IRB Connection

THE UNIVERSITY OF IOWA

HUMAN SUBJECTS OFFICE

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HawkIRB

Upcoming Training Sessions

New Project Application
July 17, 2015 9-11 AM
101 Hardin Library

Continuing Reviews, Mods…
July 23, 2015 3-4:30 PM
HP Smith Conference Room (W256 GH)

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HSO Office Hours
June 3—August 26, 2015

Wednesdays 2-4PM in
101 Hardin Library

No appointment necessary

It's OK to Delegate, but Remember… It's Still Your Study!

When submitting a HawkIRB application, the Principal Investigator (PI) signs an Assurance Document stating that s/he is "ultimately responsible for the conduct of the study." While delegation of some duties may be necessary, the PI is responsible for providing adequate supervision. The PI is also accountable for any regulatory violations that result from failure to provide such supervision.

Inadequate PI supervision may result in subjects being enrolled after approval has expired, failing to consent subjects prior to conducting investigational procedures, or subjects receiving incorrect doses of study drugs. This can lead to loss of IRB approval, FDA warning letters, or the inability to use or publicize some or all of the study's data.

Factors such as an inexperienced staff, complex clinical trials, or one PI overseeing multiple sites can negatively affect the PI's ability to provide the level of supervision necessary. PIs should be alert for 'drift' that can occur over the course of a study. This can result in study procedures being performed in ways that are not approved by the IRB. For example, in a longitudinal study, if the PI does not supervise the training of new staff but delegates this to existing staff, employee turn-over may result in staff not following the IRB-approved plan. Ultimately, this could result in noncompliance

with UI policies and federal regulations.

The research team (RT) must be properly trained and licensed (if relevant) for the task. In addition, the protocol must be followed regarding who performs delegated duties, even if state law permits someone with different qualifications to do so. For example, if the protocol calls for an RN to perform a procedure, it is not permissible to use a nurse's aide, even if state guidelines allow it. This kind of mistake can be avoided when the RT understands the study as a whole. Once the study is approved by the IRB, all research team members can view the entire plan in HawkIRB, not just their assigned duties.

Delegation is extremely common; nonetheless, the PI is always responsible for the delegates' actions. The PI should develop a plan for the supervision and oversight of the trial. Examples include a start-up meeting, regular staff meetings to exchange information regarding the progress of the study and/or any changes to the protocol, as well as to ensure consistent consenting and study procedures, and reporting and addressing adverse events over the course of the study. (Click these links for more information about Delegates in HawkIRB and Use of the Delegate Permission System).

How Do I…??   Can I…??   What is…?

The Human Subjects Office (HSO) website has a 'Frequently Asked Questions' (FAQ) page with links to categories of topics about which we regularly receive inquiries. This provides easy access to the answers that researchers commonly ask!

Some of the topics covered include:

- Starting an IRB application
- Making modifications to an existing application
- HIPAA Privacy Rule in research
- Short Form Consent Process
- Mailed Consent Process: Handling Corrections

FAQ

We've developed these pages specifically to assist researchers, so feel free to peruse this information!

If you still have questions, feel free to give us a call at 335-6564.
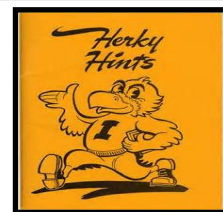
For researchers that don't work in HawkIRB on a consistent basis, revising a document as part of a modification application can be challenging. This article will identify a few oft encountered pitfalls that can occur and explain how to avoid them - which will help reduce the number of workflow items returned to you!

When revising a document as part of a modification application, the most apparent thing to do is to click on the 'Attachment Changes' tab available on the Modification Index page. This will open a page that includes all IRB-approved documents for the project.

Modification Index		Continuing Review Index		
P&T	MRPC	Frequent Mods	**Attachment Changes**	Project Index

Next to each document, on the far right-hand side of the page, there will be an 'Edit' link.
Click on the 'Edit' link for the document you wish to revise.

Attachment Name	Category	Ver	Size		Attached
Is summer your favorite season.rtf	Consent & Assent Forms	14	277 k E		EDIT

The document will be listed at the top of the page along with a step-by-step description of how it should be revised.

Edit Electronic Attachment

Step 1: Click on the link below and save the document to your local disk drive. Remember to give your documents a short, study-specific name.

Attachment: Is summer your favorite season.rtf **1**
Category: Consent & Assent Forms
Version: 15

Step 2: Make changes to the document that you saved in Step 1. If modifying an already IRB-approved document, please turn on "track changes" in your word processor. **2**

Step 3: Once you have saved your changes, indicate the document name below and press the "Upload Attachment" button. The edited document will appear in the list of attachments above.

Attachment Name: Browse... **3**
Comments:

Upload Attachment **4**

Click here to add a new attachment.

Ver	Ver
14	15

5
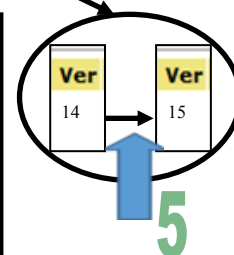
Each step has its own possible snare, so follow these pointers!

1. Click on the attachment title and open the document. Be sure to open the IRB-approved document in HawkIRB. Don't open one you have saved elsewhere, e.g., in your files or on your desktop or one that has an expired IRB-approval date or the '$Stamp' coding.

2. Always use the 'tracked changes' function. This allows the HSO/IRB reviewers to see not only what has been changed, but confirm what has not been changed. If changes are not tracked, HSO staff may delete the untracked version and return the application to you to attach a tracked version.

3. Do NOT click on the 'Click here' link. This is only used if you are attaching a completely new document to the project. When revising a current document, use the 'Browse' button to find the document with the 'saved changes'.

4. Click the 'Upload Attachment' button.

5. You will see the 'Ver' number for the revised document increase one. This is confirmation you have attached the document in the correct manner.

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Herky Hints cover, new student orientation manual, 5³9³ [Subject Vertical File Collection (RG 01.15.03), Miscellaneous category, folder "Freshman orientation," University Archives, Department of Special Collections, University of Iowa Libraries]

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