

How to write a good consent form

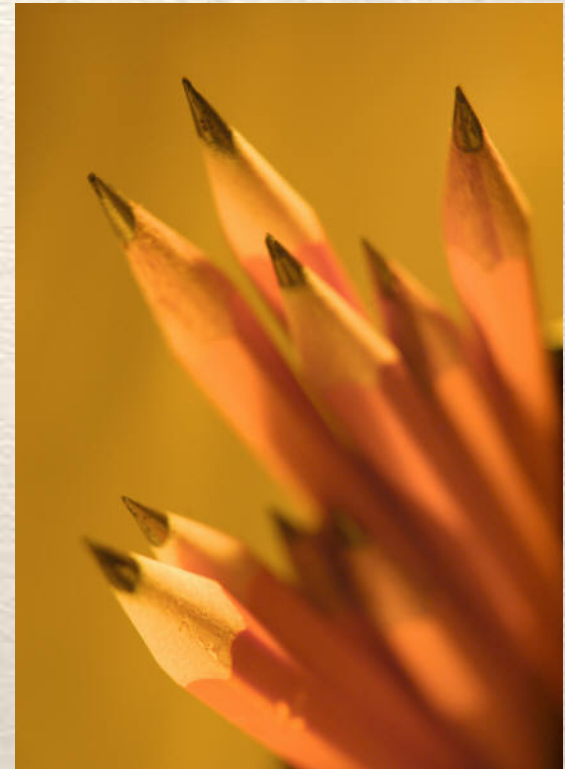
ITHS CRES Lecture
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Mandy Vick

Research Compliance Monitor
Regulatory Support & Bioethics Core
Institute of Translational Health Sciences
vicka@u.washington.edu

My background

- Quorum Review IRB
 - Created a process for consent form writing and editing services for FDA-regulated clinical studies
 - Wrote and/or edited almost 3000 consent forms
- UW Human Subjects Division
 - Created the compliance review process
 - Investigated about 75 noncompliance allegations per year, many of which involved the consent form as a seminal document determining whether compliance violations impacted participants' rights
- ITHS
 - Created the compliance monitoring process
 - Conduct annual and semi-annual consent audits of the UW and Children's CRCs
 - Assist researchers with IRB submissions, including writing consent documents



What we will cover

- Background of Informed Consent
- Mission
- Consequences
- Consent Writing Process
 - Improving Readability
- Examples of Improved Readability
- Resources

Background

Of Informed Consent

Background

- Why do we have consent forms?
 - It's **required** by federal regulations, resulting from decades of ethical examinations concerning research:
 - 1940s - Nuremburg Trials & Nuremburg Code
ohsr.od.nih.gov/guidelines/nuremburg.html
 - 1950s - Thalidomide Studies
en.wikipedia.org/wiki/Thalidomide
 - 1960s - Willowbrook Hepatitis Studies & Declaration of Helsinki
ohsr.od.nih.gov/guidelines/helsinki.html
 - 1970s - Tuskegee Syphilis Study & Belmont Report
ohsr.od.nih.gov/guidelines/belmont.html

Background

The Belmont Report established the principle of **Respect for Persons**:

- Individuals should be treated as **autonomous agents**.
- Persons with **diminished autonomy** are given adequate **protection**.

Background

- Research participants, to the degree that they are capable, must be given the **opportunity to choose** what shall or shall not happen to them.
- This opportunity is provided when adequate **standards for informed consent** are present:
 1. Information
 2. Comprehension
 3. Voluntariness



Background

- **Standard 1: Information**
 - Content for the written document generally consists of:
 - Research **procedures**, their **purposes**, **risks** and anticipated **benefits**, **alternative** procedures (where therapy is involved), and a statement offering the participant the opportunity to **ask questions** and to **withdraw** at any time
 - Codified in federal regulations 21 CFR 50.25 and 45 CFR 46.116

Background

- Commentary on **Information**
 - We should provide “**the reasonable volunteer**” with **enough information** so they can decide whether they wish to participate in the **furthering of knowledge**.
 - In short, information provided should aim to ensure participants clearly understand:
 - range of **risk**
 - **voluntary nature** of participation

Background

- **Standard 2: Comprehension**
 - How can we give subjects the best shot at **comprehension** during the consent process?
 - **Organization of information**
 - Adapting the presentation to meet each **participant's comprehension capacity**
 - Capacity based on assessing **intelligence, rationality, maturity, and language skills**

Background

- Commentary on **Comprehension**
 - Special attention must be paid to participants who **do not** have the capacities to consent under normal circumstances:
 - Infants and young children
 - Mentally disabled
 - Comatose



Background

- **Commentary on Comprehension**
 - To the extent they are able, even these participants are extended the opportunity to **choose**.
 - Allow a **third-party designee** to act in the participant's best interest.



Background

- Standard 3: **Voluntariness**
 - A participant's consent is only **legally valid** when it is **voluntary**.
 - This requires that participants provide consent under conditions **free of coercion** and **undue influence**.



Background

- Commentary on **Voluntariness**
 - **Coercion**
 - A **threat of harm** is presented in order to obtain consent.
 - **Undue influence**
 - An **excessive, unwarranted, inappropriate, or improper reward or inducement** is presented to obtain consent.
 - If the participant is **especially vulnerable**, standard inducements can shift to become undue influences.

Background Summary

- Belmont report
 - Element 1: Respect for Persons
 - Three Standards for Informed Consent:
 - Information, Comprehension, Voluntariness
 - Federal Regulations
 - OHRP: 45 CFR 46.116
 - www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
 - FDA: 21 CFR 50.25
 - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=50.25

Mission

Of Writing a **Good** Consent Form

Mission

- By writing a good consent form, we can uphold the ethical precepts of the Belmont Report.
- We aim to ensure that potential participants understand information provided so they can **make a free, voluntary choice about participating** in research.



Consequences

What's the **harm** if the consent form isn't good?

Consequences

- The consent form is a **legal document**.
 - Its contents are subject to **federal regulatory requirements**.
 - 45 CFR 46.116
 - 21 CFR 50.25
 - The federal regulations require that the consent form must be in “**language understandable to the subject.**”

Consequences

- Failure to meet federal regulatory requirements can lead to:
 - **Citations of serious noncompliance** by the IRB, which are reported to federal regulatory agencies and the institution
 - Institutional consequences, such as **loss of research privileges**
 - **Legal suits** filed by research participants, which may also lead to loss of research privileges or even **debarment**



The Consent Writing Process

Responsibility

Regulations

IRB Templates

Readability

Source for Readability Tip Slides:

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

Consent writing process

- Who should write the consent form?
 - The best choice is the **staff member responsible for obtaining informed consent.**
 - That allows the staff member to be most familiar with the consent form.



Consent writing process

- Where do we begin?
 - In general, with the **federal regulations**
 - OHRP: 45 CFR 46.116
 - FDA: 21 CFR 50.25
 - And the **IRB's Consent Form Template**
 - University of Washington Human Subjects Division
 - Seattle Children's IRB
 - FHCRC IRB (Cancer Consortium IRB)

Consent writing process

Required elements of informed consent:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent.

When appropriate, one or more of the following elements of Information shall also be provided to each subject:

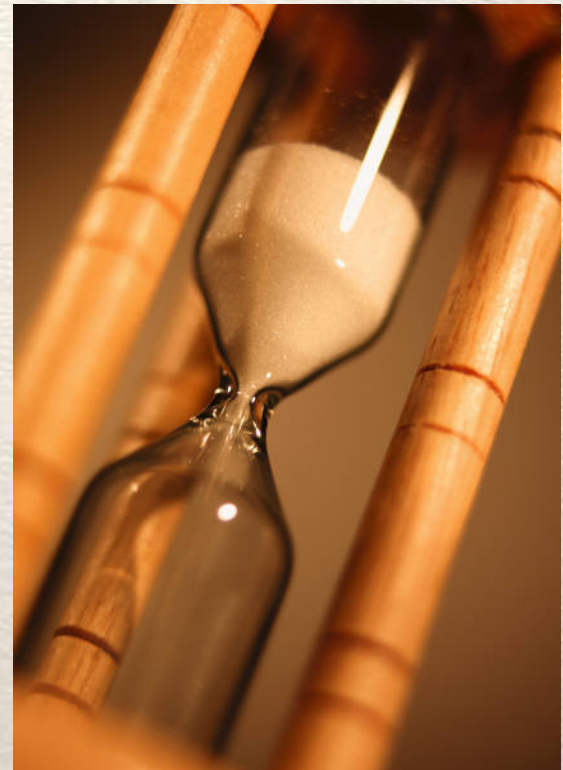
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

Consent writing process

- Make sure you have a **finalized** source document:
 - Grant
 - Protocol
 - IRB Application
- In other words, don't start the consent writing process until the study plan is completely vetted.
 - This prevents you from having to revise the consent form as the study plan is revised. If the study plan is in flux, it's easy to miss details that need to be changed throughout the consent form.

Consent writing process

- Set aside **two blocks** of time.
 - Use the first block to **draft** the consent form
 - Use the second to **proofread** the form
 - Ask the PI to proofread for you
 - Use a proofreading checklist



Consent writing process

- Using IRB templates
 - While much of the template includes required language, a few sections are open to your own words:
 - Purpose
 - Procedures
 - Risks
 - Always start with a clean version of the template off the IRB website.
 - Do not use a previous study's form. It may be out of date with current IRB requirements, and may lead to unnecessary errors in content.

Consent writing process

- Using IRB templates
 - With an electronic copy of your **source document** open, **copy and paste** information related to **purpose, procedures, and risks** into the corresponding sections of the consent template.
 - This ensures the consent contains **accurate study details**.
 - **Edit** this content into **lay language** appropriate for your participant population.

Consent writing process

- The main concern for writing a good consent form is **readability**.

Tips to **improve readability** include:

1. **Using plain language**
2. **Writing in conversational style**
3. **Filtering content and ordering of information**
4. **Knowing your audience**
5. **Formatting**
6. **Evaluating readability using ready-made formulas**



Consent writing process

- **Readability Tip 1: Use plain language**
 - Use common, everyday words.
 - Stay away from academic or scientific language.
 - Edit rigorously, and replace or define jargon.
 - Search for multi-syllable words that you can replace with simpler alternatives.
 - Look out for short words with complex or multiple meanings.
 - When you can, use examples, analogies, and visual aids.



Consent writing process

- **Readability Tip #2: Write in conversational style, as if you were speaking**
 - Use active voice.
 - It is more readable. “We will ask you questions about your health” is active, while “You will be asked questions about your health” is passive.
 - Write in the first person.
 - Use pronouns, like “I,” “we,” and “you.”
 - Read your document aloud.

Consent writing process

- **Readability Tip #3: Filter content and order information**
 - Know your reader.
 - What information is most important to them?
 - How can I order the information items to make the most sense?
 - Are there concepts that may not be clear to someone who doesn't know what I know?
 - Ask someone who is unfamiliar with your project to read your document and give feedback.
 - This could be a friend, relative, or neighbor who is fairly representative of your audience.

Consent writing process

- **Readability Tip #3: Filter content and order information (continued)**
 - Use short sentences and limit paragraphs to one main idea.
 - Avoid information overload.
 - Organize the information to make sense to your readers.

Consent writing process

- **Readability Tip #4: Know your audience**
 - Consider their literacy level, age, culture, ethnicity, or potential chronic health conditions.
 - Does the form include information or assumptions that may not be meaningful?
 - Is there anything that may be misinterpreted or off-putting within their cultural or social environment?

- **Readability Tip #4: Know your audience (continued)**

- Do they have special needs related to language or other abilities?
 - Use **large font** for the elderly or for other populations who may have poor eyesight, like people with diabetes or glaucoma.
 - Use the **simplest language possible** when writing assent forms for minors, and consider using **graphical methods** (cartoons, pictures) to help describe the study.

Consent writing process

- **Readability Tip #5: Formatting**
 - Allow adequate white space and generous margins.
 - Readers are often discouraged by dense-looking pages. One page crammed with information is often more intimidating than multiple pages.
 - Break up chunks of dense copy.
 - This can cause readers to miss important information.
 - Convert lists of 3 items or more into bulleted lists with one point per line, and use a numbered list if the order of items is important.

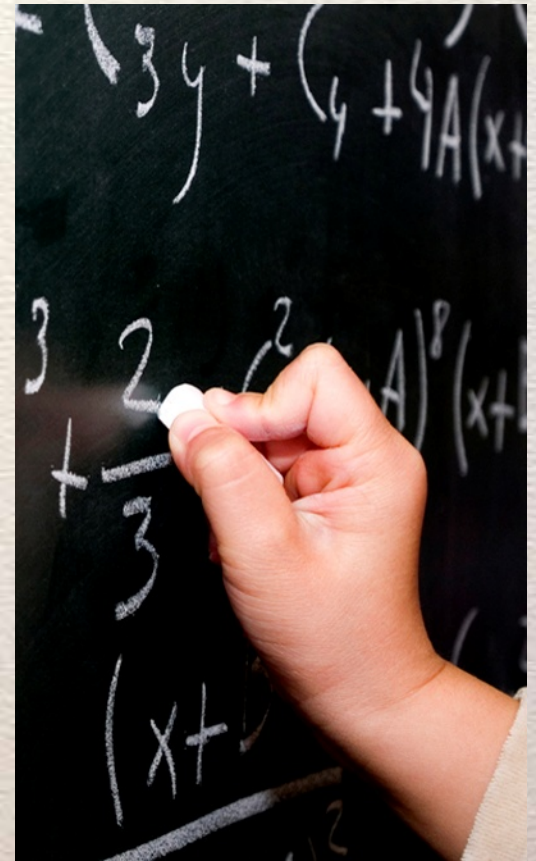
Consent writing process

- **Readability Tip #5: Formatting (continued)**
 - Give your readers “road signs.”
 - Headers for each section
 - Emphasize important information.
 - Use **bold** or larger font, borders, or other graphical elements. This draws the reader’s attention to critical information, even when they are only skimming the consent.
 - Avoid using justified margins, *putting sentences in italics*, or ALL CAPITAL LETTERS, as it increases the strain on the reader.



Consent writing process

- **Readability Tip #6: Evaluate readability using ready-made formulas**
 - Flesch-Kincaid formula
 - Results can be obtained quickly and automatically using the readability analysis tool in Microsoft Word.
 - The readability tool in Microsoft Word also provides the Flesch Reading Ease score and the percent of passive sentences.



Examples of Improved Readability

Purpose
Procedures
Risks

Source for Procedure Slides:

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

Examples of Improved Readability

Purpose: Typical Example

Although research supports the protective effects of high fruit and vegetable intake, the compounds responsible for this action have not been definitively identified. In this randomized clinical trial, *we aim to evaluate the effects of 30 days of carotenoid enrichment from food or supplements in healthy human volunteers.* Carotenoids are a class of lipid soluble compounds in fruit and vegetables that contribute to the rich colors in plant foods.

Plain Language Example

Research tells us that eating lots of fruits and vegetables helps keep people healthy, but we don't know exactly why. In this study, we want to find out what happens when people eat a lot of a vegetable substance called a carotenoid. Carotenoids are found in fruit and vegetables, and give these foods their rich colors. For 30 days during the study, we will ask 48 healthy people to eat carotenoid-enriched food or ask them to take carotenoid supplements.

Examples of Improved Readability

Readability Statistics:

Typical Example

- Grade level = **14.5**
- Reading Ease = **31.4**
- 33% passive sentences

Readability Statistics:

Plain Language Example

- Grade level = **9.5**
- Reading Ease = **60.3**
- 0% passive sentences

Examples of Improved Readability

Procedures: Typical Example

If you agree to participate in this study we will schedule a telephone interview at a time that is best for you. The telephone call will last about 30 to 60 minutes and will ask about your experiences with headaches and mood. The interview will be audiotaped and then transcribed so that we may record your responses. No one other than the research team and the transcriptionists will hear the audiotapes. We will reimburse you \$30 for your time if you participate in the telephone interview.

Plain Language Example

If you agree to be in this study, we will set up a phone survey at a time that is best for you. The call will last about 30 to 60 minutes.

We will ask about your experiences with headaches and mood. We will record the interview on an audiotape and then write down your answers. No one other than the research team and the person who writes down the answers will hear the tapes.

We will give you \$30 for your time if you take part in the phone survey.

Examples of Improved Readability

Readability Statistics: Typical Example

- Grade level = 9.5
- Reading Ease = 57.5
- 20% passive sentences

Readability Statistics: Plain Language Example

- Grade level = 4.9
- Reading Ease = 84.9
- 0% passive sentences

Examples of Improved Readability

Risks: Typical Example

POTENTIAL RISKS OR DISCOMFORT

A POTENTIAL RISK FOR PARTICIPATING IN THE INTERVIEW IS LOSS OF CONFIDENTIALITY. However remote the possibility, it is possible that a confidentiality breach could release participant names. Also, some people feel that providing information for research is an invasion of privacy. Some people feel uncomfortable when an interview is audio recorded.

Plain Language Example

Are there any risks to me?

The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is low.

Some people may feel uncomfortable having the interview recorded. You may skip any question or stop the interview at any time.

Examples of Improved Readability

Readability Statistics:

Typical Example

- Grade level = **13.6**
- Reading Ease = **19.7**
- 0% passive sentences

Readability Statistics:

Plain Language Example

- Grade level = **5.8**
- Reading Ease = **75.1**
- 0% passive sentences

Resources

For writing a **good** consent form

Resources



Resources

- **PRISM Readability Toolkit**

- Authored by the Group Health Center for Health Studies
- Copyrighted, public domain resource that you may feel free to use and share as you see fit.
- To receive updated versions, please register your email address online at
http://www.surveymonkey.com/s.aspx?sm=4_2b6cCfUKcjVtUKiwmKE87w_3d_3d

Resources

- Toolkit includes:
 - Appendix A: Instructions for Checking Readability in Microsoft Word™
 - Appendix B: Alternative Wording Suggestions
 - Appendix C: Examples of Improved Readability
 - Appendix D: Examples of Improved Formatting
 - Appendix E: Repository of Readability References and Resources

Resources

The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research

The Agency for Healthcare Research and Quality (AHRQ) has developed the *Informed Consent and Authorization Toolkit for Minimal Risk Research* to facilitate the process of obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from potential research subjects. This toolkit contains information for people responsible for ensuring that potential research subjects are informed in a manner that is consistent with medical ethics and regulatory guidelines.

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Current as of September 2009

Suggested Citation:

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Resources

- **AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research**
 - Authored by the Agency for Healthcare Research and Quality (AHRQ)
 - Copyrighted, public domain resource that you may feel free to use and share as you see fit.
 - Available online at:
www.ahrq.gov/fund/informedconsent/

Summary

What to take back to work...

Summary

- I hope you can apply the following in your consent writing process:
 - Ethical precepts of informed consent
 - Necessity for the informed consent document
 - Ways to work with IRB templates
 - Methods to improve readability

Questions?

Feel free to contact me with future questions:

Mandy Vick

vicka@u.washington.edu

206-598-4124