

Tools & Tips for Writing a Clear and Appropriate Informed Consent Document

According to the UMB HRPP Policies and Procedures, readability of an informed consent document should be no greater than a 7th grade reading level. In order to measure readability using Word, go to

- TOOLS, then OPTIONS, then SPELLING AND GRAMMER
- Select “Check grammar with spelling”
- Select “Show readability statistics”
- Click OK
- Proceed through the spell check, and when finished, the readability level should be displayed.

If the readability is still greater than 7th grade reading level after implementing the techniques discussed above, do the following:

- a. Delete the Subjects Rights section and complete the above operation again
- b. If the readability level is still too high after completing a) it may be beneficial to have someone uninvolved in the research offer suggestions for how to simplify the consent document.

Bibliography:

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3. Washington DC. The US Census Bureau. Census Bureau Projects Tripling of Hispanic and Asian Populations in 50 Years; Non-Hispanic Whites May Drop To Half of Total Population: Washington DC, 2004.

Other Resources:

1. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. Health literacy: report of the Council on Scientific Affairs. JAMA 281 (6): 552-557, 1999.
2. Calkins, DR, *et al.* Patient-physician communication at hospital discharge and patients’ understanding of the postdischarge treatment plan. Archives of Internal Medicine 157 (9):1026-1030, 1997.
3. Center for Health Care Strategies, Inc. Health Literacy Fact Sheets, 1 – 9. <http://www.chcs.org>
4. Committee on Health Literacy. Institute of Medicine. Health literacy: a prescription to end confusion. Washington, D.C.: National Academies Press, 2004.
5. Doak, Cecilia and Doak, Leonard. Teaching patients with low literacy skills, 2nd edition. Philadelphia, J.B. Lippincott: 1996.

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6. Health Literacy Consulting. Figuring Out About Numbers. Tips for February 2004. <http://www.healthliteracy.com/tip-may2005.html>
7. Medline Plus. How to Write Easy to Read Health Materials. <http://www.nlm.nih.gov/medlineplus/etr.html>
8. The National Cancer Institute. Simplification of Informed Consent Documents. <http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs>
9. Paasche-Orlow, MK, *et al.* Readability standards for informed consent forms as compared with actual readability. *New England Journal of Medicine* 348 (8): 721-726, 2003.
10. Parikh, N.S., *et al.* Shame and health literacy: the unspoken connection. *Patient Education and Counseling* 27: 33-39, 1996.
11. Partners Healthcare. Alternative Lay Language for Medical Terms in Consent Forms. <http://healthcare.partners.org/phsirb/irbforms/dict2.pdf>
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13. Schwartzberg, Joanne G. Low health literacy: what do your patients really understand? *Nursing Economics* 20 (3): 145 – 147, 2002.
14. Medline Plus. <http://www.nlm.nih.gov/medlineplus/etr.html>
15. Center for Health Care Strategies, Inc. <http://www.chcs.org>
16. Society for Technical Communication, Usability Special Interest Group. <http://www.stcsig.org/usability/topics/readability.html>