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

Resource Slides

Office of Intramural Research
Office of Human Subjects Research Protections

“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

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

NCI Risk Terms Library *

Adverse Event	Informed Consent Term
Gastric ulcer	Sores in stomach
Gastroenteritis	Pain in belly
Gastrointestinal hemorrhage	Internal bleeding
Gastrointestinal necrosis, with combination regimens	Damage to the bowels
Gastrointestinal perforation	A tear or a hole in the bowels which may cause pain or that may require surgery

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

NATIONAL COMPREHENSIVE CANCER NETWORK
NCCN ONCOLOGY RESEARCH PROGRAM

NCCN Informed Consent Language (ICL) Database *

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	

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

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 at 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

Nemours KidsHealth

for Parents | for Kids

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

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

Word! Cystic Fibrosis

Listen | AAA |

Cystic Fibrosis

Say: SIS-tik fi-BRO-sus

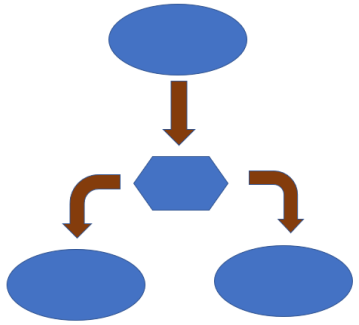
You may know that you have mucus in your nose, mouth, and lungs, and that it helps keep you healthy. But kids with the condition cystic fibrosis have bodies that make thick, sticky mucus. This causes problems in their lungs and their digestive tract. The condition makes it hard for them to breathe and 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

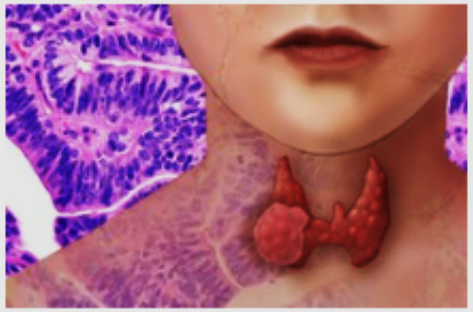
Example: NCI Visuals Online

Before using an image:

- 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



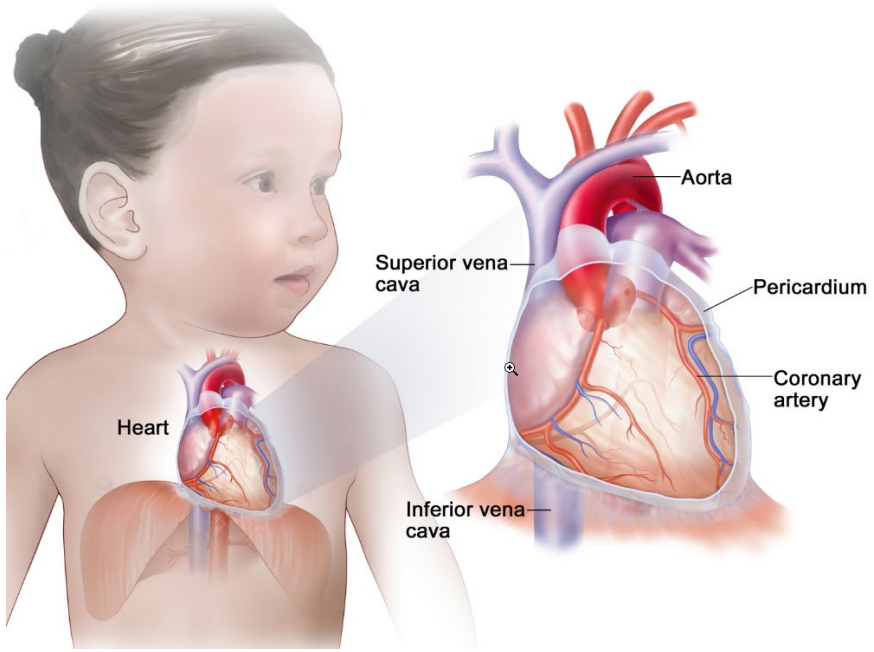
Add to My Pictures

View/Download:

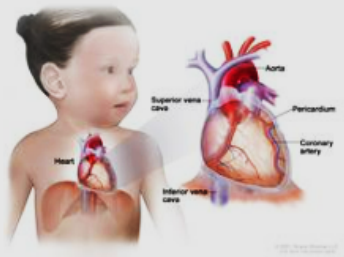
Small: 720x474	View	Download
Medium: 1500x988	View	Download

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
Reuse Restrictions:	**None** - This image is in the public domain and can be freely reused. Please credit the source and, where possible, the creator listed above.

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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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
- NCCN Informed Consent Language (ICL) Database
- Common Terminology Criteria for Adverse Events (CTCAE)-Informed Consent Terms Spreadsheet
- Lay Language Glossary as listed on the Stanford Research Compliance Office Page Definitions & Lay Glossary of Medical Terms
- NCI Risk Terms Library MICROMEDEX Scientific Terms -Informed Consent Terms Spreadsheet-Risks and Adverse Event Terminology

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

Resources related to improving use of "plain language" and simplified alternative word suggestions (general)

- Active and Passive Voice (plainlanguage.gov)
- 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))
- Use Simple Words and Phrases (plainlanguage.gov)

Additional Training Resources, Checklists, and Toolkits

- AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research
- AHRQ's Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals
- CMS Toolkit for Making Written Material Clear and Effective
- McGinty, Kathy, Nine Easy Steps to Longer Sentences in plainlanguage.gov (humor)
- NCI Checklist to Develop Easy-to-Read Informed Consent Documents
- Plainlanguage.gov Resources
- Plain Language: Getting Started or Brushing UP (NIH)
- PRISM (Program for Readability in Science & Medicine) Toolkit

Readability Tool Information

- CMS Toolkit for Making Written Material Clear and Effective SECTION 4/Part 7: Using readability formulas: A cautionary note
- NCI-Using Online and Manual Readability Tools to Assess the Reading Level of Informed Consent Documents
- 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**, make sure the **Check grammar with spelling** check box is selected
    4. Select **Show readability statistics**
    5. 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.

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.)

References & Resources

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References & Resources

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US DHHS OHRP *About Research Participation* and *Videos on Clinical Research Basics*

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