THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 1, Issue 3
July 2013

Human Subjects Research in the News:

Breakthrough: Robotic Limbs Moved By the Mind
CBS News, June 2013

Beyond the Human Genome: How Epigenetics May Alter Your Destiny
LiveScience, June 4, 2013

Don't Hold Your Breath: Why Science Won't Save Us from Old Age Anytime Soon
Slate, May 31, 2013

Study: Looking at Own Facebook Profile Bad for Brain
The Atlantic, June 3, 2013

Watchdog Halts Action on Researchers
New York Times, June 5, 2013

HAWKIRB

Upcoming Training Sessions

After IRB Approval …
July 18, 2013: 2:30PM-4PM
HP Smith Conference Room (W256 GH)

HSO Office Hours Summer 2013
Wednesdays, 2-4PM
101 Hardin Library
No appointment necessary.

Top 5 Monitoring Findings of 2012

No one likes to relive their mistakes, but we can learn from them. To help researchers identify and prevent the errors commonly found during IRB Monitoring and Education Compliance visits, below are the top 5 monitoring findings from 2012:

1. Insufficient documentation of consent and/or inconsistent information in the Informed Consent Document (ICD)

- Using expired ICDs (Modification and/or Continuing Review approved by the IRB and the new version of the ICD was not used) to document consent
- Subject, subject's parent/legal guardian or Legally Authorized Representative not signing and/or dating the signature box
- Recording subject identifiers (Social Security Number, Medical Record Number, etc.) on the ICD

2. Lack of detail in Section X.4 describing how information/data will be collected and stored

- Not providing the storage location of paper/hard copy records and/or biologic samples
- Listing the PI or a research team member responsible for IT security rather than a departmental IT person

3. Incorrectly attaching documents in HawkIRB

- Attaching documents in the wrong category
- Not uploading consent, assent, and/or recruitment materials in Rich Text Format (.rtf) leading to an unpopulated IRB-approval stamp

4. Lack of detail in Section VII.E.6 describing study procedures

- Providing information that is inconsistent with other sections of the HawkIRB application and/or the ICD
- Providing information that is requested in other sections of the application

5. Incomplete description of the enrollment and consent process in Section VII.D.29

- Not addressing all parts of the question (i.e. recruitment, consent, and efforts to minimize coercion and undue influence)

HSO Mainline Questions: Do I have to fill out an IRB application?

We all know the regulatory process requires time and attention. This month's question may seem simple. After all, if you want to use the Harvard Brain Bank to identify a novel neuroanatomical structure, you are working with human brains. Human brains surely equal human subjects research and requires IRB review, right? Since the federal regulations define human subjects as "living individuals," a brain bank project would likely not require IRB review, because if you donated your brain, you won't be meeting that *living individual* criteria.

The point is, this question can't usually be answered with a straight yes or no response. I often receive phone calls from investigators asking this question and I am always happy to give my educated opinion. But that is all I am able to offer. Typically, only an IRB Chair can determine if a project meets the regulatory definition of human subjects research—this is a case where you need an "official opinion." *Prestigious Journal#1* is unlikely to accept your manuscript for publication if you note "Sarah said it wasn't human subjects research." Fortunately, we have developed a short form to provide an official, documented determination. If your project requires IRB review, the Human Subjects Research Determination (HSRD) form will initiate a draft New Project a application in your HawkIRB inbox using the information you provided. That means the first sections of your new application will be completed (saving you a bit more of that scarce resource, time). And remember, we're happy to answer your questions!

-Sarah Heady
IRB Assistant

NEWS FLASH!

You may have recently noticed a new link in HawkIRB. Portal links to the Research Portal, a dynamic interface that will be the primary point of contact between the institution and researchers. The Research Portal will provide a single entry point for investigators and staff to access administrative applications for research, personalized information, and announcements.

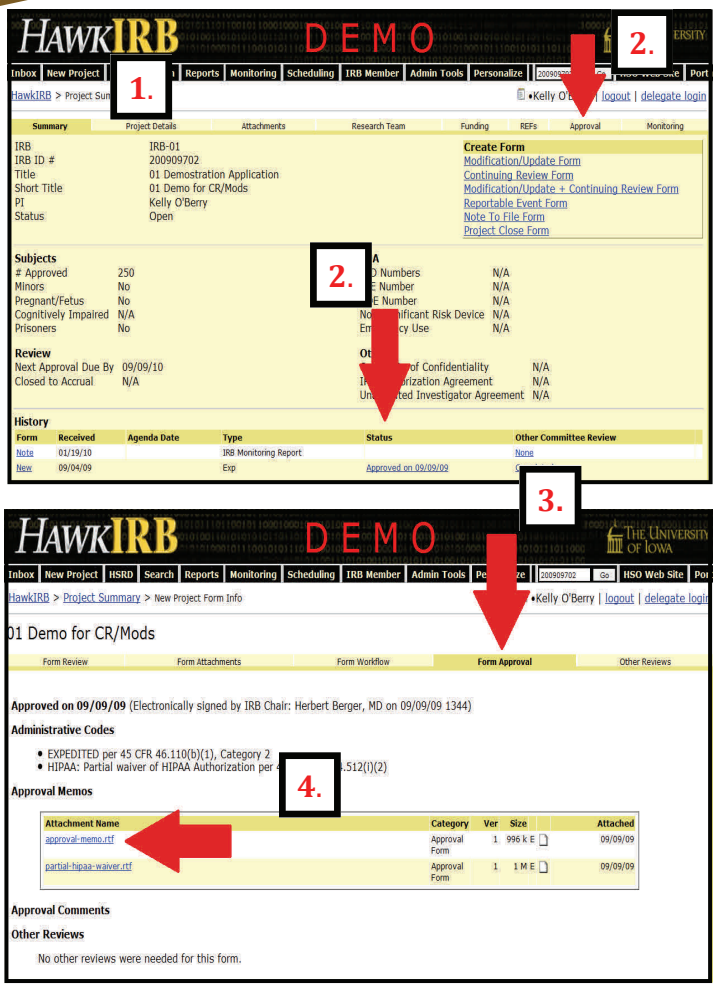
Access Portal by logging into HawkIRB or read more about the Research Portal project here.

HawkIRB: How Do I.....

Find My Approval Memo?

Have you ever found yourself clicking through HawkIRB, not quite sure how you located your IRB Approval Memo the last time you needed it? Below are step-by-step instructions for finding your Approval Memo in just a few clicks:

1) Log into HawkIRB, go to the Project **Summary** page
2) Click on the links located under **Status** which tell you the date the HawkIRB form was approved (New Project, Modification, and/or Continuing Review) and click on the **Form Approval** tab; Or
3) From the **Project Summary** page, click on the **Approval** tab. Here you will find the most recent IRB Approval Memo for the study
4) Click on **approval-memo.rtf** link to access the memo



Get to Know.....

J. Andrew Bertolatus, HSO Executive Director and James Walker, UI Institutional Official

Left to right: Jim Walker & Andy Bertolatus

Andy Bertolatus has been an IRB Chair since 2000 and the HSO Executive Director/Primary IRB Chair since 2010. Dr. Bertolatus oversees the three IRBs at the University of Iowa as well as the development and implementation of HSO policies and procedures. Jim Walker is the Associate Vice President for Research, Regulatory Affairs and also serves as the Institutional Official, overseeing Compliance and Regulatory Affairs at the UI. As the Institutional Official, Dr. Walker signs the University's Federalwide Assurance (FWA) document filed with the Office for Human Research Protections (OHRP). Through the FWA, the UI is held accountable to federal agencies for the protection of human subjects.

Human Subjects Office

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