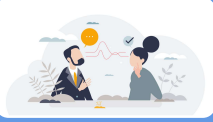




Informed Consent Form Readability as Ethical Practice

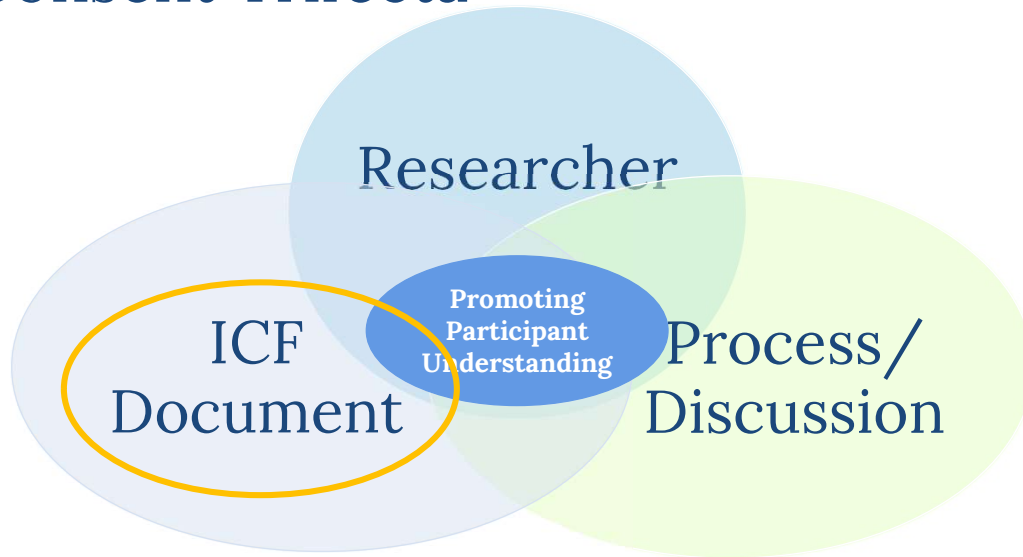
Stephanie Warth
Human Subjects Education Manager, CRRO

1

-  Describe why readability matters in informed consent, including ethical and practical consequences of low readability.
-  Identify common readability problems in consent forms and how they affect participant understanding.
-  Apply practical tools to assess and revise consent text to improve readability.

2

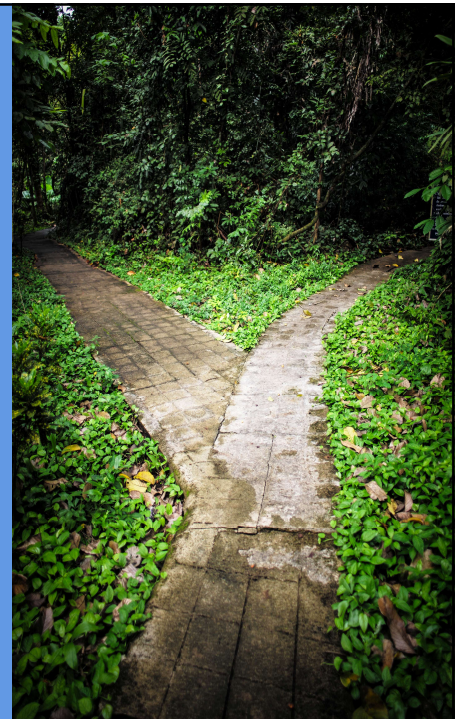
“Consent Trifecta”



3

Belmont Report – Respect for Persons

- To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.
- To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to *deny an individual the freedom* to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.



4

54% of US adults read below a 6th grade level

21% of US adults are illiterate

US department of Education and National
Center for Education Statistics, 2020



5

Health literacy is the
“capacity to **obtain, process,
and understand** basic health
information and services
needed to make appropriate
health decisions.”

Only 12% of US adults had
proficient health literacy in
2003 survey.



America’s Health Literacy: Why We Need Accessible Health Information.
An Issue Brief From the U.S. Department of Health and Human Services.
2008.

6

Toni Cordell

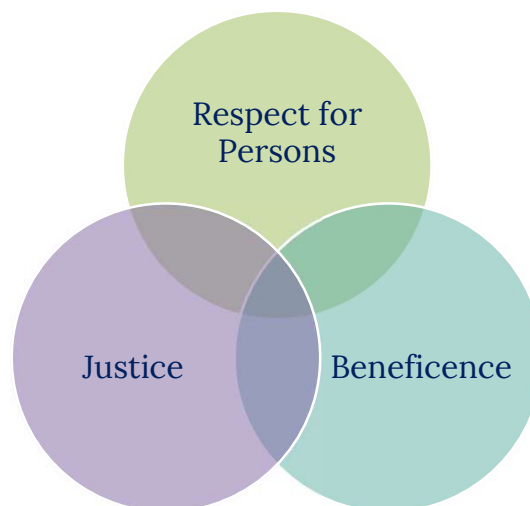


*“Research participants may understand **as little as one-third** of standard consent documents, especially when literacy is a barrier.”
(Kripalani et al., 2008)*

[Clinical Research in Low-Literacy Populations: Using Teach-Back to Assess Comprehension of Informed Consent and Privacy Information](#)

7

Increasing Readability Fulfills Belmont Principles



8

Why does consent form readability matter?

Supports Building Trust

Aids in Setting Expectations

Improves Retention

Improves Participant Adherence

Increases Participation

Higher Levels of Satisfaction

9



Readability

The **ease** with which a reader can successfully decipher, process, and make meaning of the text read.

10

Slide 9

SW1 Need to figure out where the MRCT numbers come from. A study?

Warth, Stephanie, 2026-04-15T14:06:41.840

Common Problems in Consent Forms

Overly complex language

Dense formatting

Content copied directly from protocols or grant applications

Complicated legal sounding language in passive voice

Too much information and unnecessary details

11

SW1

Increasing Readability

Avoid jargon

Shorter sentences

Active voice

Increase white space

Break up text with lists

Simplify words

12

Slide 12

SW1 Explain why it is important

Warth, Stephanie, 2025-09-18T19:27:13.131

Avoiding Jargon

Jargon is a type of specialized language used by people in a particular **profession, field, or group**. It includes **words, phrases, or expressions** that are familiar to insiders but often confusing or meaningless to outsiders.



13

Common Examples of Jargon in Consent Forms

Randomization

- You will be placed into a study group by chance

Inclusion/Exclusion Criteria

- A list of requirements a person must meet to take part in the study.

Vital Signs

- Measurements of the body's most basic functions. Or list what you are measuring

Adverse Events

- A health problem that happens during the study.

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

14

Shorter Sentences



- Start with the verbs. Long sentences likely have at least two **verbs**.
- Keep an eye on commas and other **punctuation**.
- Be careful with **adjectives**.

15

Shorter Sentences

From a description of study activities:

Questionnaire: Prior to starting the text messaging program, you will be asked to complete a questionnaire about your knowledge, attitudes, and practices related to HIV risks and wellness, as well as demographic information.



Questionnaire: Before you receive text messages, you will be asked about your demographic information. You will also be asked about your knowledge, attitudes, and practices related to HIV risks and wellness.

16

Use Active Voice

Active Voice

- The subject of the sentence performs the action.
- Ex. The dog bit the man



Passive Voice

- The subject receives the action
- Ex. The man was bitten by the dog.



17

Passive Voice vs. Active Voice

You are being asked to be
in a research study

More information about
risks can be found later in
this form

Permission may be
withdrawn to keep
samples and data

We are asking you to
be in a research study

You will find more
information about risks
later in this form

You may withdraw your
permission to keep
samples and data

18

Increasing White Space

White space is **unmarked** space in the design of a document, including **how much room is left between** sentences, paragraphs or graphics

Research has shown that the use of white space between lines of paragraphs and its left and right margins **can increase comprehension by 20%**

19

Increasing White Space

Margins set to .5 inches or greater

Increase space before and after paragraphs

Increase spaces between lines

Using Lists

20

Utilizing Lists

Utilizing lists allows you to direct the reader's attention to **key details, simplifies** long sentences and paragraphs, and increases white space.

Information obtained from your medical record will include prior medical history, diagnosis date of osteoarthritis, demographics, and vital signs.



Information obtained from your medical record will include:

- Prior medical history
- Diagnosis date of osteoarthritis
- Demographics
- Vital signs

21

Simplifying Words

Depart

Accompany

Accrue

On a monthly basis

For the duration

Leave

Go with

Add

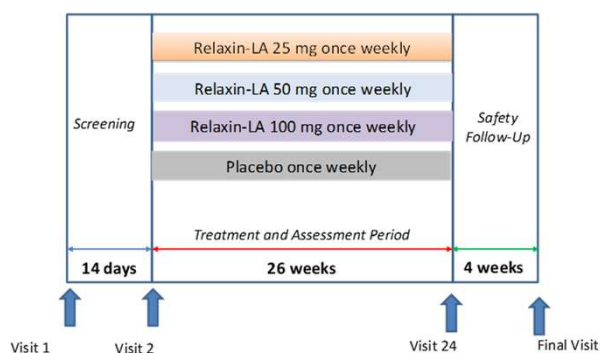
Each month

During

22

Additional ideas

Using images, graphs, or charts to illustrate complex ideas or instructions



23

Putting It All Together

Version 1

Birth Sister support in labor generally starts when you are in active labor at the hospital and lasts for 2 hours after you have had your baby. This is an average of 12 hours. The Birth Sister will call you within one week of being assigned to the program to introduce herself and then at 24 weeks of pregnancy to schedule a visit with you at the place of your choosing. Many women enjoy having a home visit, but the Birth Sister can also meet you in the clinic or another place you mutually agree upon.

Flesch-Kincaid Reading Ease	53.8
Flesch-Kincaid Grade Level	11.7

Version 2

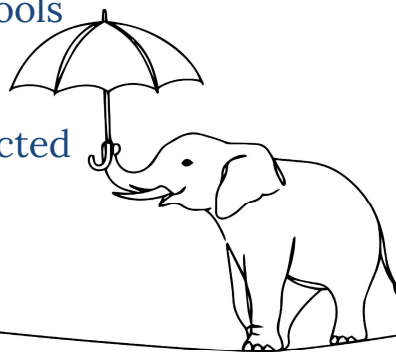
Birth Sister support in labor usually starts when you are in active labor. The support lasts for 2 hours after you have had your baby. This is an average of 12 hours. After you are assigned to the program, the Birth Sister will call you within one week. She will introduce herself. Then, at 24 weeks of pregnancy she will schedule a visit with you. You can choose a home visit or to meet in the clinic. You can meet somewhere else if you both agree.

Flesch-Kincaid Reading Ease	73
Flesch-Kincaid Grade Level	5.8

24

AI Caveats and Limitations

- It will change the required language in the ICF template
- Security concerns with public AI tools
- AI hallucinations
- Garbage in and garbage out
- Use TerrierGPT so that IP is protected



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Additional Institutional Resources

CRRO Seminars

<https://www.bumc.bu.edu/crro/training-education/past-seminars/>

- March 2022: Applying Health Literacy Principles to Clinical Research Studies: A Quick Guide for Study Teams
- August 2023: Consents: The Good, The Hard, The Beautiful
- September 2024: Tools in the Consent Backpack: Unpacking How to Include Participants with Limited English Proficiency

RPN Workshops

<https://www.bumc.bu.edu/crro/research-professional-network/resources-programs/past-rpn-workshops/>

- March 2023: eConsent: Benefits, Challenges, and Considerations
- February 2026: Informed Consent: Being the Participant Advocate

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Additional Resources

- Clinical Research Glossary - <https://mrctcenter.org/glossary/>
- Use of Plain Language to Increase Understanding - <https://mrctcenter.org/resource/use-plain-language-to-increase-understanding/>
- Flesch-Kincaid Reading Ease Calculator - <https://goodcalculators.com/flesch-kincaid-calculator/>
- TerrierGPT - terriergpt.bu.edu
- Shortening Sentences - <https://gsas.harvard.edu/news/keep-it-short-keep-it-sweet>