



DON Human Research Protection Program

Department of the Navy Human Research Protection Program

Consent Readability



Regulations



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32 CFR 219.116 and 21 CFR 50.20

“...no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative...”

The information that is given to the subject or the representative shall be in **language understandable to the subject** or the representative.”



Readability



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A part of “language understandable to the subject” includes the reading level (or readability) of the consent document.

Readability is the ease in which text can be read and understood.



US Reading Levels



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The US Department of Education, Institute of Education Sciences conducted large scale assessments of adult proficiency in 1992 and 2003 using a common methodology from which trends could be measured.



US Reading Levels



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- The study involved lengthy interviews of over 90,700 adults statistically balanced for age, gender, ethnicity, education level, and location (urban, suburban, or rural) in 12 states across the U.S. and was designed to represent the U.S. population as a whole.



US Reading Levels



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- This government study showed that 21% to 23% of adult Americans:
 - were not "able to locate information in text",
 - could not "make low-level inferences using printed materials", and
 - were unable to "integrate easily identifiable pieces of information"



US Reading Levels



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Summarizing several studies done in the United States and Canada, the average reading skill level was estimated to be at around the 8th to 9th grade (University of Utah Health Sciences Center).

However, this same study found that about one in five adults had a reading skill level at the 5th grade level or below.



Measuring Readability



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- In 1943, Rudolf Flesch published his Ph. D. dissertation entitled “Marks of a Readable Style,” which included a readability formula for predicting the difficulty of adult reading material. Investigators began using it to improve communications in many fields.



Measuring Readability



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- In 1948, Flesch published his Reading Ease formula in two parts. Rather than using grade levels, it used a scale from 0 to 100, with 0 equivalent to the 12th grade and 100 equivalent to the 4th grade.
- The Flesch Reading Ease formula became one of the most widely used, and the one most tested and reliable.



Measuring Readability



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- In 1975, in a project sponsored by the Navy, the Reading Ease formula was recalculated to give a grade-level score. The new formula is now called the Flesch–Kincaid Grade-Level formula.* The project's purpose was to develop a method for measuring the ease of reading technical Navy training materials aimed at enlisted personnel.

*Kincaid, J. P., R. P. Fishburne, R. L. Rogers, and B. S. Chissom. 1975. *Derivation of new readability formulas (Automated Readability Index, Fog Count, and Flesch Reading Ease Formula) for Navy enlisted personnel*. CNTECHTRA Research Branch Report 8-75.



Measuring Readability



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Caveat:

Readability formulas provide only **an estimate** of the reading ease or difficulty of a text.

They should be used only as a guide, not as an absolute indicator of readability.



Microsoft Word[©] Readability Statistics



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Microsoft Word[©] has a feature that allows a writer to check the readability scores of a document with both the Flesch Reading Ease and Flesch-Kincaid Grade-Level formulas.



Microsoft Word[©] Readability Statistics



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- Under the “Review” tab, click on the “Spelling & Grammar” option.
- In the lower left corner of the text box that appears, click on the “Options” button.
- Check the next text box that says “Show Readability Statistics.”
- After the spelling check is complete, the following pop-up will appear with the readability statistics for the document :



Microsoft Word[®] Readability Statistics



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The image shows a screenshot of the "Readability Statistics" dialog box in Microsoft Word. The dialog box has a title bar with a question mark and a close button. It contains three sections: "Counts", "Averages", and "Readability". Each section lists a metric and its corresponding value.

Counts	
Words	428
Characters	2442
Paragraphs	15
Sentences	24

Averages	
Sentences per Paragraph	4.0
Words per Sentence	16.0
Characters per Word	5.5

Readability	
Passive Sentences	16%
Flesch Reading Ease	29.6
Flesch-Kincaid Grade Level	12.4

OK



Methods to Increase the Readability of Consent Documents



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Use “Lay” Terminology

Studies by William Waggoner in 1994 and 1995 tested lists of commonly used terms (25 terms and 27 terms respectively) found in clinical research studies.

A few of the findings included:

12 % knew what an Institutional Review Board (IRB) was

10% knew fully what a culture was

35% knew who an “Investigator” was

22% knew what the phrase “the drug you were to take was chosen randomly” meant



Possible Word Substitutions



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Adversely effect

hurt

Approximately

about

Benefit

help

Compensate

pay

Comply with

follow

Discontinue

end, drop, stop

Eligible to enroll

can join, can sign up

Evaluate

check, rate, test

Identify

name, find, show



Possible Word Substitutions



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If you require assistance

if you need help

Initial visit

first visit

Monitor

check, watch

Notify

tell, let know

Objective

goal, aim

Participate

take part

Regarding

about, of, on

Terminate

end, stop



Methods to Increase the Readability of Consent Documents*



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Avoid Long and Complex Sentences

Sentences should be 10 words or less. Avoid sentences of more than 20 words. Sentences should not be complex.

For example, instead of writing “The study survey is five pages long and it will take you about 45 minutes to finish,” divide the sentence into two. “The study survey is five pages long. It will take you about 45 minutes to finish.”



Methods to Increase the Readability of Consent Documents



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Write in the Active Voice

Sentences written in the passive voice are more difficult to understand.

For example, instead of writing “Release of this information is controlled by the Privacy Act,” write it “We cannot give out this information because of the Privacy Act.”



Methods to Increase the Readability of Consent Documents



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Write Sentences in the Second Person

Sentences written in the third person are more difficult to understand.

For example, instead of writing “The subject must follow all directions.” write “You must follow all directions.”



Methods to Increase the Readability of Consent Documents



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Use Words that are Less Than Three Syllables

Words with three or more syllables require greater than an 8th grade reading level to understand.

One of the most commonly used phrases in a consent document is “We are asking you to participate...”
Instead of using “participate” use the phrase “take part in” or “be a part of.”



Methods to Increase the Readability of Consent Documents



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Use Short Paragraphs

Keep paragraphs to six or fewer lines. Where possible, use lists.

Use a Large Type Font (12 – 14)

Increase the type size so it is easy on the eyes, especially with slow readers.

Avoid Contractions

Poor readers often skip the second half of a contracted phrase, so often read a sentence to mean the opposite.



Methods to Increase the Readability of Consent Documents



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Use Titles or Section Headings

Breaking up the document into sections with headings, thereby increasing “white space” helps guide the reader through the information. People will refuse to read documents that exhaust their eyes.



Methods to Increase the Readability of Consent Documents



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Use Pictures or Illustrations Where Possible

Pictures can break up a sea of gray in a document and give clues to what is important. Pictures should be related to the text and be located near the part of the text they help explain.

Avoid “Legalese” or Technical Language

Use words from subjects’ spoken language. If a technical word is needed, define it in the text.



Questions

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Please contact DON HRPP with any follow-up questions or concerns.

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