

# GETTING YOUR ICF APPROVED ON THE FIRST TRY

Emory IRB Office

# WEBINAR OBJECTIVES

- To give ideas of how to simplify informed consent documents
- To provide examples of how to improve consent forms
- To provide additional sources that can improve the writing of a document



# MISSION IMPOSSIBLE?

Not impossible (it happens all the time!)

- We will provide some tips of how to do it!
- Out of our control (pending items)



# FIRST...READING LEVEL!

8<sup>th</sup> grade level: how to do this?

- Use one- or two-syllable words
- Use short sentences and paragraphs
- Define medical/technical terms in lay language
- Organize information in sections with clear headings



# FIRST...READING LEVEL!



- Print all headings in bold
- Use spacing to emphasize important concepts
- Avoid contractions (don't)
- Address the consent document to the reader by using the **active voice** and the word "you" throughout

# KEEP YOUR SENTENCES SHORT AND SIMPLE.

Say one thing per sentence and say it plainly.

## Example:

*Your participation in the main study will not be affected in any way if you choose to not allow your left-over samples to be used for research not specified in this protocol.*

- 14.8 grade level, unclear language, excessive use of the word “not.”

Versus....

# KEEP YOUR SENTENCES SHORT AND SIMPLE.

## Example:

*You may continue to be in the main study even if you do not agree to future use of your samples.*

- 8.3 grade level, one clear point.

# KEEP YOUR CLAUSES INDEPENDENT

Break down larger sentences and paragraphs into their component parts.

## EXAMPLE

- The study drug will be given to you by intravenous infusion (IV), through a vein usually in your arm or a central venous catheter (catheter placed into a large vein), over a 1-2 hour period, depending on the dose you will receive.
  - 1 sentence, 19.2 grade level

Versus...



# KEEP YOUR CLAUSES INDEPENDENT

## EXAMPLE

- The study drug will be given to you by intravenous (IV) infusion. We usually use a vein in your arm for the infusion. The drug may instead be given through a central venous catheter. A catheter is a tube placed into a large vein. Your study doctor will determine the best way to give you the drug. The infusion will take about 1-2 hours.
  - 6 sentences, 5.6 grade level

# KEEP YOUR WORDS SMALL

Use words and phrases found in common conversations, not legal documents.

## EXAMPLES:

- Approximately vs. About
- Take part/Be in vs. Participate
- End vs. Terminate
- Do vs. Perform
- Get or Have vs. Receive (a treatment)

## USE “YOU” AND “WE”

Avoids passive sentences and circuitous language.

EXAMPLE:

- None of the currently available treatments for advanced melanoma are certain to be curative, so new treatments or combinations of treatments need to be developed.
  - Flesch-Kincaid Grade Level: 15.4

Versus...

## USE “YOU” AND “WE”

### EXAMPLE:

- There are no certain cures for advanced cutaneous melanoma. We want to find new treatments or combinations of treatments. We hope these new treatments will work better than the current ones.
  - Flesch-Kincaid Grade Level: 6.7

# KEEP PARENTHESES MINIMAL (PART 1)

Define terms in sentences, not asides.

EXAMPLE:

- Current treatment is largely based on using drugs such as pyridostigmine (which is used to help block some of the activity of this disease), and prednisone (a corticosteroid drug used to help control and improve disease symptoms)

Versus...

## KEEP PARENTHESES MINIMAL (PART 2)

### EXAMPLE:

- Current treatment is largely based on using drugs such as pyridostigmine and prednisone. Pyridostigmine helps block some of the activity of this disease. Prednisone is a corticosteroid drug that helps control and improve disease symptoms.

# KEEP PARENTHESES MINIMAL (PART 3)

Use lay language first, put the technical terms in parentheses.

EXAMPLES:

<b>Not this ☹️</b>	<b>But this 😊</b>
Grade 2 conduction block (a condition in which the electrical activity of the top of the heart is delayed in getting to the bottom of the heart)	A condition in which the electrical activity of the top of the heart is delayed in getting to the bottom of the heart (grade 2 conduction block)
Changes in the cornea (the front part of the eye)	Changes in the front part of the eye (cornea)

# KEEP FORMATTING SIMPLE (PART 1)

## Don't do this:

- In the event of an injury or illness resulting from your participation in this research study, your study doctor will TRY TO HELP YOU GET appropriate health care, including first aid, emergency treatment and follow-up care either at Emory University or another appropriate health care facility. If you experience an illness, adverse event, or injury that is the direct result of a medication, device, intervention, procedure, or test required for this study, THE SPONSOR will pay usual and customary medical fees for reasonable and necessary treatment. NEITHER the sponsor NOR EMORY UNIVERSITY PLAN TO PAY FOR expenses that COME FROM pre-existing medical conditions, underlying disease, or your FAILURE TO FOLLOW THE STUDY INSTRUCTIONS OR PROTOCOL. In addition, THE SPONSOR DOES NOT PLAN TO pay for expenses that result from Emory's negligence OR WILLFUL misconduct . The study doctor and THE SPONSOR will determine if the adverse event or injury was a result of your participation in this study. **If the cost of treating your research related injury was incorrectly billed to a government program by Emory University, the payment will be returned and THE SPONSOR will be billed.** By signing this form you have not given up your legal rights. EMORY DOES NOT PLAN TO PAY ANY EXPENSES FOR STUDY RELATED ILLNESS OR INJURY UNLESS DIRECTLY CAUSED BY EMORY'S NEGLIGENCE OR WILLFUL MISCONDUCT.



## KEEP FORMATTING SIMPLE (PART 2)

- Be consistent in font choice and size throughout the consent.
- Use bold, italic, underline, and caps lock sparingly, if at all.
- Ensure body text is Left Aligned, not Justified.
  - This happens more often than you'd think.

**keep it  
simple.**

# ON THE SAME NOTE OF SIMPLICITY..

## Eliminate Unnecessary Words

- Challenge each word – is it necessary?

### EXAMPLES

- “Before” vs. “prior to”
- “It is required that you” vs. “You must”
- “Conducting an investigation” vs. “Studying” or “testing”

## OTHER TIPS

- Bulleted Lists are your friends.
  - Risks/Side Effects sections.
- Use initials instead of check-marks, when applicable.
- Older patients (and IRB members) appreciate larger fonts.
- Keep paragraphs short, one idea per paragraph.
- Use the current templates. We're always updating and improving them!

# RESOURCES ON ICF WRITING

- [http://ctep.cancer.gov/protocolDevelopment/docs/NCI\\_IC\\_Template.docx](http://ctep.cancer.gov/protocolDevelopment/docs/NCI_IC_Template.docx): Some of our template sections must be used instead, but the remaining sections of this sample are useful.
- <http://www.hemingwayapp.com/>: great tool that allows you to insert your text. It tells you what sentences are too long and the overall readability of your text.
- Simplification of medical terms:  
<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/simplification-guide-medical-terms>

# RESOURCES ON ICF WRITING

- How to review with Flesch-Kincaid (Word)?
  - Click the File tab, and then click Options.
  - Click Proofing.
  - Under When correcting spelling and grammar in Word, make sure the Check grammar with spelling check box is selected.
  - Select Show readability statistics.
  - After you enable this feature, open a file that you want to check, and check the spelling. When Outlook or Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

## OUT OF OUR CONTROL ☹️

- *Costs and In case of injury* language
  - Could be a pending item if more than minimal risk
  - Cost language comes from Office for Clinical Research; Injury language comes from Office for Sponsored Programs (unless study has no billables or is unfunded)
  - IRB gets email from OCR/OSP, and logs info in history to avoid delays
- Not using latest version of ICF/HIPAA (yes, one document now)
- Not adding all procedures and risks from protocol to ICF
- Not deleting optional items or comments
- Not adding your contact information to ICF

# WE NEED YOUR FEEDBACK!

- Please give us your feedback about today's webinar so we can improve future ones.
- You can also help us by suggesting topics.
- Access the survey at <https://www.surveymonkey.com/s/betterICF>



# IF YOU HAVE ADDITIONAL QUESTIONS...

- Website: [www.irb.emory.edu](http://www.irb.emory.edu)
- Main Phone: 404-712-0720
- Education and QA Team
  - Maria G. Davila at (404)712-0724 or [maria.davila@emory.edu](mailto:maria.davila@emory.edu)
  - Shara Karlebach at (404)712-0727 or [shara.karlebach@emory.edu](mailto:shara.karlebach@emory.edu)
  - Sean Kiskel at (404)712-0766 or [skiskel@emory.edu](mailto:skiskel@emory.edu)
  - Kevin Wack at (404)712-5220 or [kwack@emory.edu](mailto:kwack@emory.edu)







**Thank you!**