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Vol. 1, No. 9, September 2005 "Can You Handle the Truth?"

Cuz We Got To: Readable HIPAA Authorizations

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Despite all the good intentions behind HIPAA, the addition of HIPAA authorizations to the informed consent process struck a blow for incomprehensibility. In the absence of case law or much regulatory guidance, it has been natural for attorneys to draft them with a "better-safe-than-sorry" philosophy.

According to CFR 64.508(c)(3), "The authorization must be written in plain language." This requirement is as clear as regulations get. (Informed consent forms must be written in language "understandable to [each] subject", a much more difficult standard to meet. [45 CFR 46.116]) The average adult in the U.S. reads at about the eighth-grade level, so HIPAA authorizations must be written for them.[1] An authorization may have to be written at a lower reading level if the population for the study is known to have worse reading skills. The young, the old, the poor, and the new (immigrants), for example, read English, on average, at a lower than average level.

HIPAA authorizations can be – and are – standardized across studies. It is therefore well-worth the investment to create readable templates. The U.S. Health Resources and Service Administration provides guidance and a handy thesaurus for drafting readable HIPAA authorizations at http://www.hrsa.gov/language.htm. Figure 1 on the next page presents a streamlined version of the NIH's sample HIPAA authorization template. This version is written in language that is plain to people with eighth-grade reading skills. Figure 2 presents the original NIH version, modified to be somewhat comparable to the revised version.[2] This version is written in language that is plain to people with college-level reading skills. Table 1 compares the two versions using Microsoft Word's readability tools.

Table 1: Readability Comparison

Statistic	Original	Streamlined
Words (lower is better)	596	307
Words/Sentence (lower is better)	25.1	13.5
Characters/Word (lower is better)	5.0	4.5
Passive Sentences (lower is better)	38%	0%
Flesch Reading Ease (higher is better)	35.7	61.6
Flesch-Kincaid Reading Level (Grade)*	12.0+	8.0

* Higher is better. Microsoft Word does not calculate reading level above twelfth grade, so 12.0 may be an underestimate.

It is certainly possible to quibble with the streamlined version. It may be missing some important details or perhaps not comply fully with some interpretations of HIPAA requirements. These are questions for the lawyers to argue. What may not be argued, however, is that the average potential subject, already dazed by the informed consent form, is much more likely to read and understand the streamlined version. HIPAA regulations require, in effect, that any change that decreases readability be offset by another change that increases it.

Figure 1: Authorization to Use and Share Your Health Information

Acme Research ("Acme") is conducting the following research study:

[name of study]
[purpose of study]

In this study, Acme will collect and use information about your health. The law requires Acme to protect the privacy of your information.

By signing this document, you authorize Acme to collect, use and share this health information about you:

[types of information and uses]

Acme may share this information with:

[recipients or classes of recipients]

Privacy laws may not require people who receive your information to protect it. It is therefore possible that they may share it with others without your permission. We may use or disclose your information in a way that you cannot be identified. The law may also require disclosure of your information. For example, the government may need it to protect public health.

If you want to join the research study, you have to sign this document. If you sign it now, you may change your mind later. Just tell Acme you changed your mind in a letter. Mail the letter to Acme at 123 Easy Street, Small Town, CA 98765. If you change your mind, you will probably have to drop out of the study. Also, Acme will still be able to use and disclose information it collected before it received your letter.

During the study, you will not have access to your health information except if it is required for medical care. When the study is over, you may obtain a copy of your health information, but not other information that Acme created for research purposes.

This Authorization does not have an expiration date.

_____

Your signature or the signature of your personal representative

_____ _____

Date The printed name of the person who signed above

_____

If applicable, your personal representative's authority to sign for you

Figure 2: Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at Acme Research ("Acme") to use or disclose (release) your health information that identifies you for the research study described here:

[Provide a description of the research study, such as the title and purpose of the research.]

The health information that we may use or disclose (release) for this research includes [complete as appropriate]:

The health information listed above may be used by and/or disclosed (released) to:

[Name or class of persons involved in the research; i.e., researchers and their staff]

Acme is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note:

- You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.
- You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, Acme may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to: [Acme and contact information].
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.
- Your health information will be used or disclosed when required by law.
- Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.
- No publication or public presentation about the research described above will reveal your identity without another authorization from you.

[continues on next page]

Figure 2 (Continued): Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

- To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that [name of the covered entity] maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at [name of the covered entity] to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by Acme. If it is necessary for your care, your health information will be provided to you or your physician.
- If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

_____	_____
Signature of participant or participant's personal representative	Date
_____	_____
Printed name of participant or participant's personal representative	If applicable, a description of the personal representative's authority to sign for the participant

Notes

1. "Developing Written Learning Material: A Proactive Approach", R.G. Brockett, Lifelong Learning, 1984 Vol. 7
2. Available at http://privacyruleandresearch.nih.gov/authorization.asp#samplelang

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