

Human Subjects Research in the News:

[Bioethics Commission Posts Data on Federally Supported Research Involving Human Volunteers](#)

President's Commission for the Study of Bioethical Issues, March 2013

[Medical Research Cuts Have Immediate Health Effects](#)

The Atlantic, April 2013

[Study of Babies Did Not Disclose Risks, U.S. Finds](#)

NY Times, April 2013

[Human Genome, Then and Now](#)

NY Times, April 2013

[What Is "Minimal Risk" For Research with Children?](#)

Nicole Strand, March 21, 2013

[Cancer Researchers Revisit 'Failed' Clinical Trials](#)

Nature, April 2013

HAWK IRB

Upcoming Presentations

[How to Complete a New Project Application](#)

May 9, 2013: 10:30AM -1PM

Hardin Information Commons EAST

[After IRB Approval ...](#)

May 14, 2013: 9:30AM-11AM

HP Smith Conference Room
(W256 GH)

[Consent/Assent for Minor Subjects and Cognitively Impaired Adult Subjects](#)

May 23, 2013: 3PM-4PM

Ellig Classroom
(N120 CPHB)

Plain Language: Facilitating Subject Understanding of Research

Requirements

Federal regulations ([45 CFR 46.116](#)) require the elements of consent be provided in "understandable language" to the subject during the consent process. However, federal regulations and [guidance](#) do not offer an explicit definition for what is considered "understandable." Many words and concepts used in research settings are complicated and unfamiliar to the average adult. The use of technical language in consent materials is not limited to biomedical research. All disciplines of research use language that may not be understood by a layperson. Further complicating the matter, nearly half of American adults read at or below an 8th grade level. For this reason, the UI IRB recommends that participant materials are written at or below the 8th grade reading level. Researchers are also encouraged to use plain language whenever possible in study materials provided to participants.

What is Plain Language?

Plain language, or the development and delivery of communication that engages the intended audience, means using evidence-based standards in structuring, writing, and designing materials. When using plain language, the resulting texts are easy to read, user-friendly, and reader-focused.

Available Resources

A variety of [resources](#) are available to assist in the development of materials that are readable and participant centered. There are many formulas available to determine the reading level of a document, including [readability statistics tools](#) available in Microsoft Word. Additionally, researchers can refer to lay language [glossaries](#) or [thesauruses](#), publicly available [toolkits](#), and [tips](#) to help facilitate subject understanding.

11 tips to improve readability of consent materials

1. Check the reading level
2. Choose common, everyday words
3. Use active voice
4. Write in the first-person
5. Keep sentences short and to the point
6. Limit paragraphs to one main idea
7. Use clear and descriptive headings
8. Consider the needs of the audience
9. Organize and format the document so that key information is clear and easy to find
10. Use adequate white space and margins
11. Ask others to read and edit the document

Revisions to the Declaration of Helsinki

The [World Medical Association](#) (WMA) has opened a 2-month public consultation on proposed revisions to various principles found in the [Declaration of Helsinki](#). In an attempt to update ethical practices for clinical trials, the draft includes language

addressing additional protections for vulnerable groups, providing compensation and treatment for subjects who suffer harm, precise requirements for post-study arrangements, and a more systematic approach to the use of placebos. Additionally, the revised

text provides better readability by reorganizing the document with sub-headings. Comments on the revisions should be submitted to the WMA secretariat by June 15th. Read the full draft [here](#).

IRB Policy Reminder of the Month

Recording Additional Information on Informed Consent Documents

When documenting informed consent, only the required fields of the informed consent document (ICD) should be completed. Unless adequate justification is provided, additional information should not be recorded on the ICD.*

Social Security Numbers or Medical Record Numbers

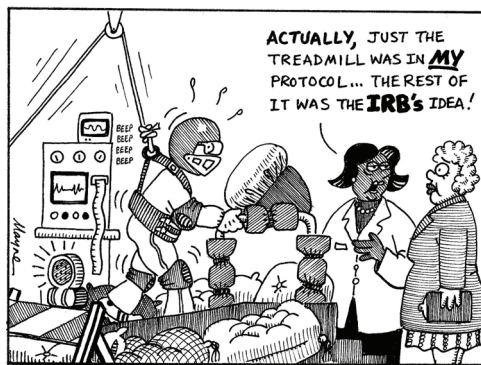
should never be recorded on the ICD.

With adequate justification, the IRB may allow the inclusion of the subject's study ID number on the consent document.

Writing identifiers on

the signed ICD provides another link between the subject and their identifiable information. To protect subject confidentiality, screening information, contact information, and other study data should be collected on source documents, not on the consent document.

* VAHCS/IRB-03 researchers: Refer to VAHCS



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Get to Know.....

The IRB-02 HSO Staff Group and Chairs



(Left to Right) HSO staff Patti Gillette, IRB Chair Janet Williams, HSO staff Joanie Wilson, IRB Chair John Wadsworth, HSO staff Bill Hubbard

Contact any member of the IRB-02 staff group or IRB-02 Chairs if you have questions about the IRB review process for Social Behavioral Educational Research or Community Based Research (SBER/CBR). You may contact Patti Gillette directly regarding any issues related to the operations of IRB-02 and the conduct of social, behavioral, educational and community-based research (patricia-gillette@uiowa.edu).

Issues to Consider when a Principal Investigator Leaves the University of Iowa

Whether leaving the UI for new employment, continuing education or other opportunities, investigators often ask about the transfer of human subjects data and/or biologic samples. The [UI owns the primary research results](#) generated from all research conducted under its jurisdiction. Therefore, when a PI plans to leave the UI and wants to take the original data to the new institution, the transfer of the data/samples must proceed according to [established guidelines](#).

If the PI will not have continued access to identifiable research data /samples and is not taking data to the new institution:

- **If the study is not complete** - submit a Modification form in HawkIRB to change the PI named on the application
- **If the study is complete** - submit a Project Closure form in HawkIRB

If the PI will take [identifiable](#) research data /samples to the new institution, or plans to have continued access, s/he should:

- Submit a Modification form in HawkIRB requesting IRB approval to take the data/samples or to have continued access
- Contact [Division of Sponsored Programs](#) (DSP) to determine whether s/he needs a Materials Data Transfer Agreement
- Obtain a letter from the PI's UI department head that documents awareness/approval of the transfer of the data/samples and outlines the department expectations for the transfer and use of the data/samples

For additional information, refer to the [Researcher Handbook](#).

Human Subjects Office

Office of the Vice President for Research and Economic Development
105 Hardin Library for the Health Sciences
600 Newton Rd.
Iowa City, IA 52242-1098

Phone: (319) 335-6564
Fax: (319) 335-7310
E-mail: irb@uiowa.edu

hso.research.uiowa.edu