



## Tips for Preparing Research Documents that are Easy for Participants to Understand:

The regulations state that “Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate ([45 CFR 46.116](#)).

Lay Language and readability of research documents is not limited to the informed consent form. This concept applies to all participant-facing materials including surveys, questionnaires, interview questions, recruitment flyers, brochures etc.

The use of plain language in government communications is the law. [Plainlanguage.gov](#) states: "Language that is plain to one set of readers may not be plain to others. Plain Language is communication your audience can understand the first time they read or hear it. Material is in plain language if your audience can:

- Find what they need.
- Understand what they find the first time they read or hear it.
- Use what they find to meet their needs.”

“There are many techniques that can help you achieve this goal. Among the most common are:

- Reader-centered organization
- “You” and other pronouns
- Active voice, not passive
- Short sentences and paragraphs
- Common, everyday words
- Easy-to-follow design features (lists, headers, tables)”

In addition to these techniques listed on [plainlanguage.gov](#), there is an easy way to evaluate the reading level of documents in Microsoft word:

### How to Check the Reading Level of a Document in Microsoft Word:

1. From the “Home” toolbar, click “Editor” located on the far-right end of the toolbar
2. A menu on the right side of your window will appear. Scroll down that menu to “Insights” and click “Document Stats”.
3. Click “okay” on the next window that appears. It may take a few moments for Microsoft Word to calculate the stats of your document.

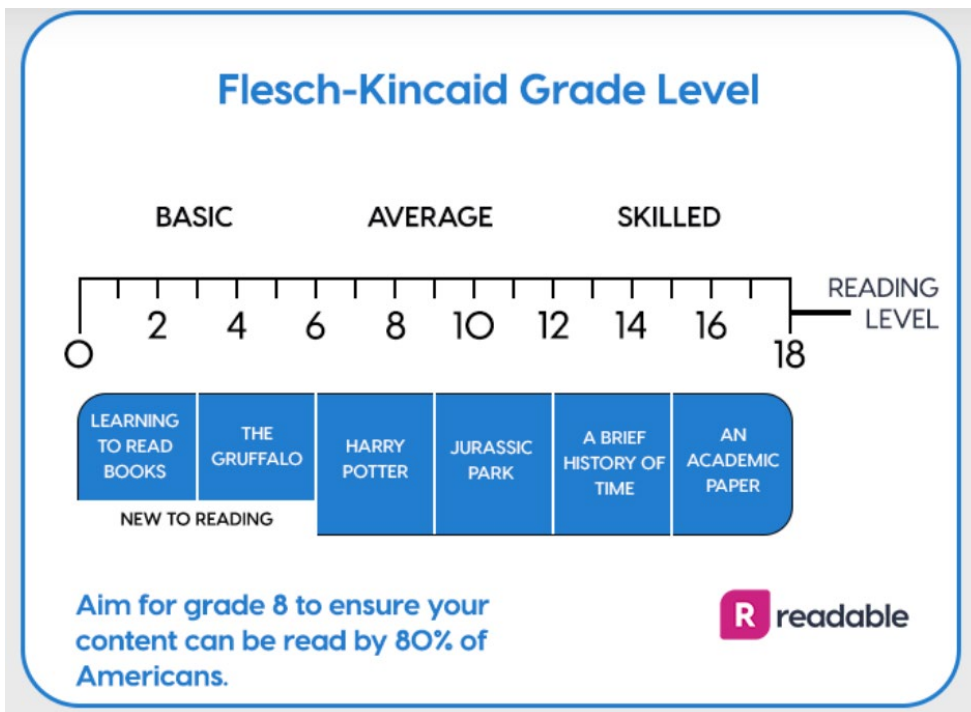
4. A window will appear titled “Readability Statistics”. Readability statistics of the document are listed in the last section of this window.

### **Flesch Reading Ease Test:**

This test rates text on a 100-point scale. The higher the score, the easier it is to understand the document. For most standard files, you want the score to be between 60 and 70.

### **Flesch-Kincaid Grade Level**

The Flesch-Kincaid Grade Level is equivalent to the US grade level of education. It shows the required education to be able to understand a text.



<https://readable.com/readability/flesch-reading-ease-flesch-kincaid-grade-level/>

### **Recommended Lay Language Resources:**

Multi Regional Clinical Trial Center (MRCT)- Clinical Research Glossary: <https://mrctcenter.org/clinical-research-glossary/glossary-words/>

Federal Plain Language Guidelines: <https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf>

University of Michigan Plain Language Medical Directory: <https://apps.lib.umich.edu/medical-dictionary/>

Federal Plain Language Guide: Simple Words & Phrases: List of commonly used complex words and suggested substitutes: <https://www.plainlanguage.gov/guidelines/words/use-simple-words-phrases/>

National Cancer Institute (NCI) Dictionary of Cancer Terms: <https://www.cancer.gov/publications/dictionaries/cancer-terms/>