

**How to write a good**

**consent form**

ITHS CRES Lecture

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Research Compliance Monitor

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**My background**

•

Quorum Review IRB

–

Created a process for co

nsent form writing and

editing services for FDA-

regulated clinical studies

–

Wrote and/or edited almo

st 3000 consent forms

•

UW Human Subjects Division

–

Created the complian

ce review process

–

Investigated about 75 non

compliance allegations

per year, many of which in

volved the consent form

as a seminal document

determining whether

compliance violations impac

ted 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

–

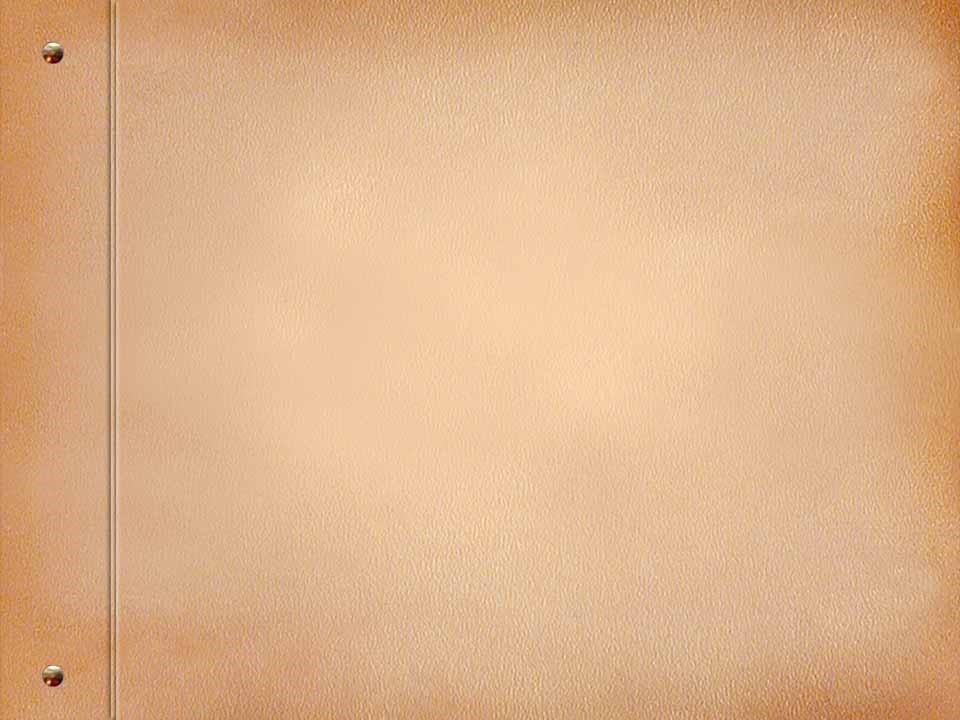
Improving Readability

•

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:

•

1940

s - Nuremburg Trials & Nuremburg Code

ohsr.od.nih.gov/guidelines/nuremberg.html

•

1950

s - Thalidomide Studies

en.wikipedia.org/wiki/Thalidomide

•

1960

s - Willowbrook Hepatitis Studies & Declaration of

Helsinki

ohsr.od.nih.gov/guidelines/helsinki.html

•

1970

s - 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:

•

I

nfants and young children

•

M

entally disabled

•

C

omatose



**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

•

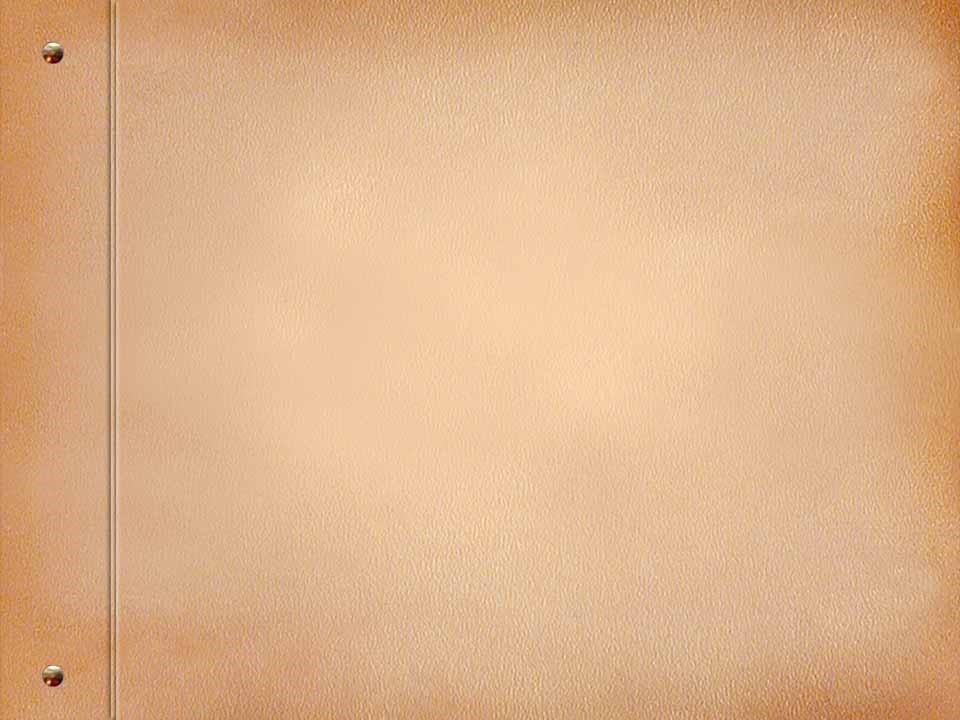
FDA: 21 CFR 50.25

–

www.accessdata.fda.gov/scripts/c

drh/cfdocs/cfCFR/CFRSearch.cf

m?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**

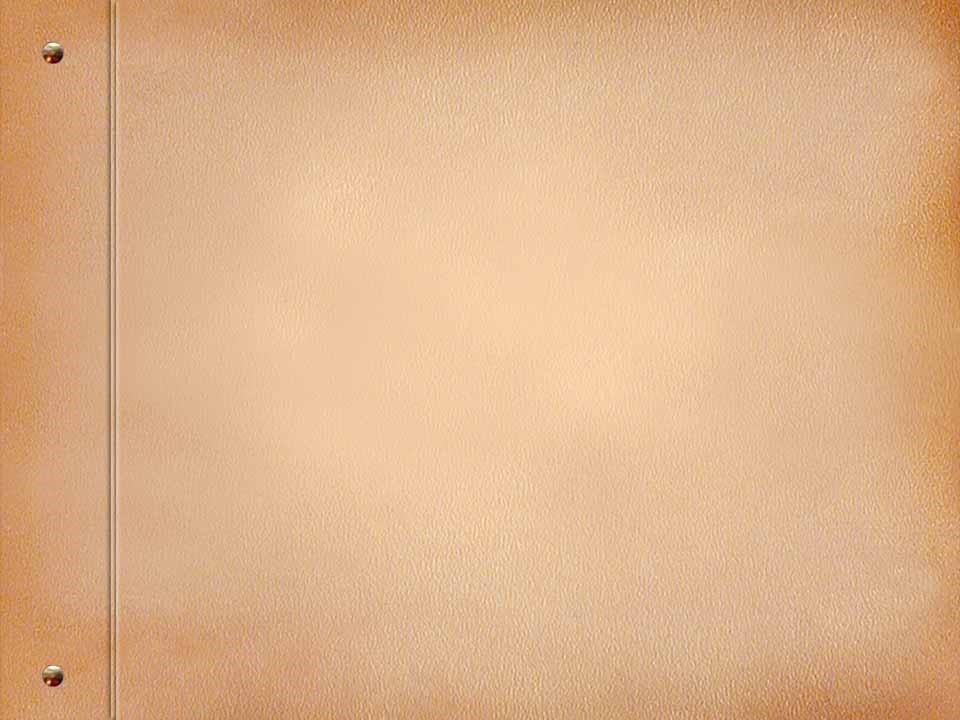
**a free, voluntary choice**

**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**

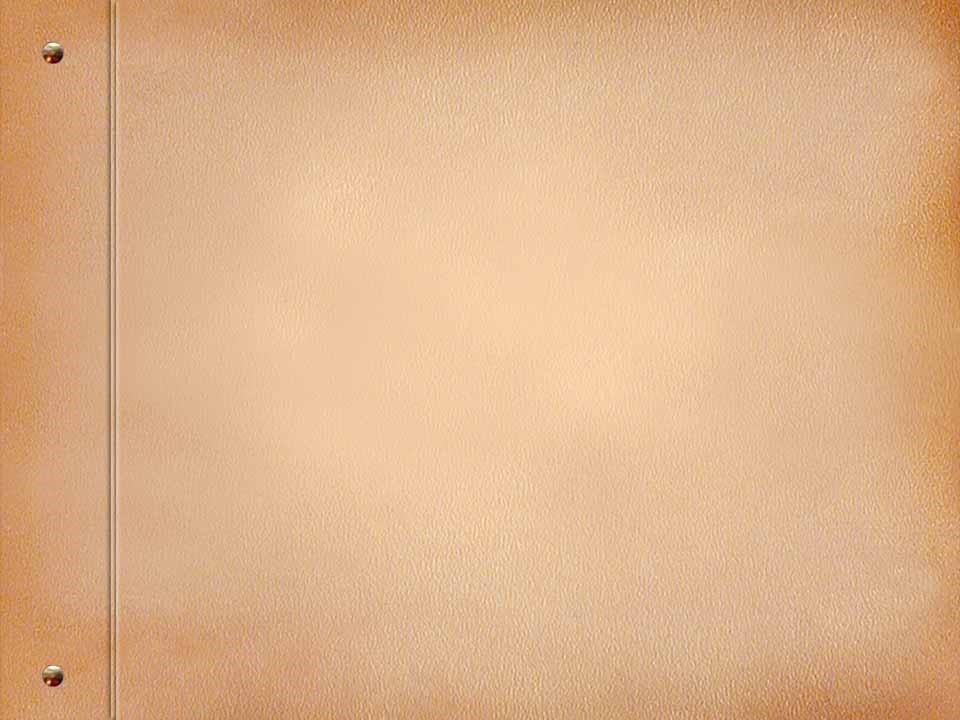
filed by research

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 th

e 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.

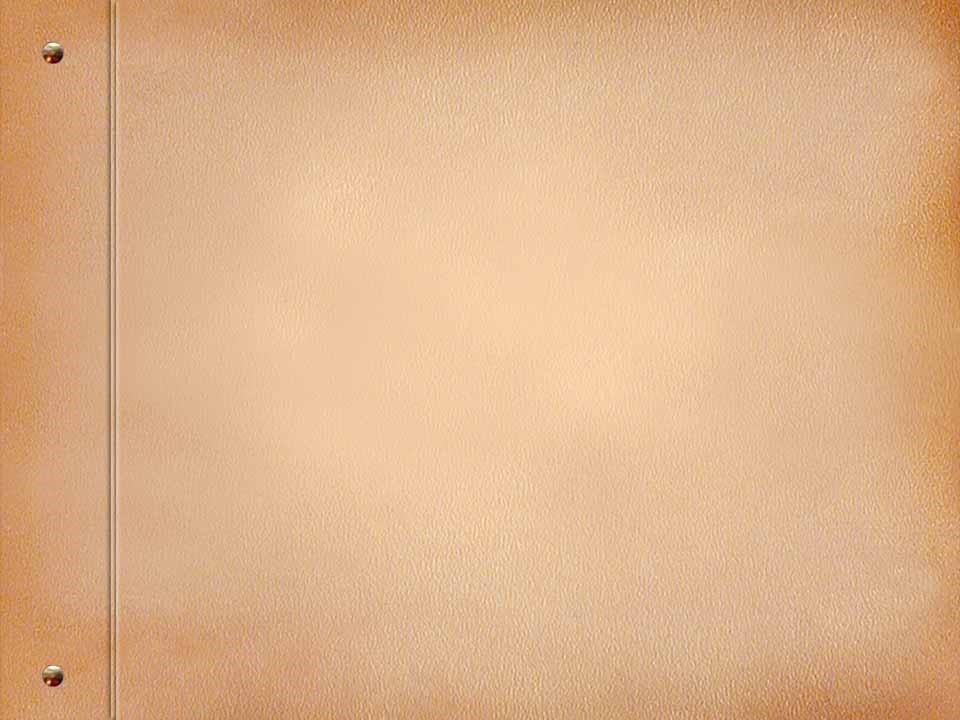
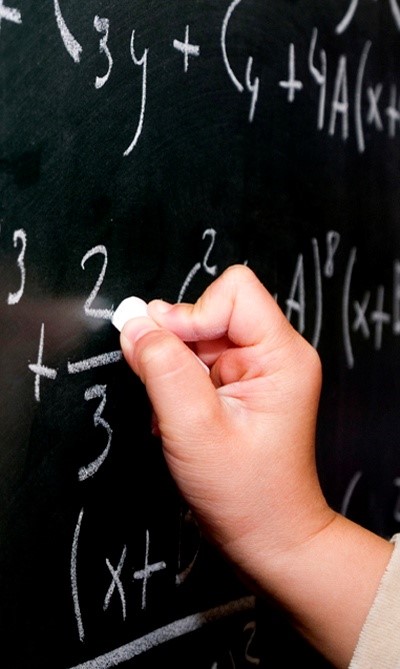
•

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. Howe ver 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 =

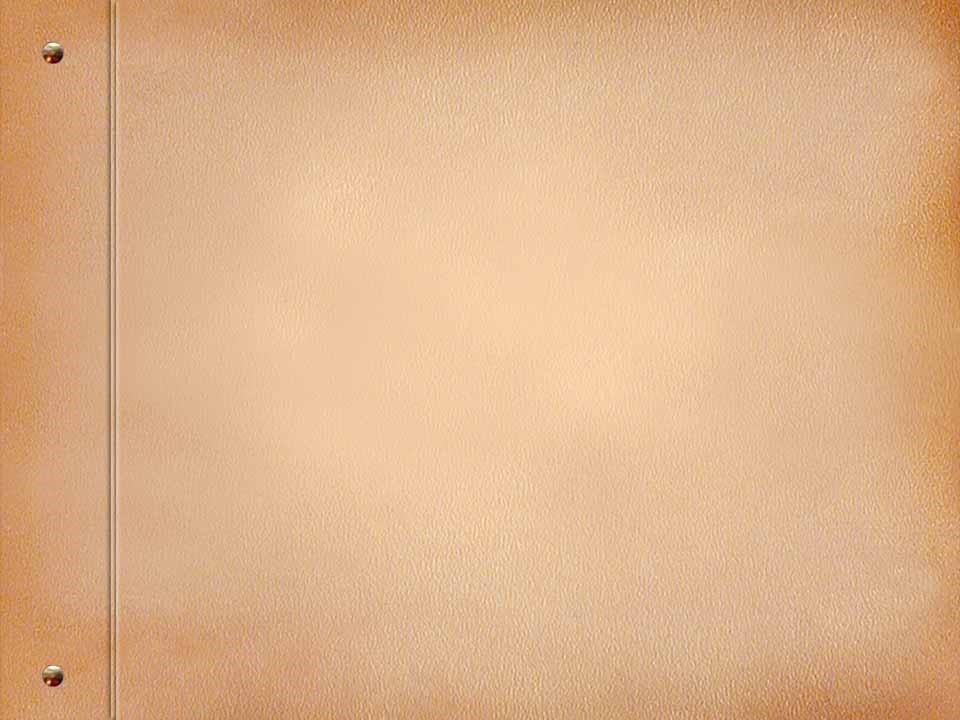
**75.1**

–

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\_2b6cCfUKcjVt

UKiwmKE87w\_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

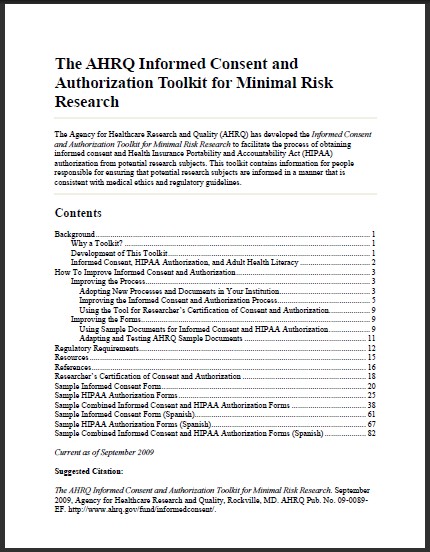
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Appendix E: Repository of Readability References

and Resources



**Resources**



**Resources**

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**AHRQ Informed Consent and**

**Authorization Toolkit for Minimal Risk**

**Research**

–

Authored by the Agency for Healthcare Research

and Quality (AHRQ)

–

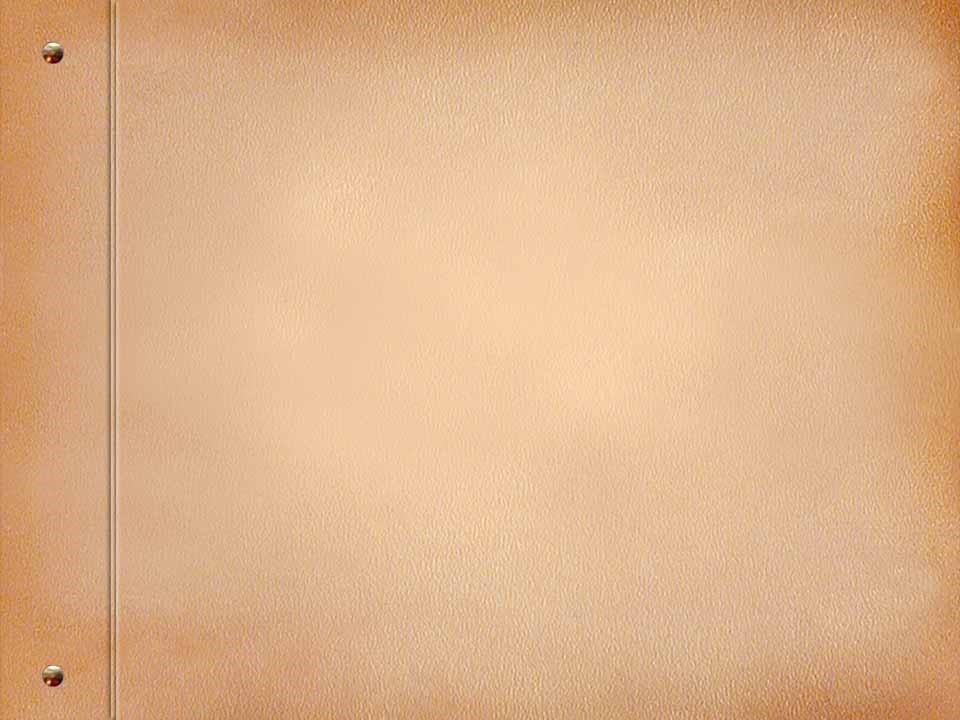
Copyrighted, public domain resource that you may

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

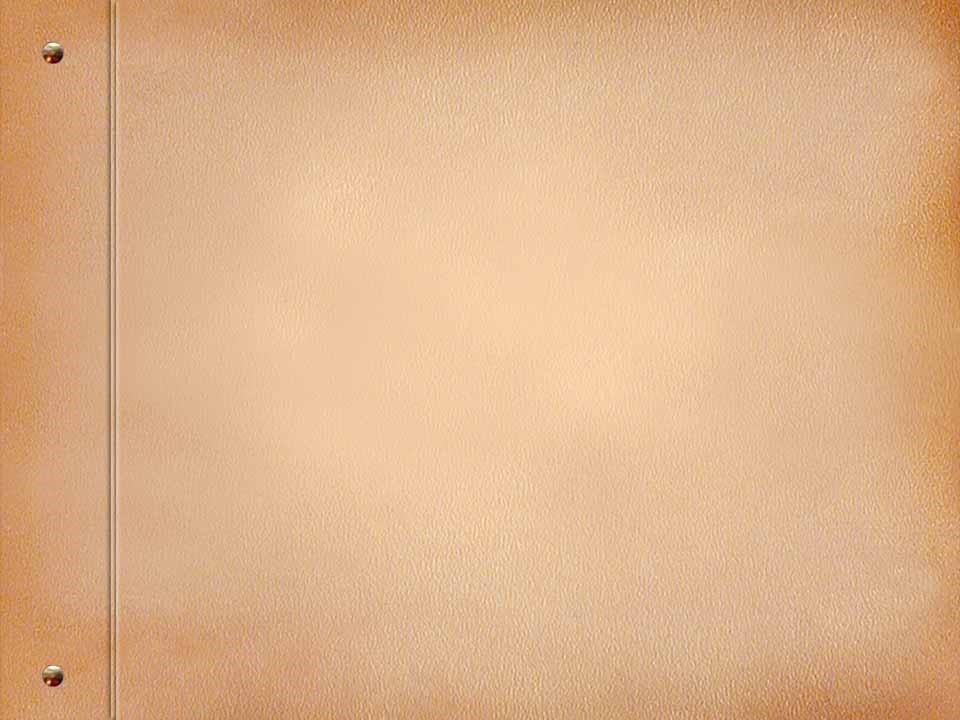
document

–

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