Conducting a Participant-Centered Informed Consent Process

Putting Participants First in Research Conversations

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Obtaining Continuing Education Credit

Date: August 20, 2025

Title: Conducting Participant-Centered Informed Consent Processes

ATTENDANCE CODE: **COZQES**

- Step 1: Text Attendance Code to 413-200-2444
- Step 2: Complete the Evaluation (from your smartphone, tablet, or computer)
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Learning Objectives:

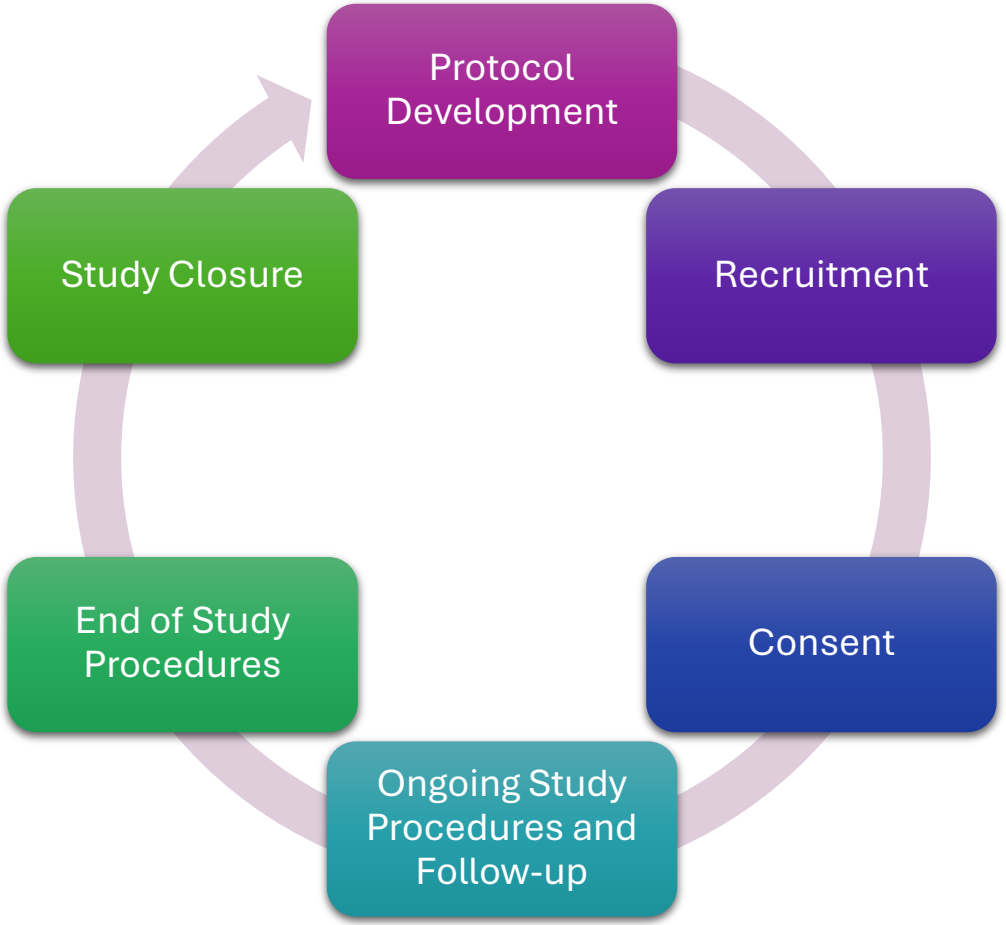
- ❑ Describe the components of participant-centered informed consent
- ❑ Identify confusing elements in consent documents
- ❑ Explain how context supports participant understanding
- ❑ Recognize how word choice can influence comprehension

Interactive/Activity

Jot down one consent challenge you've experienced to reflect on later!

How is Research Communicated to Potential Participants?

Study Life Cycle



The Research Consent Process

This process involves an information exchange and ***on-going communication*** that takes place between the investigator (researcher) and the potential research participant (subject) for the duration of the research.



The Belmont Report



Respect For Persons



Beneficence



Justice

Key Information

The revised **Common Rule** requires consent information to "begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research" (45 CFR 46.116(a)(5)(i)).

FDA's proposed regulations would add identical language to 21 CFR 50.20(e)(1).

FDA Draft Guidance Key Information and Facilitating Understanding in Informed Consent

Elements of Informed Consent

Basic Elements	Common Rule	FDA NPRM*
Identifiable private information or identifiable biospecimens	45 CFR 46.116(b)(9)	3 additional elements of informed consent that include biospecimens
Additional Elements		
Use of biospecimens for commercial profit	45 CFR 46.116(c)(7)	proposes harmonization with the common rule requirements for informed consent.
Return of research results	45 CFR 46.116(c)(8)	Requires a statement on whether clinically research results including individual research results, will be disclosed to participants.
Research involving biospecimens; might include whole genome sequencing	45 CFR 46.116(c)(9)	Aligns with current regulation
***NPRM** = Notice of Proposed Rule Making		

What is Participant Centered Informed Consent?

The Participant-centered consent process treats the research conversation like a bridge, not a barrier. The focus is on the individual: their questions, cultural context, concerns, and right to walk away at any time. This process starts before signing the form and continues throughout participation in the research.

Health Literacy

Personal Health Literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

*Healthy People 2030

HHS Health Literacy



What is Participant-Centered Informed Consent?

- A process, not a form
- Centers on the participant's experience
- Encourages questions, reflection, and autonomy
- Builds trust through transparency and empathy

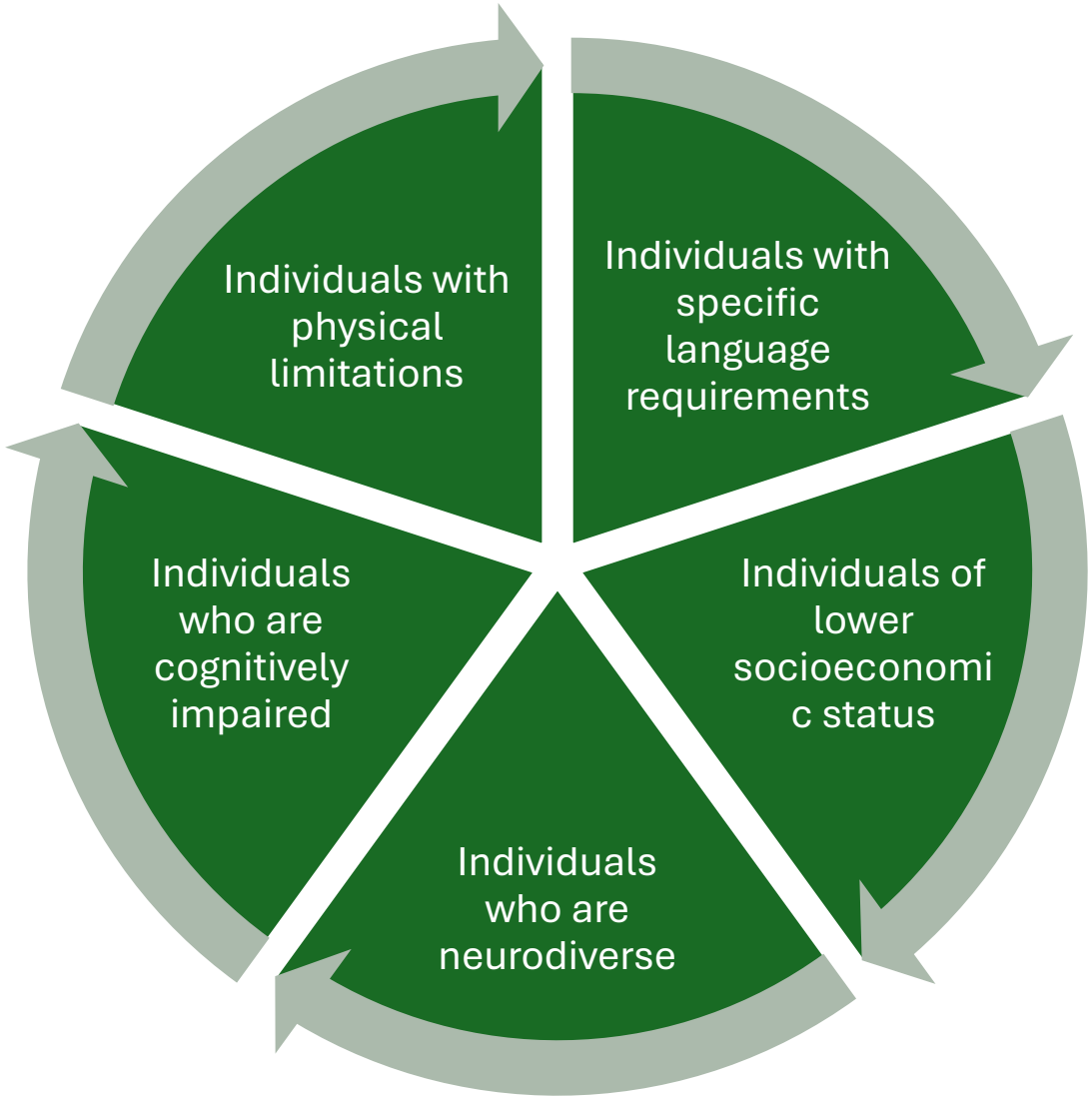
Core Components of Participant-Centered Informed Consent process will :

- Facilitate a clear, meaningful explanation of the study (purpose, procedures, risk, benefits).
- Contribute to an open and ongoing dialogue
- Tailor the consent discussion recognizing cultural and personal values
- Emphasize voluntary participation
- Assess participant understanding of the research.

Good consent is person-first, not paper-first

Respecting the Vulnerabilities of Our Community

The Vulnerable within our Community Include:



Baystate Policy: BC 1.600 - Americans with Disabilities Act (ADA) Services for Patients

Who Enriches the Culture Within Our Community?

The Spanish-speaking community remains the largest language group, representing approximately 80% of the population. This is followed by speakers of Russian, Vietnamese and Portuguese. In recent years, there has been a noticeable increase in Brazilian Portuguese speakers, in addition to the longstanding European Portuguese population.

Over the past 3 years, the Haitian Creole-speaking community has increased at both Baystate Medical Center (BMC) and Baystate Franklin Medical Center (BFMC). Additionally, a number of special status refugees have settled in the West Springfield and Greenfield areas.

Getting to Know Your Audience

- How do we learn about the people that are part of the greater audience?
- How do we organize the information that is communicated to our audience?
- How do we communicate this information clearly?



Foreign Language Consent Process

BC 10.125-Translations and Use of Interpreters in Research

Consider the following before submitting to the IRB:

- Review the original document for grammatical errors and spelling
- Explain unusual jargon, acronyms or abbreviations
- Decide if any part of the document should remain in English for example the title of the consent.

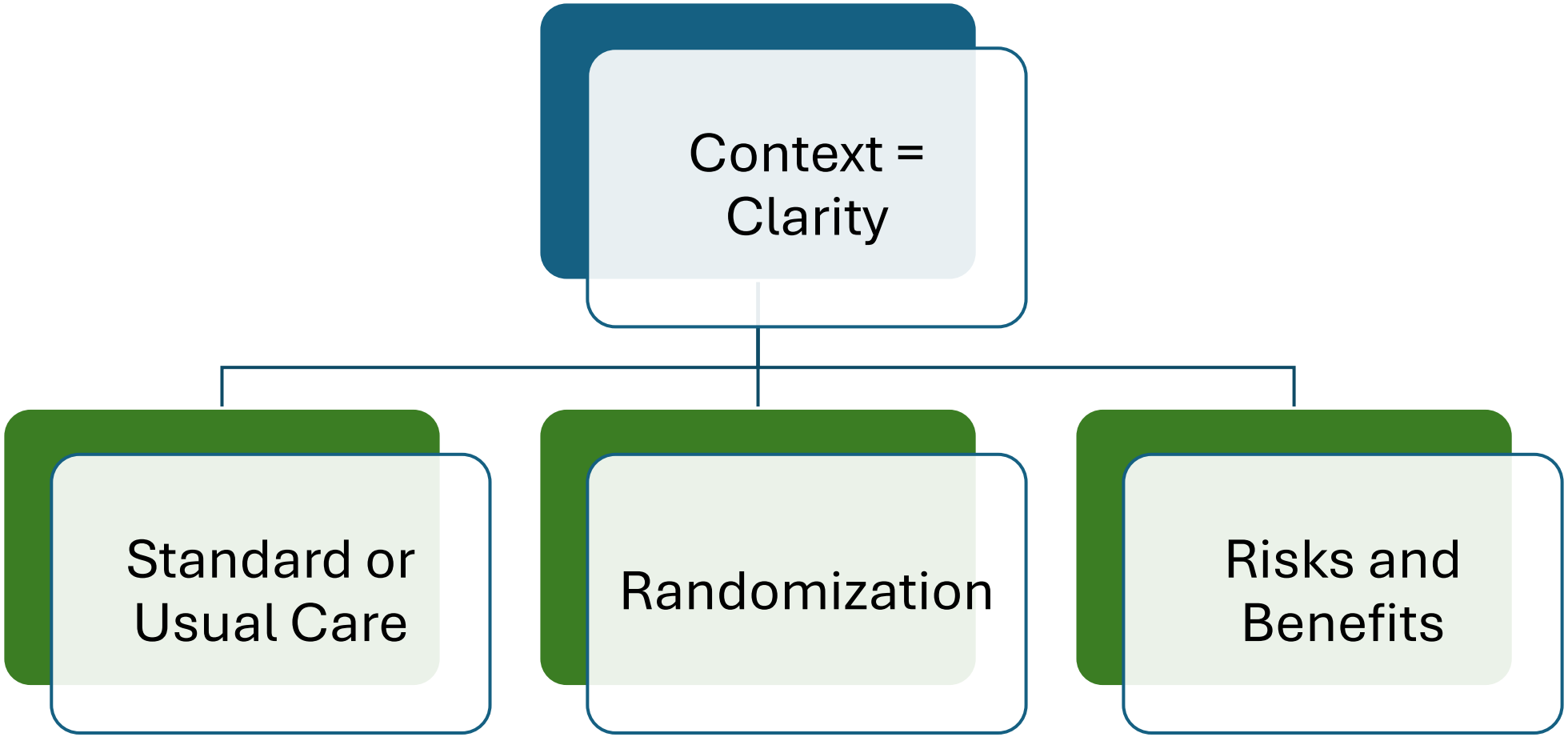
Interpreter Services will translate the final stamped version of the English informed consent document.

- Submit the final translation with the certificate of translation to the IRB as an amendment.
- If a translation is not available, a short form consent may be utilized with an English consent document.

The Power of Providing Context

When context is missing, potential participants may misunderstand key details.

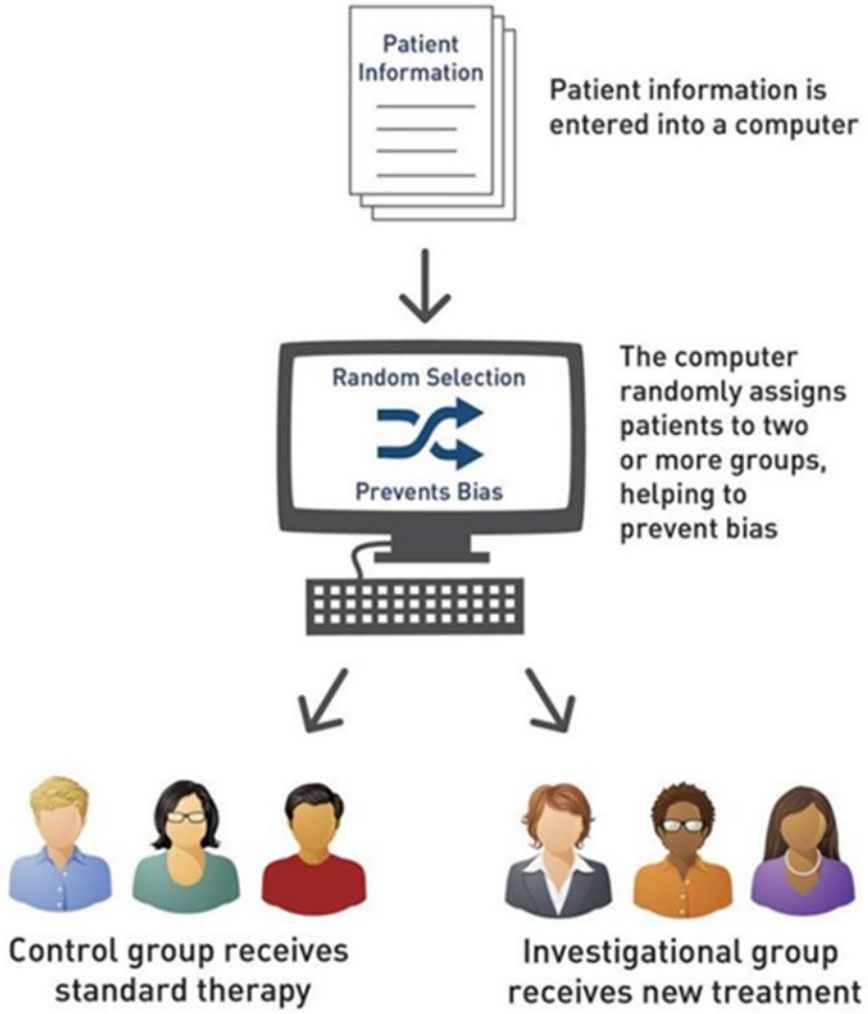
The Power of Providing Context



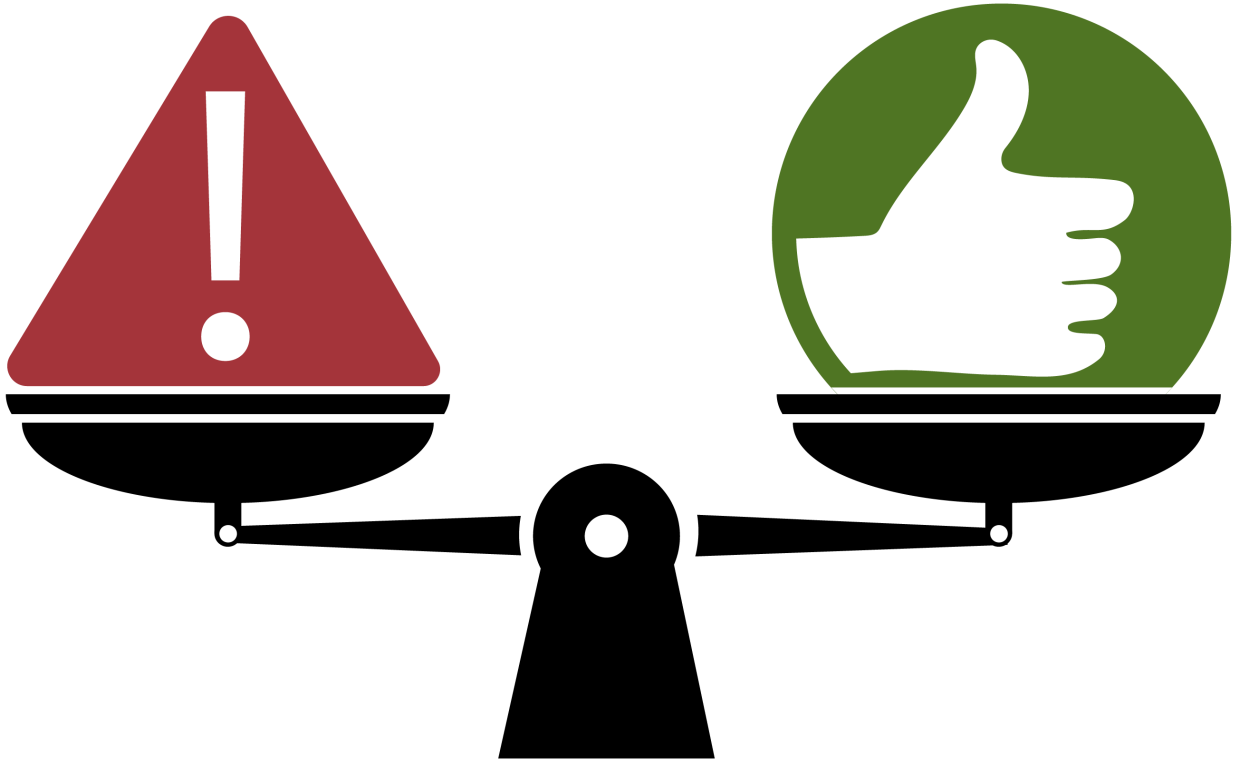
Usual Care/Standard of Care vs. Research Context

- Usual care is defined as the currently recommended treatment delivered by responsible clinicians.
- In the research ethics literature, there is a considerable body of argument that interprets the standard of care as roughly the treatments and interventions that patients in a particular healthcare system can routinely access, even if those treatments and interventions are known not to be the best available.

Randomization Context



Risk and Benefit Ratio



Word Choice and Formatting of the ICF

In 2017 the Department of Education estimated that 52% of U.S. adults had low level literacy proficiency. This means about half of U. S. adults read below the 6th grade level.

https://nces.ed.gov/surveys/piaac/2017/national_results.asp

Spotting Confusing Language



Medical jargon: “Randomization”, “Placebo”, “Double-Blind”



Vague timelines: “Regular follow-up”



Complex procedures: “Venipuncture”, “Biopsy”



Ambiguous Risk/Benefit Statement

What Terminology Requires Clarification?

HOW LONG WILL YOU BE IN THIS STUDY?

The maximum time you will be in the study is 6 years and 4 months as follows:

- Screening (up to 5 weeks)
- Double-Blind Period (52 weeks)
- Long-term Extension (LTE) Period (5 years from the LTE Day 1)
- Safety Follow-up Period (90 days)

Formatting with a Purpose

Avoid:

- Confusing sentence structure
- Dense paragraph structure
- Limited “white space”
- Varied fonts throughout the document
- Narrow margins < 1 inch
- Misuse or overuse of formatting for emphasis

Readability Scores

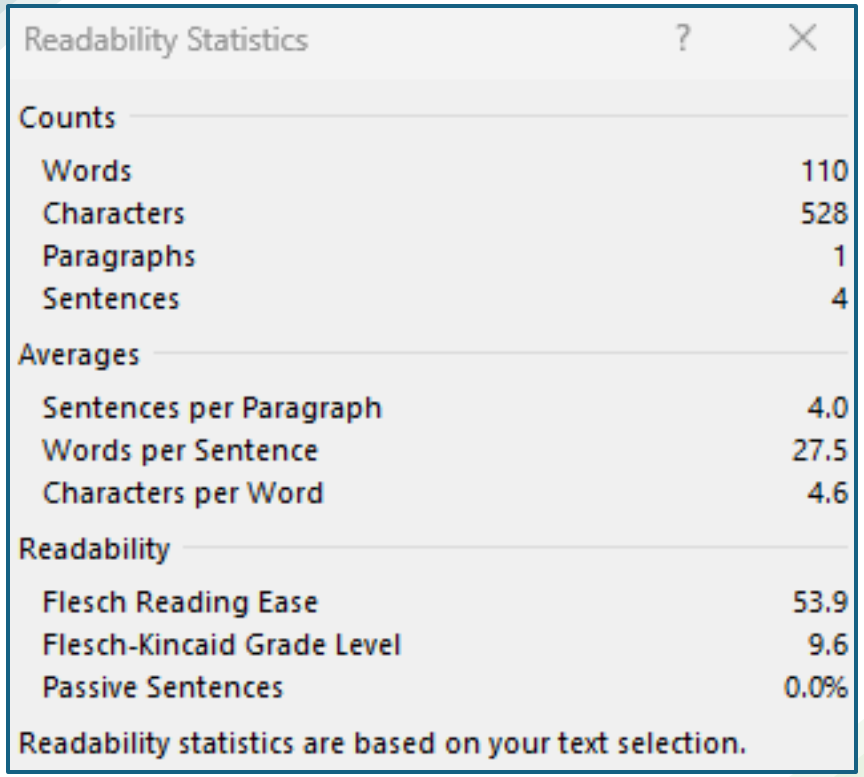
Readability Scoring Tools

BC 6.935 - Use of Artificial Intelligence (AI) and Generative AI (GenAI) Policy

Assessment Tool	How the score is calculated	What the score tells you
Flesch Reading Ease	Sentence length (words/sentence) Word complexity (**syllables**/word)	A score of 1(very confusing) to 100 (very easy); Compared to the Flesch-Kincaid Grade Level, emphasizes the importance of **short words**
Flesch-Kincaid Grade Level	Sentence length (words/sentence) Word complexity (**syllables**/word)	US grade level based. Compared to Flesch Reading Ease, emphasizes the importance of short sentences.
Automated Readability Index	Sentence length (words/sentence) Word complexity (**characters**/word)	US grade level based. Uses the number of characters rather than the number of syllables to measure word difficulty
Gunning Fog Index	Sentence length (words/sentence) Word complexity (**percentage of hard words**)	US grade level based. Defines words with three or more syllables as hard.
New Dale-Chall Formula	Sentence length (words/sentence) Word complexity (**percentage of hard words**)	US grade level based. Defines words that aren't on a list of words familiar to most fourth graders as hard.

Use of Readability Scoring Tools

Study drug administration: Participants will take 1 tablet with 240 mL (about 8 oz) of water within 30 minutes of bedtime each night. Participants should have a meal or snack within 3 hours before taking the study drug; they should not go to bed hungry. For the first week, participants will take the tablets provided in a blister pack; these contain a lower (run-in) dose of study drug (Drug X 2.5 mg/Drug Z 37.5 mg or matching placebo). Thereafter, the participants will take the tablets provided in the bottles; these contain the higher target-dose of the study drug (study drug 2.5 mg/study drug 75 mg or matching placebo).



Use of Readability Scoring Tools

How to take the study drug:

- Within 3 hours of bedtime, you should eat a meal or snack. You should not go to bed hungry.
- 30 minutes before bedtime take 1 tablet of drug X with 240 ml (about 8 ounces or 1 cup) of water.

Dosing Schedule:

- **Week 1:** You will take a lower dose of drug X or the matching placebo. A blister pack will contain a tablet for each day of the week.



- **After Week 1:** You will take a higher dose of drug X or matching placebo. This is a target dose that will be in a bottle.

Readability Statistics

Counts	
Words	102
Characters	387
Paragraphs	6
Sentences	7
Averages	
Sentences per Paragraph	1.7
Words per Sentence	13.4
Characters per Word	3.5
Readability	
Flesch Reading Ease	87.9
Flesch-Kincaid Grade Level	4.3
Passive Sentences	0.0%

Readability statistics are based on your text selection.

Applying Principles of Participant Centered Informed Consent

What Stands out to You?

While the medication used in this study, ABC123, is a combination of 2 drugs: Drug X and Drug Z, the following warnings and precautions are specific to Drug X and may not apply to this combination therapy. This information is provided for your awareness to support informed decision-making. Reported risks associated with Drug X include but are not limited to: suicidal thoughts (noted in children and adolescents), severe liver injury, serious cardiovascular events (such as stroke and heart attack), changes in blood pressure and heart rate, new psychotic or manic symptoms, aggressive behavior or hostility, and prolonged erection (lasting more than four hours without sexual arousal).

Breaking Down the Sentence Structure

*Flesch Kincaid Grade Level

- While the medication used in this study, ABC123, is a combination of 2 drugs: Drug X and Drug Z, the following warnings and precautions are specific to Drug X and may not apply to this combination therapy. (16.0*)
- This information is provided for your awareness to support informed decision-making. (15.5*)
- Reported risks associated with Drug X include but are not limited to: suicidal thoughts (noted in children and adolescents), severe liver injury, serious cardiovascular events (such as stroke and heart attack), changes in blood pressure and heart rate, new psychotic or manic symptoms, aggressive behavior or hostility, and prolonged erection (lasting more than four hours without sexual arousal). (28.7*)

Identify Readability Improvements

The medicine used in this study is called ABC123. It is made from two drugs: Drug X and Drug Z.

The warnings below are only about Drug X. They may not apply to ABC123 as a whole. This information is shared to help you make smart and safe choices.

Some risks linked to Drug X include but are not limited to:

- Thoughts of hurting oneself (especially in kids and teens)
- Serious liver problems
- Heart issues like stroke or heart attack
- Changes in blood pressure or heart rate
- Seeing or hearing things that aren't real, or feeling very excited
- Acting angry or aggressive
- Long-lasting erections (more than 4 hours without being sexually excited)

How Does a Minor Change Impact Readability?

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What Stands out to You?

Acute respiratory distress syndrome (ARDS) is a type of respiratory failure caused by rapid and widespread inflammation in the lungs.

Adults who suffer major COVID-19 complications, such as ARDS, appear to have a major inflammatory storm (that is, they have an exaggerated immune and inflammatory response). Therefore, targeting the inflammatory response may reduce COVID-19-related complications in adults at risk or with evidence of an inflammatory storm. The study drug, DEF45, is a monoclonal antibody that interferes with a type of receptor that is involved in activating the body's response to infection. Evidence from both animal and human studies indicates that the study drug, DEF45, may play a role in reducing this inflammatory process from occurring in the lungs – potentially preventing and/or reducing the severity of ARDS due to COVID-19. Given the way DEF45 works in the body and the evidence that we have so far, we are conducting this study to see if DEF45 could be an effective treatment for ARDS due to COVID-19, and whether it reduces ventilation rates and mortality.

Breaking Down the Sentence Structure

Acute respiratory distress syndrome (ARDS) is a type of respiratory failure caused by rapid and widespread inflammation in the lungs. (14.6*)

Adults who suffer major COVID-19 complications, such as ARDS, appear to have a major inflammatory storm (that is, they have an exaggerated immune and inflammatory response). (16.7*)

Therefore, targeting the inflammatory response may reduce COVID-19-related complications in adults at risk or with evidence of an inflammatory storm. (18.1*)

The study drug, DEF45, is a monoclonal antibody that interferes with a type of receptor that is involved in activating the body's response to infection. (14.9*)

Evidence from both animal and human studies indicates that the study drug, DEF45, may play a role in reducing this inflammatory process from occurring in the lungs – potentially preventing and/or reducing the severity of ARDS due to COVID-19. (20.1*)

Given the way DEF45 works in the body and the evidence that we have so far, we are conducting this study to see if DEF45 could be an effective treatment for ARDS due to COVID-19, and whether it reduces ventilation rates and mortality. (18.1*)

*Flesch Kincaid Grade Level

Identify Readability Improvements

ARDS is a serious lung problem. It happens when the lungs get very inflamed and stop working well. People with bad cases of COVID-19 can get ARDS.

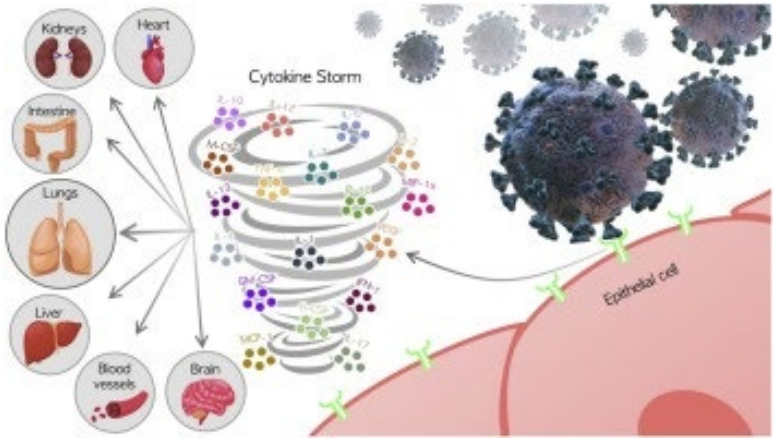
When someone has COVID-19 and gets very sick, their body may react too strongly. This strong reaction is called an inflammatory storm. It can make breathing hard and damage the lungs.

Doctors are testing a new medicine called DEF45. It is a special kind of medicine called a monoclonal antibody. DEF45 works by blocking a signal in the body that causes inflammation.

Studies in animals and people show that DEF45 might help stop the lungs from getting too inflamed. This could help prevent ARDS or make it less serious.

The goal of the study is to see if DEF45:

- Helps treat ARDS caused by COVID-19.
- Lowers the number of people who need breathing machines.
- Reduces the number of deaths.



Best Practices & Red Flags

Do!

- Use teach-back
- Slow down
- Explain the “why” behind each procedure
- Emphasize voluntariness

Don’t!

- Read the form word-for-word
- Don’t assume the participant understands the consent content
- Don’t pressure or persuade

Resources and Policies

- FDA Guidance Informed Consent August 2023
- Agency for Health Care Quality (AHRQ)
- Multi-Regional Clinical Trials Center (MRCT)
- OHRP: Participant-Centered Informed Consent Training
- Kripalani S, Goggins K, Couey C, Yeh VM, Donato KM, Schnelle JF, Wallston KA; Vanderbilt Inpatient Cohort Study. Disparities in Research Participation by Level of Health Literacy. Mayo Clin Proc. 2021 Feb;96(2):314-321. doi: 10.1016/j.mayocp.2020.06.058. PMID: 33549253; PMCID: PMC7874435.
- Kutner M, Greenberg E, Jin Y, Paulsen C. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy (NCES 2006–483). Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2006.
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Thank You!

We need your feedback!