

# Welcome!

- The session will begin shortly; if you are joining us on Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- This presentation will include breakout sessions.
- Not registered? Please register now using the QR code.







# Writing a Research Informed Consent Form



Kaori Kubo Germano, PhD, *Sr. Manager, Clinical Research Education and Communications* Jessica Kisenwether, PhD, CCC-SLP, CIP, QA and Education Manager

## Jessica Kisenwether, Ph.D., CIP, CCC-SLP



9+ years of experience in human research protections, serves as a regulatory expert for multiple institutions.

Licensed speech-language pathologist in PA and NY.

18 years of research experience in the area of speech science, specifically subjective and objective measures of voice, swallowing, dysfluency, and speech.

Published in numerous journals and presented at state, national, and international conferences



Joined WCM in 2022

## Kaori Kubo Germano, Ph.D.



5+ years in human subjects research regulatory compliance.

Former professor of Developmental Psychology at the State University of New York, mentored 41 theses.

15 years of research experience in the area of neurodevelopment, aging, and psycholinguistics, with numerous publications and conference presentations

Joined WCM in 2021



## **Objectives**

- Cover the fundamental aspects of Informed Consent
  - o How do we ensure volunteers' comprehension?
- Considerations and tools to make your Informed Consent Form:
  - $\circ$  Readable
  - Accessible
- Let's Practice: Apply tools and concepts to improving a consent form



## **Fundamental Aspects of Informed Consent**



For more information about the aspects of informed consent, watch our METS from December 2023

### Weill Cornell Medicine

Research Regulatory Requirements, Ethical Considerations, & Creating Your Informer Consent Form

Informed Consent in

Presented by Kaori Kubo Germano, PhD Sr. Manager, Cilnical Research Education and Communications

Office of Human Research Compliance Melissa Epstein, PhD, MBE, CIP Executive Director

Weill Cornell

https://research.weill.cornell.edu/irb

## **Fundamental Aspects of Informed Consent**



### Comprehension

### **Voluntariness**

Weill Cornell

Presented by Kaori Kubo Germano, PhD Sr. Manener, Olaicel Research Education and Ci

For more information about the aspects of informed consent, watch our METS from December 2023

### Weill Cornell Medicine

Office of Human Research Compliance Melissa Epstein, PhD, MBE, CIP Executive Director

Informed Consent in

Regulatory Regulatory

https://research.weill.comell.edu/irb

### Comprehension

**Per 45CFR46.116(a)(3):** The information that is given to the subject or the legally authorized representative shall be in **language understandable to the subject** or the legally authorized representative.

**Per 45CFR46.116(a)(5)(ii):** Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather **facilitates the prospective subject's or legally authorized representative's understanding** of the reasons why one might or might not want to participate.



## **9 Basic Elements of Informed Consent**

## 9 ğ 2 8 ICF 3 4 6 5

#### 5. WHO WILL KNOW?

A statement describing how confidentiality

will be maintained

9

#### **1.** WHAT IS IT ABOUT?

A statement about, and description of, the study

#### 2. WHAT ARE THE RISKS?

A description of risks or discomforts to the subject

#### **3.** WHAT ARE THE BENEFITS?

A description of any benefits to the subjects

#### **4.** ARE THERE ALTERNATIVES?

A disclosure of appropriate alternative procedures or courses of treatment

### 9. WHAT HAPPENS AFTER?

A statement about what will be done with collected information

#### 8. IS IT MANDATORY?

A statement that participation is voluntary

#### **7.** WHO IS THE CONTACT?

Contact information for questions or more information

#### 6. IS THERE COMPENSATION?

For greater-than-minimal risk studies, compensation and/or medical treatment



## The Flesch-Kincaid Readability Test

Score	Grade Lovel	Difficulty
100 - 90	5 <sup>th</sup> grade	Very easy
89 - 80	6 <sup>th</sup> grade	Easy, conversational
79 – 70	7 <sup>th</sup> grade	Fairly easy
69 – 60	8 <sup>th</sup> - 9 <sup>th</sup> grade	Easily understood by 13-15 year old students
59 – 50	10 <sup>111</sup> – 12 <sup>111</sup> grade	Fairly difficult
49 – 30	College	Difficult
30 - 10	College Graduate	Very difficult
10 - 0	Professional	Extremely difficult
<u> </u>		

A 2003 study found that **only 8%** of medical school research consents in the United States meet their own readability standards. The average reading level was 10.6 to collegelevel. (Paasche-Orlow et al.).

### Our previous informed consent template had a Flesch-Kincaid Reading ease of 47.1

Score	Grade Level	Difficulty
50 - 30	College	Difficult

## **Our Templates**

- WCM Assent •
- WCM Biomedical Informed Consent
- WCM Humanitarian Use Device Informed Consent
- WCM Informed Consent Addendum
- WCM Intermediate-Size **Investigational Treatment** Informed Consent
- WCM Pregnant Partner Non-Subject Informed Consent
- WCM Pregnant Partner Research Subject Informed Consent
- WCM Repository Informed Consent
- WCM SBER Informed Consent
- WCM Single Patient Investigational Treatment Informed Consent

 Note: this template can be used in paper form or made into an e-consent document Grev boxes with black text in brackets are to be completed Red, italicized text in brackets is help text and/or a prompt for information that also must be included. Orange text is optional, sample wording Do NOT delete the paragraph headings. · Edit this document to reflect your activity and relevant IRB requirements. · Additional applicable sections can be found in Appendix A. · If you are collecting and storing data and/or samples solely for future research use, please use the Repository Informed Consent Form template Appendix A.] With the guidance language removed, this template has the following readability scores: Flesch Reading Ease: 58.7 Flesch-Kincaid Grade Level: 9.0 Appendix A.1 **Research Consent** [Title of Project] · What am I being asked to do? [Brief Ilf for Parental/Guardian Permission]: · How long will the study last? If you jo In this document, "I/mv/vou/vour" mean your child [the child]. If y hours] hours over [include the number research activities, how long each activ longer required. [Minors should sign the adult consent at that time permitted here if a statement regarding [If use of an LAR]: during standard of care is appropriate i Any possible risks or discomforts? In this document, "I/my/you/your" mean the participant you are gi differ from standard of care] Will this study help me? [Include the from standard of care] · Do I have to join? You do not have to Please read this form or have this form read to you. Take your ti participating, if appropriate.] Make sure we evolain the study to you. Ask us any questions. Y the study with your doctor and family, loved ones, or friends. The ch yours. If you decide to join, please sign and date this form. If you are now or have been (within the last ( Why is this study being done? tell the research team. You are being asked to join a research study that is being done b is funded, identify the funding source.] We hope to learn [descr What will I be asked to do? [Using plain lang project] . You are being asked to join because [insert inclusion/ the participants will do, what will happen during whether any procedures are experimental, time Important information for you to think about: will be randomization, etc. If applicable, include regulations. videotaping. State what will be recorded (partici be identifiable?) Include the setting of the record tabulation of finite criteria by the research team. or other students who are not members of the r -- If your research involves deception, give as m statements that are part of the experimental deception. -If your research involves an interview or a survey, be transparent in the types of questions to be asked and inform participants that they can skip any question that makes them uncomfortable and they can stop the interview/survey at any time. -If your research involves genetic testing, specify why it is necessary to achieve the goals of the study. -If applicable, provide any information on contraception, barrier use and pregnancy testing requirements for the study. Explain what should occur if they or their partner become pregnant while participating in the study.] [Does this study involve HIV testing? If yes, add template language for HIV Testing found in Appendix A.] IDoes this study involve genetic testing? If yes, add template language for Genetic Testing found in Annendix A1 Do I have other choices? [Explain other choices participants have if participants have any, including commonly used therapy(ies) or disclose standard diagnostic procedures or treatment being withheld, other research studies, etc. Please specify if any of the study drugs/interventions/devices are available off-label or through standard of care.]

Who will be in the study? About Ifif multisite: Inumber people will take part in this study at all sites, and [number] people will be asked to join the study at Weill Cornell Medicine/New York Presbyterian (NYP) Hospital.

New information that may change your decision to join: During the study, we will tell you if there is new information or changes to the study that could affect you, your health, or your desire to stay in the study. [If known, discuss the procedures for informing/updating participants of new information that may affect their decision to participate.]

What are the risks? [Detail any known risk of harm that the participant may experience from participating in the research including physical, psychological, social, economic, legal, or unknown risks. Any risks listed in the protocol must be addressed in the consent form. Include likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent, and side effects that may be temporary, irreversible, long-term, or lifethreatening.] . There are risks of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality when joining research study.

[Is this a genetics research study? If yes, add template language for genetics research found in

[Does the study involve opioid use? If yes, add template language for opioid use found in

What about pregnancy? [The particular treatment or procedure] may involve risks to you (or to an unborn baby, if you are or become pregnant) that are currently unexpected

What if I am harmed? [remove all information below if the study is minimal risk] If you are injured or become sick because of joining this study, you will have to pay for any emergency treatment. Weill Cornell Medicine will not pay for these services. If you have been injured or become sick because of taking part in this study, tell the researcher right away. If you have any questions or believe that you have been treated carelessly in the study, please contact the Office of the IRB at (646) 962-8200 for more information.

#### Sponsor information if applicable

The Sponsor, [identify by name] [will/will not] pay for care if you are injured or sick because of being in this study. [If the Sponsor will pay such costs, Medicare/Medicaid cannot be primary payors. If applicable, the language in this section must track the language in the Clinical Trial Agreement with the Sponsor, Please contact the contracts office at JCTOcontracts@med.comell.edu with any questions.]

The following is acceptable language if the Sponsor specifies that it will only pay costs not otherwise covered by insurance:]

If you are injured or sick because of being in this study, the Sponsor will pay for care to diagnose and treat the injury if:

- (1) You have private health insurance: the Sponsor will pay for the costs that are denied or not otherwise paid for by your insurance company.
- (2) You do not have any health insurance: the Sponsor will pay for the costs: and You have Medicare or Medicaid, claims for the costs will first be submitted to the

Page 2 of 16

Sponsor for payment, and any remaining balance not paid for by the Sponsor will be submitted to Medicare or Medicaid, applying Medicare and Medicaid billing rules and

Page 3 of 16

### **Weill Cornell Medicine**

Weill Cornell

Note (REMOVE THIS TEXT BEFORE SUBMITTING):

12

Use this template if you have completed the Therapeutic Studies JCTO Protocol

template for your study and/or you have a study which will use a device/drug or

implement a clinical trial. This template is also appropriate for genetic research

Medicine

## Where are they?



#### Human

The office of Human Research Protections plays a vital role in a and well-being of human research participants. Collaborating and support throughout the research process. From the initi combined expertise foster

In addition, we serve as a vital resource hub for our stakehold practices. Our aim is to empower research teams with the kno level of profe

At the office of Human Research Protections, we embrace the participants, we also strive to facilitate innovative and impactfu contribute to the reputation and excellence of our institut



**Research Team** Resources



#### Institutional Review Board (IRB)

The Weill Cornell Medicine Institutional Review Board (WCM-IRB) is an appropriately constituted group whose primary responsibility is to ensure that the rights and welfare of human subjects in research are protected. In doing so, the IRB must ensure all human subject research activities are conducted ethically, and in compliance with Federal regulations, the requirements of applicable New York State and local laws, and institutional policies and procedures. In accordance with the Common Rule 🗷 and FDA regulations 🗷, the IRB has responsibility for approving, modifying, and/or disapproving human subject research. The IRB also has the authority to suspend or terminate research in order to protect research subjects and for noncompliance with applicable rules and regulations.

#### Working on an Industry-Initiated and Industry-Funded Trial?

WCM is requiring that industry-initiated and -funded trials with a commercial IRB designated by the industry sponsor use that commercial IRB (e.g., WCG, Advarra, BRANY). If an industry-initiated and -funded trial does NOT have a designated IRB, you must complete a sIRB reliance request form to submit to a commercial IRB.

#### Have a reportable event?

Contact us at irb@med.cornell.edu for instructions on how to submit your report.

0

Weill Cornell Medicine Human **Research Protections** 575 Levington Avenue New York, NY 10022 Phone: (646) 962-8200



#### Forms, Templates & Guidance

This page is continually being updated: please check back often!

#### **Forms & Applications**

#### **IRB Review Application (IRA) Forms**

For all new initial applications submitted to WRG-HS, a supplemental IRB Review Application (IRA) must be attached. Please select and fill in the applicable IRB Review Application (IRA) linked below. Once complete, please upload it to WRG as part of your new submission.

- 🗟 Biomedical IRA: Use this IRB Review Application if you have completed the Therapeutic Studies JCTO Protocol template and/or have a study which will use a device/drug or implement a clinical trial.
- Biorepository IRA: This IRB Review Application template is only to be used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- Medical Education IRA: Use this IRB Review Application if your study is minimal risk and qualifies under exempt category 1 only: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunities to learn required educational content or the assessment of educators who provide instruction.
- Social-Behavioral and Educational Research (SBER) and Records IRA; Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue Use/Chart Review JCTO template, the Education Protocol Template and/or have a study which will use conduct social, behavioral, or educational research.

#### **Supplemental Forms**

- Drug Form: Used for any study involving drugs/dietary supplements.
- E Device Form: Used for any study involving medical devices (as defined by the FDA C).
- ESpecimen Form: Used for any study collecting or using Human biological specimens for research (e.g., organ tissue, plasma, urine, feces, cells). This may include specimens collected as part of routine care for use as part of the research. This includes medical waste

#### Submission Templates & Checklists

#### Templates

- As of May 17th, 2023, the ICF Templates available on our Informed Consent Templates r ge replaces all previously released templates.
- Deviation Log Template
- 📑 Adverse Event & IND Safety Reporting Cumulative Table

#### Checklists

- Submitting an IRB Application
- Duality Improvement vs. Research
- Obtaining Expanded Access IND for Treatment of Individual Patients

#### Guidance Documents

### **Weill Cornell Medicine**

**Research Pa** 

Resource

13

## **Fundamental Aspects of Informed Consent**

### Disclosure

### Comprehension

### **Voluntariness**

### Comprehension

Considerations	Workshop	Tools
<ul> <li>Readability</li> <li>Audience</li> <li>Accessibility</li> <li>Consistency</li> </ul>	• Let's Practice	<ul> <li>IRB Consultation</li> <li>Researcher</li> <li>Toolkits</li> </ul>





# **Considerations and**

### **Making your ICF** Readable & Accessible



## Readability

- Vocabulary
- Sentence length and structure
- Amount of information
- Page design and formatting
- Logical order and well-organized content
- Degree to which content is meaningful and interesting



## **Principles of Plain Language**



### **Weill Cornell Medicine**

## **Principles of Plain Language**



Use common, everyday words

- Replace or define medical terms/jargon
- Avoid repetition
- Check reading level



## Some examples:

Original	Revised
Principal investigator	Study doctor
Trial	Research study
Equilibrium	Balance
Lipid	Fat
Mortality	Death
Abrasion	Scrape
Demonstrate	Show

## Let's Practice!





https://hrp.weill.cornell.edu/educationalresources/medical-terms-lay-language

## **Principles of Plain Language**



Write in a conversational style

### Use active voice

- Passive: "You will be asked to answer questions."
- Active: "We will ask you questions."
- Write short, simple, and direct sentences
- Write in the first and second person, pronouns "I,"
   "you"
- Read your document out loud



## Example

Ridpath JR, Greene SM, Wiese CJ; PRISM Readability Toolkit. 3rd ed. Seattle: Kaiser Permanente Washington Health Research Institute; 2007.

Participants assigned to a study treatment group will make 10 visits over a 7-week period. These visits will be paid for by the study. Regardless of group assignment, all groups will be contacted at 2, 6, and 12 months after the start of the study for about a 20minute telephone interview.

Score	Grade Level	Difficulty
53.2	10.2	Difficult
<b>N</b>		-

**Cornell Medicine** 

If you are in a study treatment group, you will make 10 visits over a 7-week period. The study will pay for these visits. No matter which group you are in, we will call you for three phone surveys that will last about 20 minutes each. These surveys will take place 2, 6, and 12 months after you join the study.

Score	Grade Level	Difficulty
81.9	5.6	Easy

## Let's Practice!

You are being asked to participate in a longitudinal study about the longterm effects of vaping on lung tissue. The study procedures involve having participants undergo CT scans at initial visit, then follow up scans annually for five years. Participants will also be asked to complete an initial survey about the history of vape usage, and then one every six months.



## **Principles of Plain Language**

**O**rganize and filter information with your readers in mind

- Use short sentences 15 words on average
   Keep words to 3 syllables or shorter
- Cover key points early and provide summaries
   Keep paragraphs short and limited to one idea
- Consider cultural characteristics
  - o Literacy level, age, ethnicity, health conditions
- Ask someone else to read your draft

Ridpath JR, Greene SM, Wiese CJ; PRISM Readability Toolkit. 3rd ed. Seattle: Kaiser Permanente Washington Health Research Institute; 2007.

## Example

Ridpath JR, Greene SM, Wiese CJ; PRISM Readability Toolkit. 3rd ed. Seattle: Kaiser Permanente Washington Health Research Institute; 2007.

Can you take five minutes to provide information that will help plan an important study to aid people with arthritis pain and problems getting a good night's sleep? I am an investigator at Group Health Research Institute who is planning a major study to test new ways of helping people with arthritis pain and sleep problems.

Score	Grade Level	Difficulty
53.4	10.2	Difficult

### **Weill Cornell Medicine**

Can you take five minutes for a study about helping people with arthritis get a good night's sleep? If you have arthritis, you may know what it's like to have trouble sleeping. I am a researcher at Group Health Research Institute. I'm writing to ask for your help with a major study about arthritis pain and sleep problems.

Score	Grade Level	Difficulty
75.9	6.3	Fairly Easy

## **Principles of Plain Language**



Format the document so it's easy to read

- Use ample white space and margins
- Break up chunks of dense copy
- Put lists in bullet form
- Use headings
- Use bold, large font, or extra space

Ridpath JR, Greene SM, Wiese CJ; PRISM Readability Toolkit. 3rd ed. Seattle: Kaiser Permanente Washington Health Research Institute; 2007.

## **Formatting Tips**

- Use page numbers
- Use at least 12-point font
- Highlight important points
  - o Use <u>underlines</u>
  - o Use bold
  - o Use boxes

Avoid *italics* or ALL CAPS, AS THEY ARE HARDER TO READ ON THE PAGE



#### Susto et Esenibh

Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisi dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisi utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Agnim quis eum nim quate molorem ing ea faccummy nulla commod do dunt wisit, sum dolorer aesequiscing eui et ute vulpute enim ing endre dip euipis nulla consequam ver sim zzriusto er at. Am dolore a feuguer si ex eros ea autpat, Conse modo od duis nostrud ea facilla alis et laor susto esenibh eumsandigna commy niate feum dolutpatet, quatuerostie euisci tio odolortie magnim at, quamet ing et at volorero con. Dolenis aliqui blan volore commy nit, consequam, ver la fue de fue facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisi dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolorem inim do con hendree tumsand ipsustionsed doloreetummy Agnim quis eum nim quate molorem ing ea faccummy nulla commod do dunt wisit, sum dolorer.

#### Susto et Esenibh

Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Agnim quis eum nim quate molorem ing ea faccummy nulla conmod do dunt wisit, sum dolorer aesequiscing eui et ute vulpute enim ing endre dip euipis nulla consequam ver sim zzriusto era t. Am dolore ea feuguer si ex eros ea autpat, Conse modo od duis nostrud ea facilla alis et laor susto esenibh eumsandigna commy niate feum dolutpatet, quatuerostie euisci tio odolortie magnim at, quamet ing et at volorero con. Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliquisisti wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy

#### Aesequiscing

Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliguam velestio od min vel utat, conse tis alissecte dolore ex euis erilisi dolore. Si tin veliguisisit wisseguamet exeratem iliguisim niat doloboreet duisl utetum guat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy modo od duis nostrud ea facilla alis et laor susto esenibh eumsandigna commy niate feum dolutpatet, guatuerostie euisci tio odolortie magnim at, quamet ing et at volorero con.Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem guat wis aliguam velestio od min vel utat. conse tis alissecte dolore ex euis erilisi dolore. Si tin veliguisisit wisseguamet exeratem iliguisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Dolenis aliqui blan volore commy nit, consequam, conulla feu facin eu faccum zzrit vendip eugait verjurem quat wis aliguam velestio od min vel utat, conse tis alissecte dolore ex euis erilisi dolore. Si tin veliguisisit wisseguamet exeratem iliguisim niat doloboreet duisi utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Dolenis aligui blan volore commy nit, conseguam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisi dolore. Si tin veliguisisit wisseguamet exeratem iliguisim niat doloboreet duisi utetum guat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetumm Conse modo od duis nostrud ea facilla alis et laor susto esenibh eumsandigna commy niate feum dolutpatet. quatuerostie euisci tio odolortie magnim at, quamet ing et at volorero con. Dolenis aliqui blan volore commy nit, consequam, conulla feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliguisisit wisseguamet

### Compare





#### Exeratem iliquisim

Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu facum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolobore minim.

#### Si tin veliquissit wissequamet?

Conse modo od duis nostrud ea facilla alis et laor susto esenibh eumsandigna commy niate feum dolutpatet, quatuerostie euisci tio odolortie magnin at, quamet ing et at volorero con. Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis.

#### Am dolore ea feuguer si ex eros ea autpat?

Ea feuguer si ex eros ea autpat eum nim quate ea facilla alis et laor susto esenibh commy niate feum dolutpatet, quatuerostie euisci tio.:

- Exeratem iliquisim niat doloboreet duisl Utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Agnim quis eum nim quate molorem ing ea faccummy nulla commod do dunt wisit, sum.
- 2) Agnim quis eum nim quate Molorem ing ea faccummy nulla commod do dunt wisit, sum dolorer aesequiscing eui et ute vulpute enim ing endre dip euipis nulla consequam ver sim zzriusto er at. Am dolore ea feuguer si ex eros ea autpat, Conse modo od duis nostrud ea facilla.
- 3) Exeratem iliquisim niat doloboreet duisl Utetum quat wis nim zzriuscilis ex enim dolobore minim do con hendree tumsand ipsustionsed doloreetummy Agnim quis eum nim quate molorem ing ea faccummy nulla commod do dunt wisit, sum

#### Exeratem iliquisim

Dolenis aliqui blan volore commy nit, consequam, conulla feu feu facin eu faccum zzrit vendip eugait veriurem quat wis aliquam velestio od min vel utat, conse tis alissecte dolore ex euis erilisl dolore. Si tin veliquisisit wissequamet exeratem iliquisim niat doloboreet duisl utetum quat wis nim zzriuscilis ex enim dolobore minim.

## Exercise – pulling it all together!

Adapted from: Ridpath JR, Greene SM, Wiese CJ; PRISM Readability Toolkit. 3rd ed. Seattle: Kaiser Permanente Washington Health Research Institute; 2007.

http://bit.ly/WCM-ICF-Jamboard

If you agree to participate, the researcher will arrange a screening interview with you at our research clinic. During this interview, you will be asked to do some tasks that measure your cognitive and problem-solving abilities and answer questions about your medical and occupational history. If you are willing, a phlebotomist will obtain a blood sample of approximately 10ccs. This visit should take approximately two hours. If you are eligible to participate in the study, every two years the researchers will repeat the initial assessment procedures at the Center for Health Studies, periodically reviewing your medical record to see if there is a change.

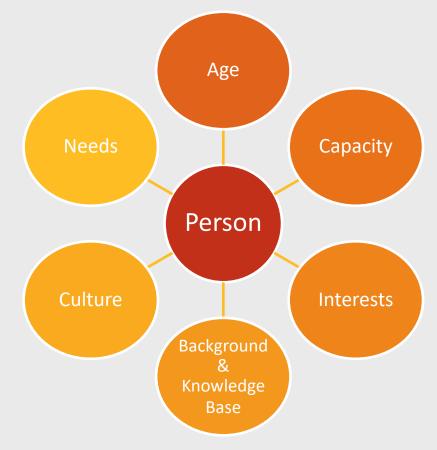
Score	Grade Level	Difficulty
35.2	13.5	Difficult
20		

## Exercise – pulling it all together!

If you agree to **participate**, the researcher will **arrange a screening** interview with you at our research clinic. During this interview, you will be asked to do some tasks that measure your cognitive and problemsolving abilities and answer questions about your medical and occupational history. If you are willing, a phlebotomist will obtain a **blood sample** of **approximately 10ccs**. This visit should take approximately two hours. If you are eligible to participate in the study, every two years the researchers will repeat the initial assessment procedures at the Center for Health Studies, periodically reviewing your medical record to see if there is a change.

	Score	Grade Level	Difficulty
	35.2	13.5	Difficult
3	1		

## Audience



## Example: Age

We are inviting you to participate in a study that will measure aspects of your voice. We will record you speaking and ask you to complete surveys about perceptions of your voice.

Score	Grade Level	Difficulty
66.3	7.9	Easily understood

We want to study your voice. I will record you talking and ask you questions about your voice.

Score	Grade Level	Difficulty
89.6	2.9	Easy, conversational

## Example: Knowledge Base/Interest

We are inviting you to participate in a study that will measure aspects of your voice. We will record you speaking and ask you to complete surveys about perceptions of your voice.

Score	Grade Level	Difficulty
66.3	7.9	Easily understood

We are interested in studying vocal athletes. We will record you speaking and measure your vocal range and abilities. We will also ask you to complete surveys about how you perceive your vocal quality.

Score	Grade Level	Difficulty
58.4	7.9	Easily understood

## Accessibility

"The quality of being able to be reached..." "The quality of being easily understood or appreciated."

### Consideration of your audience

- Do they have particular needs to be addressed?
- Do not rely on your perception of the audience
- o Get input from a community member

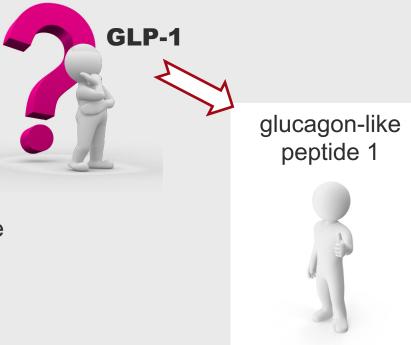


## Consistency

### anti-convulsant ≠ drug that stops seizures

### do not use "don't"

- Be consistent with use of all terminology, such as drug names and abbreviations
- Avoid contradictions
- Spell out acronyms when first used
  - Abbreviations such as DNA, HIV, and AIDS that have come to be accepted as standard need not be spelled out





### Weill Cornell Medicine

# Let's go to JamBoard http://bit.ly/WCM-ICF-Jamboard





# Helpful Tools



## Helpful Resources

- WCM ICF Templates
- WCM IRB Office: <u>irb@med.cornell.edu</u>
- <u>Consultation service</u>
- PRISM Online Training
- PRISM Readability Toolkit



Scan the QR code to request a consult during our on-site Tuesday, 1/9 through Thursday 1/11





## The PRISM Toolkit

- Ξ Weill Cornell Medicine **Human Research Protections Informed Consent Templates** As part of our continued efforts to improve the IRB application and review process, we have developed new ICF templates that address the issues identified by our stakeholders: · Different templates have been created for different types of studies (SBER, Biomed, etc.). Contact Us · Guidance language has been added to each template to reduce confusion about which template to use, as well as how to complete sections. The Key Information section has been simplified. An Assent Template has been created, with guidance included to identify applicable populations. All language utilized is at the 8th grade reading level, and has been improved to promote clarity of instructions. · The template has been shortened and simplified to facilitate completion. · All signatures have been moved to the end of the document. Weill Cornell Medicine Human **Research Protections** These new and improved ICF templates replace all previous versions posted to our site as of May 17th, 2023; any 575 Lexington Avenue new intakes initiated within WRG-HS as of June 12th, 2023, must utilize these new templates. New York, NY 10022 WCM Assent Template Phone: (646) 962-8200 MCM Biomedical Informed Consent Template • 📑 WCM Humanitarian Use Device Informed Consent Template ~ MCM Informed Consent Addendum Template Jump To Top MCM Intermediate-Size Investigational Treatment Informed Consent Template MCM Pregnant Partner Non-Subject Informed Consent Template MCM Pregnant Partner Research Subject Informed Consent Template WCM Repository Informed Consent Template MCM SBER Informed Consent Template MCM Single Patient Investigational Treatment Informed Consent Template Make sure your Informed Consent Form is a readable document! See our Guidance Document on how to prepare a readable consent form. Refer to the Program for Readability in Science & Medicine (PRISM) Readability Toolkit
- Includes a summary of some of today's content
- Links to the training
- Links to additional plain language ٠ resources
- Instructions on how to determine reading level
- Quick reference guide for readability
- Editing checklist ٠
- Template language for consent ۲ forms
- Alternative wording suggestions ۲

### **Weill Cornell Medicine**

Q Search

**.**....

IRB Member

Portal

Request a onsultation 🕑

