



How To Write An Effective Consent Form: a Workshop for Investigators, Protocol Navigators and Research Staff

Resource Slides

“Plain Language”- What is it?

Plain language uses:

- Short words
- Short, simple and direct sentences
- Short paragraphs that are limited to one idea

Tips:

- Present ideas in a logical order
- Uses active voice rather than passive voice (the subject is the doer of the act):
“We will take your blood pressure” rather than “Your blood pressure will be taken”
- Do not use symbols such as ">"; spell out "greater than"
- Do not use e.g., or etc., use instead, "for example," "so forth"

Words

- Best if 3 syllables or fewer
- Replace difficult words (~~polysyllabic~~) (~~multiple syllable~~) with simpler words
- Avoid research and medical terms when possible
 - Use lay terms and common words throughout the consent
- If complicated words are needed, define them in plain language
- Avoid abbreviations and acronyms
 - If you must abbreviate, define an abbreviation the first time you use it
- Use words and terms consistently in the consent form
- Use the simplest form of a verb that is the strongest and most direct
- Leave out unnecessary words

Resources for Simplifying Terms*

Excerpt from the PRISM Readability Toolkit, Third Edition
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Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
activate	begin, start
acute	sudden, new, recent; intense flare-up, serious pain; short-term
addictive	habit-forming
additional	added, extra, more, other
address	talk about, discuss
adequate	enough
adjacent	next to, by
administer	give
advantageous	helpful, useful
adverse	harmful, bad
adversely impact	hurt, set back
affirmative	yes, positive
aggravate	make worse

* See list of resources at the end of this slide set

Use Simple Words and Phrases (plainlanguage.gov)*

✗ Don't say

✓ Say

implement	carry out, start
in addition	also, besides, too
facilitate	ease, help
in the event of	if
in a timely manner	on time, promptly
has a requirement for	needs
utilize, utilization	use
commence	begin, start

* See list of resources at the end of this slide set



TERM	LAY TERM 1	LAY TERM 2
DVT	Blood clot formed in the veins of the leg which may manifest as a dull ache or heaviness in the limb. If the clot moves to other organs, it can be serious or life threatening.	blood clots in a vein (possible pain, swelling, and/or redness)
dysarthria	difficulty forming or speaking words	
dysautonomia	decreased function of the part of the nervous system that controls automatic functions (possible fatigue and/or low blood pressure)	
dysesthesia	painful or abnormal skin sensations	
dysgeusia	Taste changes which may affect the way foods normally taste	abnormal taste
dyskinesia	uncontrolled movements	
dyslipidemia	abnormal blood levels of fat	
dysmenorrhea	painful menstruation	

NCI Checklist to Develop Easy-to-Read Informed Consent Documents*

TEXT

Words are familiar to the reader. Any scientific, medical, or legal words are defined clearly.

Words and terminology are consistent throughout the document.

Sentences are short, simple, and direct.

Line length is limited to 30-50 characters and spaces.

Paragraphs are short. Convey one idea per paragraph.

Verbs are in active voice (i.e., the subject is the doer of the act).

Personal pronouns are used to increase personal identification.

Each idea is clear and logically sequenced (according to audience logic).

Important points are highlighted.

Study purpose is presented early in the text.

Titles, subtitles, and other headers help to clarify organization of text.

Headers are simple and close to text.

Underline, bold, or boxes (rather than all caps or italics) give emphasis.

Layout balances white space with words and graphics.

Left margins are justified. Right margins are ragged.

Upper and lower case letters are used.

Style of print is easy to read.

Type size is at least 12 point.

Readability analysis is done to determine reading level (should be eighth grade or lower).

Avoid:

- Abbreviations and acronyms.
- Large blocks of print.
- Words containing more than three syllables (where possible).

* See list of resources at the end of this slide set

NCI Checklist to Develop Easy-to-Read Informed Consent Documents*

GRAPHICS

Helpful in explaining the text.

Easy to understand.

Meaningful to the audience.

Appropriately located. Text and graphics go together.

Simple and uncluttered.

Images reflect cultural context.

Visuals have captions.

Each visual is directly related to one message.

Cues, such as circles or arrows, point out key information.

Colors, when used, are appealing to the audience.

Avoid graphics that won't reproduce well.

* See list of resources at the end of this slide set

Explain Terms

- Randomization
- Effectiveness
- Likely
- Blinding
- Risks and discomfort
 - What does it mean when risks/discomforts/side effects are common, occasional or rare?
 - How bad and how often does the harm, discomfort or side effect occur?

Sentences

- Express only one idea in each sentence
- Sentences should average 15 words or less
- Shorter sentences are also better for conveying complex information (they break the information up into smaller, easier-to-process units)
- Keep subject, verb, and object close together (The natural word order of an English sentence is subject-verb-object)
- Place the main idea before exceptions and conditions
- Don't start a sentence with "except" as this may result in the reader needing to re-read the sentence
- Use a list if the sentence contains multiple conditions or exceptions

Paragraphs

- Write short paragraphs and include only one topic in each paragraph.
- Recommend paragraphs be no more than 150 words with three to eight sentences
- A paragraph with 1-2 sentences is fine
- Have a topic sentence at the start of the paragraph which can provide a transition from one paragraph to another
- Use white space to break up blocks of text
- Break up lots of text with lists and tables
- Vertical lists highlight a series of requirements or other information in a visually clear way and help the reader focus on important material
- Use tables to make complex material easier to understand
- Including an illustration can be more helpful than describing it

Lay Terms For Use With Pediatric Participants Can Be Found In The Page Listing Glossaries at the End of This Slide Set

Word! C

Word! Cancer

Word! Canine Teeth

Word! Canker Sore

Word! Carbohydrate

Word! Carbohydrate Counting

Word! Cardiologist

Word! Caries

Word! Cartilage

Word! Cast

Word! Cells

Word! Cellulitis

Word! Cerebellum

Word! Cerebral Cortex

Word! Cystic Fibrosis



Cystic Fibrosis

Say: SIS-tik fi-BRO-sus

You may know that you have [mucus](#) in your nose, mouth, and lungs, and that it helps keep you healthy. But kids with the condition [cystic fibrosis](#) have bodies that make thick, sticky mucus. This causes problems in their lungs and their digestive tract. The condition makes it hard for them to breathe and also to get the [nutrition](#) they need from their food.



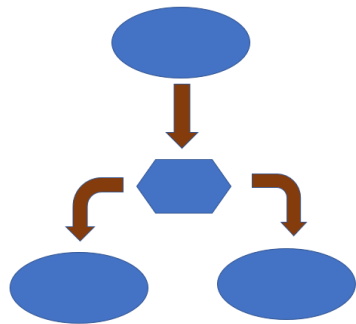
Tips for Presenting Information

- At least 12-point font
- Use underline, bold or boxes rather than italics or all caps
- Create vertical lists and tables
- Use headings and text boxes
- Avoid large block of print and instead break it up by using
 - sectioning, colors, white space and icons
 - bullet points with short phrases or sentences
- Double space or add additional spacing (referred to as leading) between paragraphs
- Compare by putting information side by side
- Use photos, graphics or tables if they will help clarify procedures
- Visual aids and schematic diagrams to explain study design



Visual Aids

- Pictures
- Videos
- Graphics
 - ✓ Icons
 - ✓ Use of color
 - ✓ Charts
 - ✓ Tables
 - ✓ Schematic/Flow diagrams



X				
	X			
	X			
		X	X	X



search



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FEATURED IMAGES

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Science and Technology



Childhood Cancer



Español



Anatomy



Historical Images



B-Roll Videos

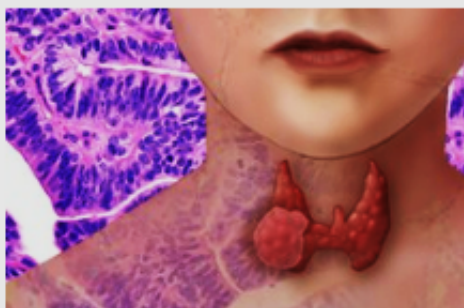
Example: NCI Visuals Online

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- click on the image and check the section labeled “reuse restrictions” to see if the image is in the public domain or subject to copyright protection

NCI Visuals Online

Thyroid Cancer



+ Add to My Pictures

View/Download:

Small:
720x474

View

Download

Medium:
1500x988

View

Download

Title: Thyroid Cancer

Description: While thyroid cancer is very treatable with surgery and other therapies, it is one of the fastest growing cancers in the United States.

Topics/Categories: [Cancer Types -- Thymic Carcinoma](#)

Type: Color, Illustration (JPEG format)

Source: National Institutes of Health

Creator: Darryl Leja, National Human Genome Research Institute, NIH

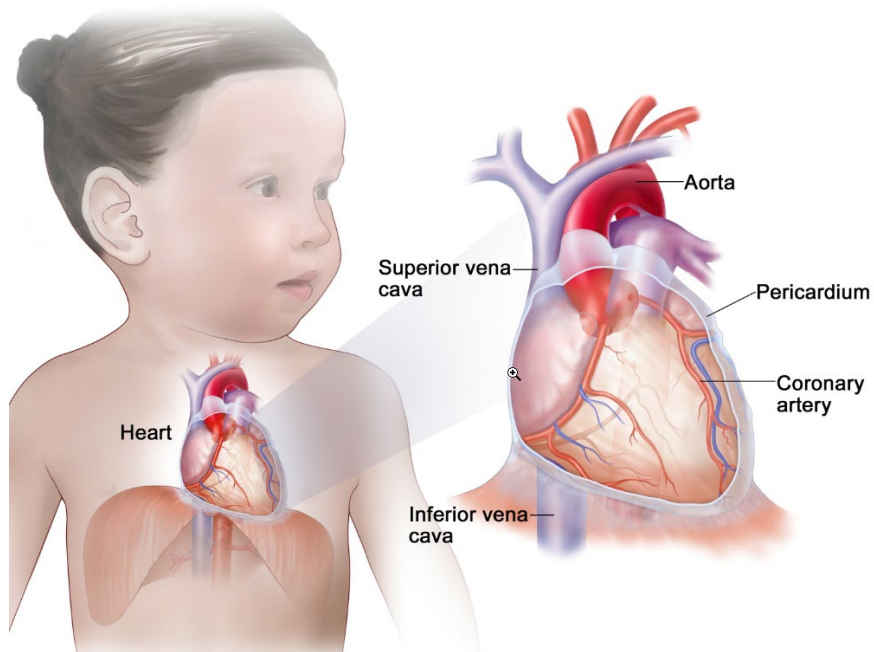
Date Created: September 24, 2014

Date Added: January 9, 2018

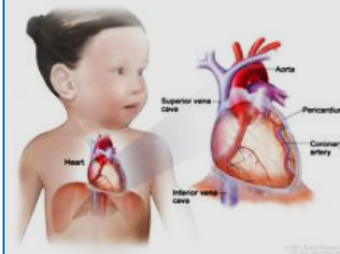
Access: Public

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NCI Visuals Online- When used for ICFs



Cardiac Tumors



+ Add to My Pictures

View/Download:

Small:
720x576

View

Download

Medium:
1500x1200

View

Download

Large:
3000x2400

View

Download

Title: Cardiac Tumors

Description: Anatomy of the heart; a pullout shows the aorta, superior vena cava, pericardium, coronary artery, and inferior vena cava.

Cardiac tumors are rare tumors that form in the tissues of the heart, including muscle tissue, connective tissue, and tissues that line the blood vessels, control heart rhythm, and cover the nerves of the heart. They may also form in the pericardium (the sac around the heart). Most cardiac tumors are benign (not cancer), but some may be malignant (cancer).

Topics/Categories: Anatomy -- Circulatory System

Type: Color, Medical Illustration (JPEG format)

Source: National Cancer Institute

Creator: Terese Winslow (Illustrator)

AV Number: CDR804602

Date Created: May 19, 2021

Date Added: June 15, 2021

Access: Public (150/300 dpi access: NIH Intranet only)

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Clinical Research Glossary

Helping you understand clinical research

The **Clinical Research** Glossary offers easy to understand clinical research definitions.

All definitions are developed by the MRCT Center and a committed team of patient advocates and other professionals in medicine and research. Before definitions are released, they are reviewed by members of the public.

The Clinical Research Glossary started as a pilot project in 2020 and is now a CDISC global standard for clear communication. This means that more and more groups are learning about and using this resource.

Welcome! We hope this resource is helpful to you.

[LEARN MORE](#)[GET INVOLVED](#)[MEET THE TEAM](#)[DOWNLOAD](#) ▼[Q SEARCH](#)

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z



Multi-Regional Clinical Trials Glossary

<https://mrctcenter.org/glossary/>



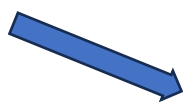
MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

ABOUT U

Search Results for: CT scan

Click here



GLOSSARY TERM

Computerized Tomography (CT) scan

A way to take pictures of the inside of a person's body using a type of radiation and a computer.

Computerized Tomography (CT) scan

cdisc



A way to take pictures of the inside of a person's body using a type of radiation and a computer.



Example of *Computerized Tomography (CT) scan* in a sentence

A CT scan is able to show specific changes in a person's body (like changes in the brain, other tissues, organs or bones).



More Info

A CT scan is a type of imaging study.

[No Title]



Related Words

[X-ray](#)

[Magnetic Resonance Imaging \(MRI\)](#)

imaging study



Other info to think about when joining a study

A CT scan may be needed in a research study.

If you know you have to get a CT scan for the research study, you can ask how the information will help the study. Also, you can ask if the CT scan results will be shared with you or your regular doctor, and how much radiation you will receive. This information could help you decide if you want to receive radiation from a CT scan done for research purposes.



Other Resources

[NCI Thesaurus](#)

[Harvard Catalyst - CT Scans for Research](#)

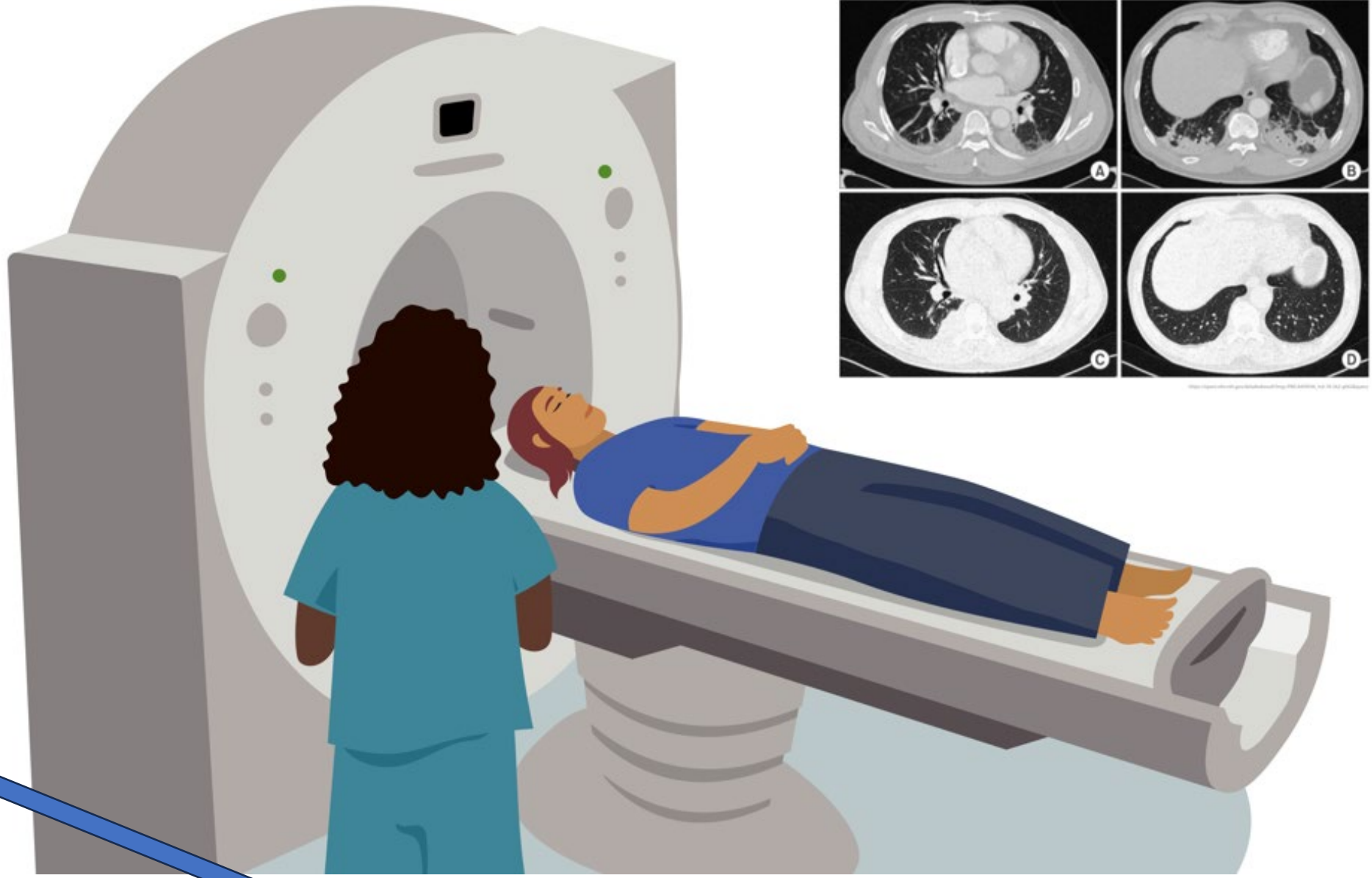


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Using AI to Simplify Consent Language

AI Tools Approved for NIH Use

- HHS ChatGPT - <https://go.hhs.gov/chatgpt>
- HHS Gemini – <https://go.hhs.gov/gemini>
- CHIRP Enterprise – <https://chirp.nih.gov/index.php> (NIH log on required)

Additional Resources

- [Introduction to Artificial Intelligence \(AI\) at NIH](#)
- [NIH AI Hub](#)
- [Artificial Intelligence in Research: Policy Considerations and Guidance](#) (NIH OSP)
- [Gen AI Toolkit](#) (NIH Library)



Readability Assessment Tools

- Readability tools use formulas to estimate the reading difficulty of text
- Readability Level Guidelines for Informed Consent Documents: The 2015 *IOM Informed Consent and Health Literacy Workshop Summary* recommended that informed consent documents be written at the 8th grade reading level or lower
- NIH IRB website instructs investigators to target the reading level of consent forms as closely as possible to Grades 6 - 8
- Examples of Readability Assessment Tools
 - **Fog Index:** assigns a grade level based on sentence length, number of words, number of polysyllabic (>3) words
 - **Flesch-Kincaid Index:** analyzes readability based on the number of syllables per word and words per sentence in addition to other measures

Assessing a Participant's Understanding of the Study

Topic area	Question
Purpose	"If you were going to tell a friend what this study was about, what would you say?"
Procedures	"What are the main things you will do or will happen to you while you are in this study?"
Randomization	"Does everyone in this study have to do the same thing?"
	"Tell me in your own words how the researchers will decide whether you get the [intervention] or the [usual care]?"
Risks	"What are the risks, or bad things that might happen to you if or when you join this study?"
Benefits	"What are the benefits, or good things that might happen to you if or when you join this study?"
Voluntariness	"What will happen if you decide you don't want to be in the study?"
	"What can happen if you decide to be in the study but later change your mind?"

Kass N, Taylor HA, Ali J, Hallez K. A Pilot Study of Simple Interventions to Improve Informed Consent in Clinical Research: Feasibility, Approach, and Results. *Clinical Trials* 2015; (12)1: 54-66.

Resources and Tools (Hyperlinks) for Use In Writing Consent Forms: Lay Language Alternatives for Medical Terms-Adults vs. Children

Resources for Adults

- [NIH IRB Consent Library](#) from OHSRP website
- [NCCN Informed Consent Language \(ICL\) Database](#)
- Lay Language Glossary as listed on the [Stanford Research Compliance Office Page Definitions & Lay Glossary of Medical Terms](#)

Resources for Pediatric Participants (e.g., for Assent Forms)

- [Children's Hospital of Philadelphia Glossary of Lay Terms](#)
- [Kids' Medical Dictionary \(Nemours\)](#)

Resources and Tools(Hyperlinks): Using Plain Language and Simplified Wording

- [Everyday Words for Public Health Communication \(CDC\)](#)
- [PRISM Alternative Wording Suggestions Appendix B-\(Kaiser Permanente Washington Research Institute Program for Readability & Science in Medicine \(PRISM\)\)](#)
- [Multi-Regional Clinical Trials \(MRCT\) Clinical Research Glossary](#)
 - MRCT- [How to credit the MRCT Center when using the Clinical Research Glossary](#)
- [NCI Checklist to Develop Easy-to-Read Informed Consent Documents \(downloads as a pdf\)](#)
- [Plain Language: Getting Started or Brushing UP \(NIH\)](#)
- [Plain Language Guide Series \(US Government\)](#)

Readability Tool Information

- E.g: Flesch-Kincaid Grade Level: based, in part, on syllables/word & words/sentence
 - To access this tool for your Microsoft Word documents:
 1. Go to **File > Options**
 2. Select **Proofing**
 3. Under **When correcting spelling and grammar in Word**, select **Show readability statistics**
 4. Open a Word document and press F7 or go to **Review > Spelling & Grammar**. When Word finishes checking the spelling and grammar, it also displays information about the reading level of the document or click the box that says “Document stats.”

Readability Tool Information (continued)

- Gunning Fog Index; assigns a grade level based on sentence length, number of words, number of polysyllabic (>3 syllables) words
- Online Utility Readability Calculator measure of readability used here is the indication of number of years of education that a person needs to be able to understand the text easily on the first reading
- SMOG Readability Formula (Healthcare is the sector in which this is mostly commonly used.)

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FDA. [Communicating Risks and Benefits: An Evidence-Based User's Guide](#). August 2011 (downloads as pdf)

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