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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.

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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

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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

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Objectives

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

Fundamental Aspects of Informed Consent

Disclosure

Comprehension

Voluntariness

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

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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

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

5. WHO WILL KNOW?
A statement describing how confidentiality will be maintained

6. IS THERE COMPENSATION?
For greater-than-minimal risk studies, compensation and/or medical treatment

7. WHO IS THE CONTACT?
Contact information for questions or more information

8. IS IT MANDATORY?
A statement that participation is voluntary

9. WHAT HAPPENS AFTER?
A statement about what will be done with collected information

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The Flesch-Kincaid Readability Test

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

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 college-level. (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

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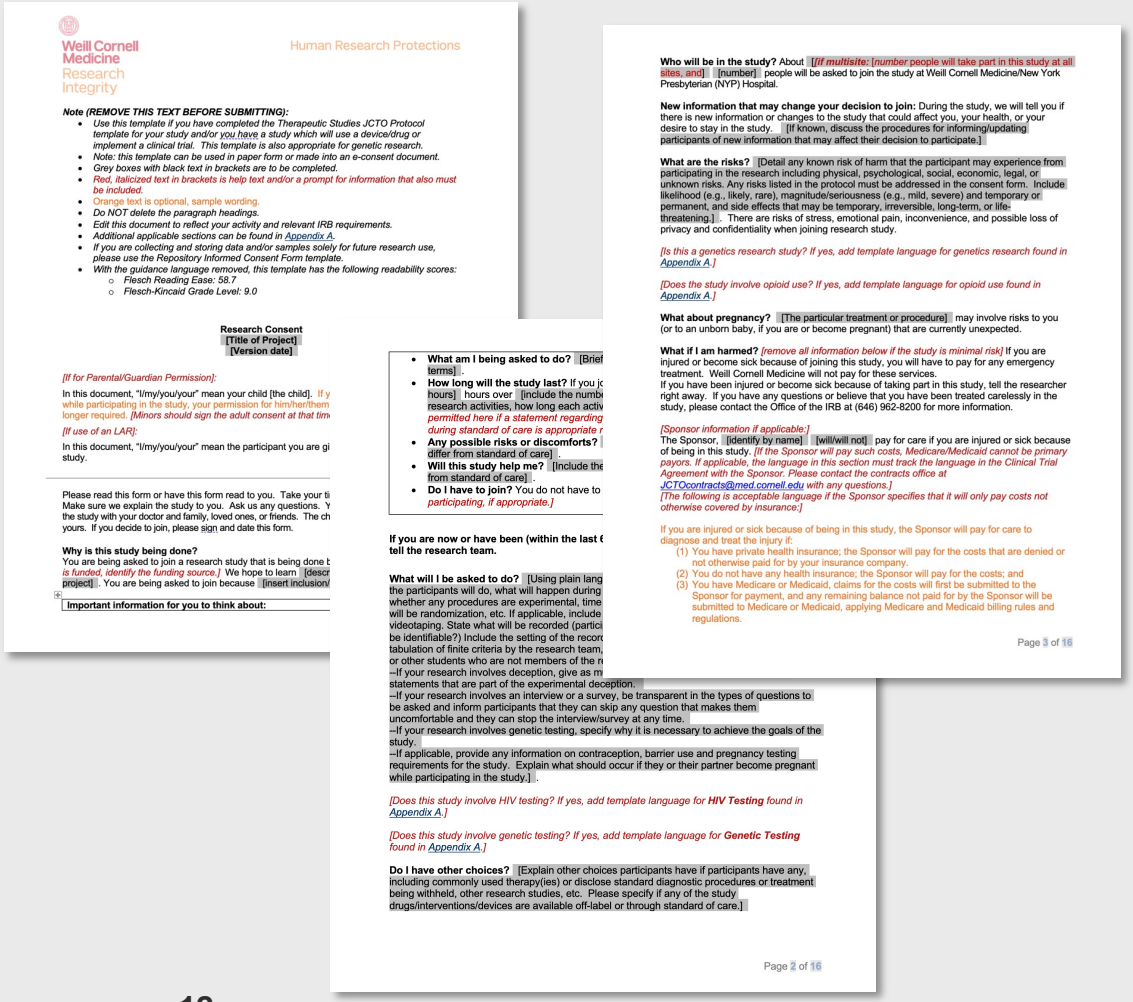
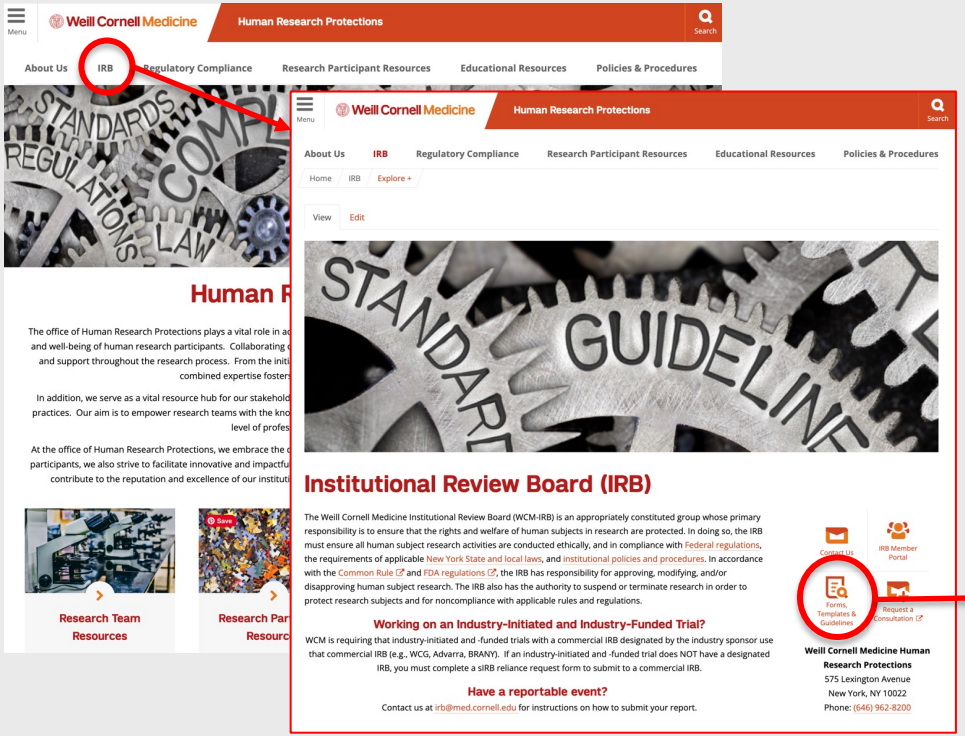
Our Templates

- 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



Where are they?



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.
- Device Form: Used for any study involving medical devices (as defined by the FDA).
- Specimen 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 page replaces all previously released templates.
- Deviation Log Template
- Adverse Event & IND Safety Reporting Cumulative Table

Checklists

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

Guidance Documents

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Fundamental Aspects of Informed Consent

Disclosure

Comprehension

Voluntariness

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Comprehension

Considerations	Workshop	Tools
• Readability • Audience • Accessibility • Consistency	• Let's Practice	• IRB Consultation • Researcher • Toolkits

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Considerations and Tools

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**

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

Principles of Plain Language

1. Use terms that are easily understandable
2. Write in a conversational style
3. Organize and filter information with your readers in mind
4. Format the document so it's easy to read

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

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Principles of Plain Language

1

Use terms that are easily understandable

- **Use common, everyday words**
- **Replace or define medical terms/jargon**
- **Avoid repetition**
- **Check reading level**

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

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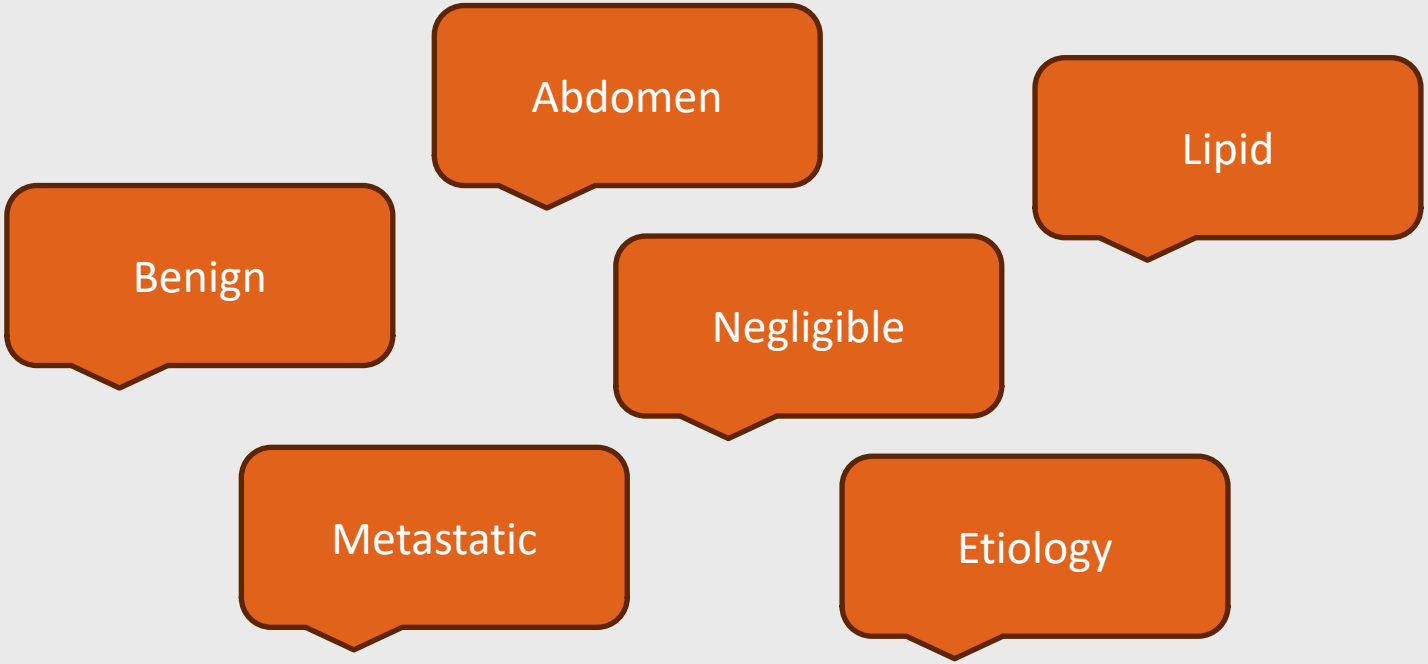
Some examples:

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

Let's Practice!



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

Principles of Plain Language

2

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**

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.

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 20-minute telephone interview.

Score	Grade Level	Difficulty
53.2	10.2	Difficult

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 long-term 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

3

Organize 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**
  - 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

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

4

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.

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Formatting Tips

- Use page numbers
- Use at least 12-point font
- Highlight important points
  - Use underlines
  - Use **bold**
  - Use boxes

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

Susto et Esenibh

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Compare

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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.

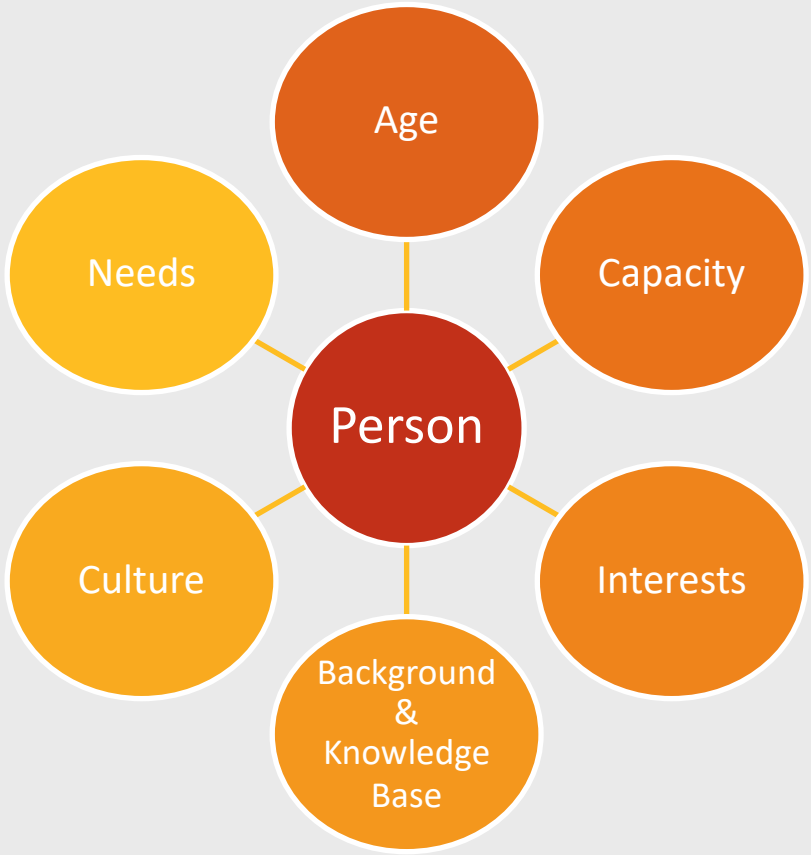
Score	Grade Level	Difficulty
35.2	13.5	Difficult

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 problem-solving **abilities and answer questions** about your m**edical 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

Audience



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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
  - 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

glucagon-like peptide 1

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Let's Practice!

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

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Helpful Tools

Helpful Resources

- **WCM ICF Templates**
- **WCM IRB Office: irb@med.cornell.edu**
- **Consultation service**
- **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

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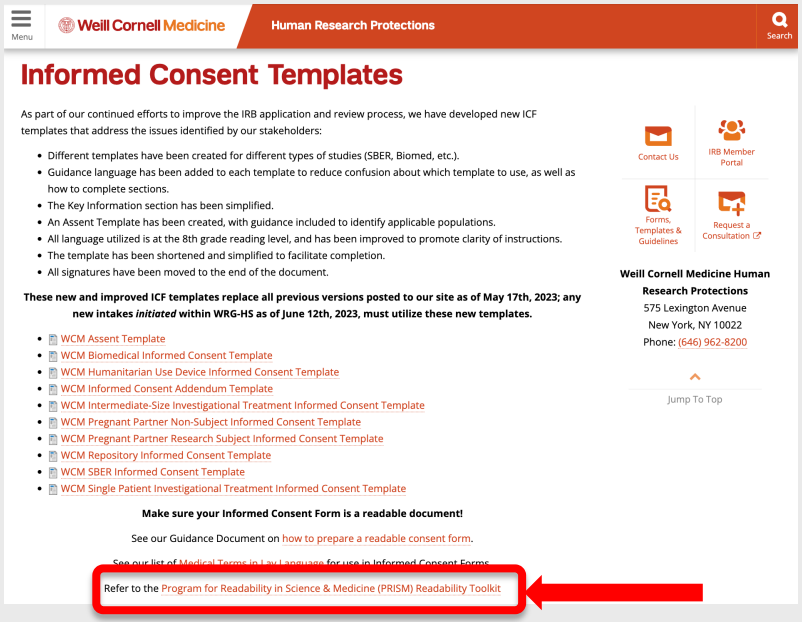
The PRISM Toolkit



- Includes a summary of some of today's content
- Links to the training
- Links to additional plain language resources
- Instructions on how to determine reading level
- Quick reference guide for readability
- Editing checklist
- Template language for consent forms
- Alternative wording suggestions

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