INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

TIPS FOR WRITING EASY-TO-READ INFORMED CONSENT DOCUMENTS

Informed consent is a process involving the exchange of information between subjects and a researcher to provide subjects with sufficient information to make informed choices about either beginning or continuing participation in a research project. Informed consent should be ongoing throughout the research project and not be regarded as simply a "form"; the consent document is merely a tool to assist the researcher. Valid informed consent requires: (1) Disclosure of relevant information to prospective subjects about the research; (2) their comprehension of the information; and, (3) their voluntary agreement, free of coercion and undue influence, to participate.

When developing an informed consent document, researchers need to consider their audience in relation to the comprehension of the information presented. The following tips are to help researchers develop clear, easy-to-read, easy-to-understand informed consent documents.

Content

√ Make sentences short, simple, and direct.
√ Limit line length to 30-50 characters and spaces.
√ Use title, subtitles, and other headers to organize the text and break it into short sections.
√ Present study purpose at the beginning of the document.
√ Clearly state each idea and sequence it logically (according to audience logic).
√ Use words familiar to the reader, i.e. "cholesterol" instead of "blood lipids."
√ Use non-scientific/non-medical terms where possible. If it is necessary to use scientific, medical, or legal terms, clearly define them.
√ Stress or highlight important points.
√ Avoid abbreviations or acronyms.
√ Avoid using words containing more than three syllables where possible.
√ Use words and terminology consistently throughout the document.
√ Use verbs in the active voice versus the passive voice, i.e. the subject is the doer of the act.
√ Use personal pronouns to increase personal identification.
√ Stress or highlight important points.
√ Be as concise as possible.
√ If possible, conduct a readability analysis to ensure reading level is no higher than eighth grade.

Appearance

√ Use a font that is easy to read.
√ Use at least a 12 point font size.
√ Use upper and lower case letters.
√ Justify left margins and make right margins ragged.
√ Employ underlining, bolding, and boxing text to give emphasis rather than capitalizing or italicizing.
√ Avoid large blocks of text.
√ Balance white space with words and graphics in the layout.

When reviewing the informed consent document, researchers should ask themselves the following questions:
1. Is the document written at a reading level understandable to the audience?
2. Is the document formatted well? Does it have headings that break the text into short sections?
3. Does the document present all the necessary information in an easy-to-understand manner?
4. Can the document be shortened without compromising clarity or other requirements?

Researchers might also have individuals they know but who are unaffiliated with the study, such as friends or family members, review the consent form in regard to the questions above.

For more information on the UNH Institutional Review Board (IRB) or institutional requirements regarding research involving human subjects, contact Research Integrity Services Director, Julie Simpson at julie.simpson@unh.edu or 862-2003. Additional materials are available on the IRB’s webpage at: http://unh.edu/research/human-subjects.