

Human Subjects Research in the News:

[The Genetics of Friendship](#)
The Scientist, July 16, 2014

[The Dilemma of the Depressed Mother-to-Be](#)
The Atlantic, Aug. 4, 2014

[How Acting Out in School Boosts Learning](#)
Scientific American, July 22, 2014

[More than just X and Y: New genetic basis for sex determination](#)
Science Daily, August 18, 2014

[Infant Possibilities](#)
Popular Science, July 30, 2014

[How Do People Survive Ebola?](#)
Live Science, Aug. 5, 2014

HAWKIRB

Upcoming Training Sessions

After IRB Approval...

September 22, 2014 2-3:30 PM
HP Smith Conference Room
(W256 GH)

HSO Office Hours

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

Mondays 2-4 PM in
N186 Lindquist Center

No appointment necessary

Keeping Current on International Research Regulations

When planning an international research study, investigators often ask where they can find specific information about human subjects research (HSR) protections that applies to the country in which they will conduct their study. The

[Office for Human Research Protections](#) (OHRP) developed the *International Compilation of Human Research Standards* for researchers, IRBs/Research Ethics Committees, sponsors and others involved in research around the globe. In addition to listing the laws, regulations and guidelines that govern human subjects research in 107 countries, it also details standards from a number of international and regional organizations. The 2014 Edition includes hundreds of updates and information for three additional nations including Cameroon, Mozambique, and Zambia.



The information is presented in table format with these five headers—Country, Key Organizations, Legislation, Regulations and Guidelines. Each country is then divided into the following categories:

1. General
2. Drugs and devices
3. Research Injury
4. Privacy/Data Protection
5. Human Biological Materials
6. Genetic
7. Embryos, Stem Cells & Cloning

Many listings feature hyperlinks to the law, regulation or guidance of interest. Additionally, the Microsoft Word version is searchable by using the 'Edit' and 'Find' features.

This is a valuable resource for investigators conducting research in other countries and will ensure you have access to the most up-to-date information during the planning stages.

Tips to Improve your Informed Consent Document

The Informed Consent Document (ICD) provides subjects a written record of study information for future reference and documents that the consent process occurred prior to the subject's participation in the study. The ICD template with required text (elements of consent) is available on the Attachment Tab in HawkIRB. The investigator should download the ICD template after completing the HawkIRB application so elements unique to the study are included in the consent document. The Human Subjects Office (HSO) staff and IRB members review the content of the ICD to ensure it is correct and consistent with the information in the application and protocol; but, it is the researcher's responsibility to ensure grammar and spelling are accurate. After entering the study-specific information into the document, the researcher should follow these steps to improve the document's appearance and ultimately, the subject's understanding of the information.



- Delete all template instructions from the document
- Ensure consistent spacing is used before and after headings and paragraphs
- Ensure consistent font types, sizes and line spacing is used
- Use the Spelling & Grammar check function in the Review Tab

When editing an ICD in workflow, the HSO requires 'tracked changes' so reviewers can see changes to the document. However, this produces a messy document, and it makes it difficult to see what the final version will look like. An easy way for researchers to view a 'clean version' of the tracked changes is to click on the Review tab of Microsoft Office and select 'Final' instead of 'Final: Show Markup' (which is the default option in the 'Display for Review' function) in the Tracking menu. This will assist in identifying inconsistent spacing or editing issues and correcting them prior to submitting the revised version.

Mainline Questions: HawkIRB Workflow

HawkIRB includes a built-in communication system HSO staff refer to as “workflow.” When staff (or IRB Chairs) need clarification about a project, we enter questions into workflow. HawkIRB sends PIs, contacts, and delegates an email notification, to let you know you should check your HawkIRB inbox. When signing in to HawkIRB (as a PI or [delegate](#)), the inbox will show the project in bold. This means no one has yet opened the workflow—very useful if multiple research team members might be collaborating to edit projects! Once the workflow has been opened, the bold formatting will disappear. To review the workflow question/s, use the “wkflw” hyperlink on the right side of the screen.

Status	Current Basket	Prev Basket	From	When	
Pending	PI Review	IRB Chair Review	Bishop	08/13/14 0835	wkflw

This will take you to the full workflow page. In the upper left corner of the screen, below the black menu header, HawkIRB displays the project title and action options.

IRB ID#:	20140000
Form Type:	New Project, Mod, CR, Mod/CR
Form Actions:	view/edit

- “View” displays the project introduction
- “Edit” displays the project index

Scrolling down the page, questions from HSO staff are displayed as well as staff contact information. This allows you to go right to the source for answers or clarifications instead of calling the HSO mainline! (But you’re always welcome to call the mainline—we’re here to help.)

Most workflow questions include “edit answer now” links that take you directly to the applicable section—these are included to make navigating the application more convenient—no need to move through each page of questions. Always remember to **save your answers to the workflow correspondence, & move from section to section using the gray back/save, index/save, and continue/save buttons.** They are found at both the top and the bottom of the yellow HawkIRB form.

The most important piece of workflow comes at the very end, so make sure you scroll ALL the way to the bottom of the page and click:

[Return Routing Slip to the HSO](#)

This returns the form directly to the HSO staff reviewing your project, and keeps the project moving forward.

“I’ve always enjoyed traveling and having experience with different cultures and different people. But it’s also a wonderful thing to be able to benefit and enable research, not only in our country but around the world.”

*- Laurel Clark, MD
NASA Astronaut*

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