**TC IRB Guidance for Drafting an Informed Consent Form**

The Teachers College [Institutional Review Board (IRB)](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/writing-for-an-irb-review/) recommends that Informed Consent Forms meet the [**Flesch-Kincaid Grade Level**](https://readable.com/readability/flesch-reading-ease-flesch-kincaid-grade-level/) (6th-8th grade level or below) readability standards.

Depending on the proposed target population to be recruited, documents that do not meet this criterion may be returned for revisions to improve participant understanding.

**Background**

The *average* reading level among U.S. adults is no higher than eighth grade. Among economically or educationally disadvantaged populations, the average reading level is even lower, about fifth grade. Many research participants do not understand consent forms because these documents are typically written at the college or graduate school level.

The Principal Investigator is responsible for ensuring that research participants have an adequate understanding of the procedures, risks, and benefits before they participate in the study. Researchers should strive to write Consent Forms at a sixth to eighth-grade level unless prospective participants are known to read at a much higher or lower reading level.

Writing Consent Forms with a low level of reading difficulty is a skill that can be learned. The information below includes tips and strategies to reduce reading levels within these documents.

**Flesch-Kincaid Grade Level**

The [Flesch-Kincaid Grade Level](https://readable.com/readability/flesch-reading-ease-flesch-kincaid-grade-level/) is a widely used readability formula that assesses the approximate reading grade level of a text, based on average sentence length and word complexity. It produces scores corresponding to U.S. grade levels. For example, if a text has a Flesch-Kincaid level of 8, this means the reader needs a grade 8 level of reading or above to understand it.

**Instructions to calculate the Flesch-Kincaid grade level of a document:**

**For PC users in Microsoft Word:**

*(1) File* tab, click the “Options” button; (2) *Proofing* tab, under *When correcting spelling and grammar in Word*, make sure *Check grammar with spelling* is selected; (3) *When correcting spelling and grammar in Word*, select the *Show readability statistics* check box; (4) After the grammar check is complete, Word will display a message box showing you the readability grade level.

**For Mac users in Word:**

*(1) Preferences* on the browser toolbar, select Spelling & Grammar; (2) Under *Grammar*, select *Check Grammar with Spelling and Show Readability Statistics*; (3) In your Word document, select *Review* > *Spelling & Grammar*; (4) Correct or ignore any spelling or grammar corrections, then click *Editor* under the *Home* toolbar and *Document stats* under *Insights;* (5) Word will open the *Readability Statistics* window with information about the reading level of your document.

**Google Doc users:**

<https://readable.com/> ($4/mo.) OR <https://hemingwayapp.com/> (free) -import or paste text for reading level.

**Tips for Drafting a Readable Consent Form:**

* Use at least 12-point font and consider a larger font based on your audience.
* Use page numbers on all participant-facing documents.
* Emphasize key points using underlines, **bold text**, or boxes.
* Avoid *italics* and ALL CAPITAL letters for highlighting.
* Use photos, graphics, or tables if they will help clarify procedures.
* Avoid large blocks of printed text.
* Keep paragraphs short and limited to one idea.
* Write short, simple, and direct sentences. Split long sentences into two for clarity:
  + **Complex:** "*The participant’s responsibilities include, but are not limited to, attending all scheduled sessions and completing assigned tasks."*
  + **Simple:** *"You must attend all sessions and complete the tasks we assign."*
* Ensure each idea in the text is clear, logically sequenced, and flows smoothly.
* Use active voice.
  + **Passive:** *"The risks and benefits will be explained by the researcher."*
  + **Active:** *"We will explain the risks and benefits to you."*
* If possible, keep words to 3 syllables or fewer.
* Use the second person (you) not the third person (the participant) to increase personal identification.
* Avoid contractions.
* Avoid repetition.
* Spell out acronyms when first used (e.g., "Institutional Review Board (IRB)").
* Capitalize proper nouns and brand names. Include the trademark (™) or registered (®) symbol the first time the name appears.
* Be consistent with the use of all terminology, such as abbreviations.
* Avoid using "e.g." or "etc." Instead, write out phrases such as "for example" or "and so forth."
* Use lists whenever possible.
* Have 50/50 blend of white space and text.

**Additional Resources**

For more detailed guidance, review the following resources:

* [TC IRB Consent with Confidence: Mastering the Art of Clear and Ethical Consent Forms (presentation slides)](https://docs.google.com/presentation/d/153BUt1XoLbujqJ7CAqs6dCn0Aj_5C_D4/edit#slide=id.p1)
* [TC IRB Consent with Confidence: Mastering the Art of Clear and Ethical Consent Forms (presentation video)](https://drive.google.com/file/d/19mZLG5XJBVRf03v4ql5t9CMOffoMvgRZ/view?usp=drive_link)

For questions related to this guidance, contact [IRB@tc.edu](mailto:IRB@tc.edu) or submit a ticket via [AskIRB](https://tc.service-now.com/home?id=sc_cat_item&sys_id=83a2ca6b1bd8b550922afee58d4bcb2f).