Published in final edited form as:
Contemp Clin Trials. 2009 March ; 30(2): 114–115. doi:10.1016/j.cct.2008.10.004.

Do Informed Consent Documents Matter?

David B. Resnik, JD, PhD, NIEHS/NIH

Abstract

This commentary argues that, despite extensive critiques of informed consent documents, there are several ethical and legal reasons for investigators and IRB members to take these documents seriously.

Keywords

Informed consent; ethics; law; documentation

Informed consent documents in biomedical research have no shortage of detractors. The standard critiques of consent documents are that they are too long, full of technical jargon, legalistic, complex, and are seldom read anyway. [1],[2],[3] Though investigators and institutional review boards (IRBs) have been aware of these problems for many years and have taken some steps to abate them, little progress has been made in making consent documents easier to read and understand.[3] As a result, commentators, scholars, and federal agencies emphasize the importance of transmitting information to the subject during the entire process of consent.[4],[5],[6] The process of consent includes the consent form as well as the conversation between the investigator and the research subject concerning topics that are contained in the consent document, such as the nature of the research, the benefits, risks, alternatives, and so on. This conversation can take place before, during, and after enrollment in a research study.[6]

These critiques of consent documents combined with the emphasis on the process of consent may lead one to downplay the importance of the consent document. If some people have drawn this conclusion, they should think again. There are several ethical and legal reasons for investigators and IRBs to take the consent document seriously.

First, a document is a permanent record. Conversations are soon forgotten or misremembered. There are important details concerning the research that the subject may need to know later on, such as whom to contact if they have a medical problem or want to withdraw, some of the common side effects of the medications they are taking as part of the study, or the different procedures they will undergo. Subjects who do not have easy access to this information can be inconvenienced, injured or may even die. Since memory is fallible, this information needs to be in writing. A consent document is a natural place to put this vital information.

Second, a document contains much more information than is usually conveyed during a conversation, such as addresses, phone numbers, detailed descriptions of research procedures,

Contact information: David B Resnik, JD, PhD, Bioethicist and IRB Chair, NIEHS/NIH, Mail Drop NH 06, Box 12233, Research Triangle Park, NC, 27709. Phone: 919 541 5658. Fax: 919 541 3845. Email: E-mail: resnikd@niehs.nih.gov.

timetables, the risks of different study medications, confidentiality protections, the availability of a treatment off-study, and so on. A consent document is a convenient place to put information that may not be conveyed during the discussion.

Third, institutional review boards (IRBs) or other committees that oversee research with human subjects have little control over conversations that take place between investigators and subjects. Though IRBs have the authority to monitor the entire process of consent, they usually devote most of their time to critiquing the consent form, rather than monitoring consent conversations.[7] A consent document has the IRB's stamp of approval, but an informal conversation may not. IRBs spend considerable time trying to eliminate language that is deceptive, manipulative, overly technical or exculpatory. It is possible that investigators may inadvertently reintroduce problematic language or expressions during their conversations with subjects that had been eliminated from the consent document.

Fourth, consent forms are legal documents. Courts have characterized consent forms as establishing contractual relationships between investigators and subjects, which imply legal duties.[8] The content of the consent document has been an important issue in numerous lawsuits against investigators and institutions brought by injured research subjects.[9] Viewing consent forms as legal documents has undoubtedly encouraged the inclusion of language in the forms to protect the institution, sponsor, or investigator from legal liability, thereby making the documents more difficult to read and understand. Though I acknowledge and regret this trend, it would be irresponsible to ignore the legal implications of consent forms. It is important to pay careful attention to these documents, since they might wind up in a court of law.

While it is important to conceive of informed consent as a process, let's not forget the consent document. It may only be words written on the printed page, but those words matter a great deal. Informed consent documents should be readable, accurate, and thorough. Technical terms should be eliminated or explained in common vernacular. Complex sentences should be broken down into simpler ones. Language that is coercive or intimidating should be rephrased. Documents should be well-organized and easy to follow. Sections should be clearly marked and partitioned, and essential information, such as whom to contact in an emergency, should be set in bold or italic typeface, if necessary. Consent documents should convey to the reader the information that an ordinary person would need to decide whether to participate in a study. [7] They should be written as if someone might actually read them.

Acknowledgements

This research was supported by the intramural program of the NIEHS/NIH. It does not represent the views of the NIEHS or NIH. I wish to thank Jerry Menikoff for helpful ideas and discussions.

Notes

1. Grossman SA, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? J Clin Oncol 1994;12 (10):2211–5. [PubMed: 7931491]
2. Sharp SM. Consent documents for oncology trials: does anybody read these things? Am J Clin Oncol 2004;27 (6):570–5. [PubMed: 15577434]
3. Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med 2003;348 (8):721–6. [PubMed: 12594317]
4. Berg, J.; Appelbaum, P.; Parker, L.; Lidz, C. Informed Consent: Legal Theory and Clinical Practice. New York: Oxford University Press;
5. Office of Human Research Protections. Informed Consent Tips. [Accessed: June 15, 2008]. Available at: http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm

6. Food and Drug Administration. Informed consent process. [Accessed: October 8, 2008]. Available at: http://www.fda.gov/oc/ohrt/IRBS/faqs.html#Informed%20Consent%20Process
7. Menikoff, J. What the Doctor Didn't Say: The Hidden Truth about Medical Research. New York: Oxford University Press; 2006.
8. Grimes v. Kennedy Krieger Institute, Inc., 366 Md. 29, 782 A.2d 807 (Md. 2001)
9. Morreim EH. Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve. Houston Journal of Health Law and Policy 2003;4(1):1–86.