trials. The University of Iowa has a fully executed IRB Reliance Agreement. Local context review requirements are under development with the NCI CIRB. This option will be coming soon. For more information on the NCI CIRB process, review the CIRB website.

3. **Single (or Central) IRB for a multi site study request involving the use of WIRB** For studies requesting to use WIRB as a central IRB, review the Western IRB (WIRB) as a Central IRB page of the HSO website. A reliance agreement called a "Joinder" agreement will be required to use WIRB in this manner.

4. **New External (or Central) IRB requests** For any other request(s) to use either a new multi site central IRB or other External IRB model, contact the Human Subjects Office via email: uirb-external@uiowa.edu or speak with the HSO External\Central IRB Coordinator by calling (319) 335-9915 and ask to speak with Anna Mertes.

Any questions regarding these enhancement to the human subjects research review process in HawkIRB should be directed to the HSO via irb@uiowa.edu or (319) 335-6564.