Informed Consent Workshop

Part 1: The consent form

The Belmont Principles

Respect for Persons

Justice

Beneficence

The Nuremberg code (1949; emphasis added):

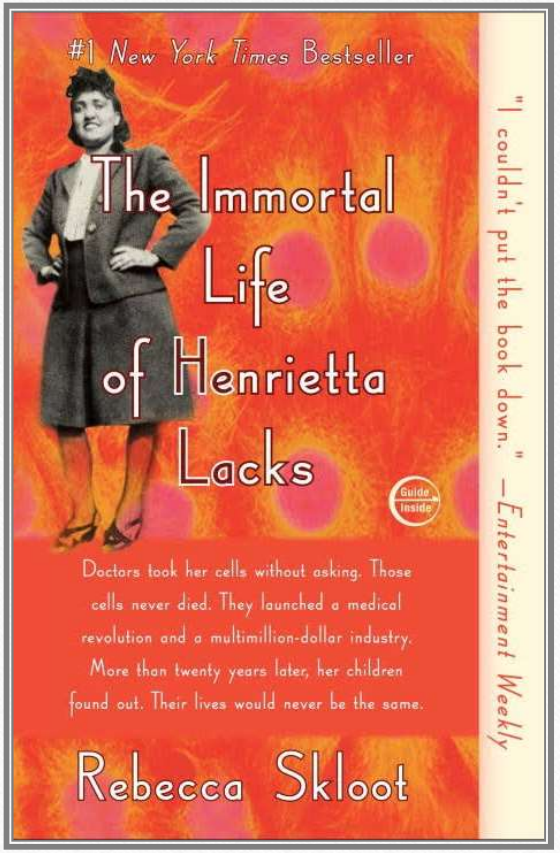
1. **The voluntary consent of the human subject is absolutely essential.**

   This means that the person involved should have legal capacity to give consent; should be so situated as to **be able to exercise free power of choice**, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; **and should have sufficient knowledge and comprehension** of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, **there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person,** which may possibly come from his participation in the experiment.

   The duty and **responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.** It is a personal duty and responsibility which may not be delegated to another with impunity.

Why is informed consent important?

Lessons from Henrietta Lacks



Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

- Researcher Susan Hsu: "We come to draw blood to get HLA antigen, we do genetic marker profile because we can deduce a lot of Henrietta Lacks genotype from the children and the husband."

- Day Lacks: "They said they got my wife and she part alive […] They said they been doin experiments on her and they wanted to come test my children see if they got that cancer killed their mother."

Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

- Hsu: "They are very receptible [sic] to us when I made phone call. They are pretty intelligent. I think Mr. Lacks pretty much already knew that his wife made a contribution and are very aware of the value of HeLa cells. They probably heard people talking that the cell line is such important thing. Everybody talking about HeLa back then. They are a very nice family, so they very nicely let us draw blood."

- "[Day] did what he'd always done when he didn't understand something a doctor said: he nodded and said yes."

Barriers to Informed Consent

Barriers to Informed Consent

- Language
- Education
- Backgrounds
- Follow-through and Contact information
- Lack of cultural / interpersonal empathy and understanding

Lessons from Henrietta Lacks

Example from *The Immortal Life of Henrietta Lacks* (pp 182-90):

"I feel very bad," she said. "**People should have told them**. You know, we never thought at that time they did not understand. […] Just tell them I'm really grateful […] **They should be very proud** of the mother or the wife – I think that **if they are angry probably they didn't realize** how famous the cells are now in the world. It's unfortunate thing what happened, **they still should be very proud**, their mother will never die as long as the medical science is around, she will always be such a famous thing. […] **If they are willing, I wouldn't mind to go back and get some more blood**." (emphasis added)

Requirements for Informed Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. **The information that is given to the subject or the representative shall be in language understandable to the subject** or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Source: 45 CFR 46

http://uwm.edu/irb/consent-form-templates/

How to write

Rules from an English professor

(With edits from an IRB professional)

Rules to follow

- Always consider your audience when writing.
- Watch grammar and spelling.
- Avoid run-on sentences. Use short sentences that get to the point. Once you've made your point, stop your sentence. Start a new sentence if you still have more to say.
- Sometimes less is better.

Rules to ignore

- ✗ Write in a formal tone.
  - ✓ Write like you would talk.
- ✗ Don't use "you" or "I" or "we"
  - ✓ Use pronouns. Extensively.
- ✗ Assume that your audience has the same level of knowledge/expertise that you do.
  - ✓ Nope. Only if your research subjects have advanced degrees in your field.
- ✗ Use present tense.
  - ✓ Only when it makes sense. Future tense will be more common.

My own addition

- Use the “grandma test”

Federal Plain Language Guidelines

http://www.plainlanguage.gov

- Avoid technical language
- Write short sections with only one topic per section
- Write short sentences
- Use active voice
- ~~Utilize~~ Use the simplest form of a verb
- Include examples
- Include only information that is relevant to your audience
- Use question/answer format
- Minimize abbreviations
- Use contractions (don't instead of do not)
- Instead of paragraphs, try using:
  - Bullet points
  - Lists
  - Tables
  - Pictures and illustrations

Examples of good consent documents

Sample text 1

You are being asked to be in a research study. You can choose to be part of this study. You can choose not to be in the study. You can leave this study at any time.

What will be studied?

The medications you are taking, your trust in the medical system, and family caregiving

Why is this study being done?

Medications that people take affect their health and illness. Nurses need to know more about the issues that can affect medication-taking in African American women

What are the goals of the study?

To learn how to better care for African American women

Where is the study being done?

At HealthClinic and FirstChurch

How many subjects will be in the study? 110

How much time will the study take?

Two meetings. One for about 30 minutes and two weeks later a second meeting for about 1 hour

Sample text 2

What will I be asked to do if I participate in the study?

If you agree to participate here today you will be asked to answer the questions on the survey truthfully. I would like to record your answers because, as a non-native speaker of Portuguese, I want to be able to listen to your responses again in order to make sure I am using them correctly in my project. If you are not comfortable being recorded, that's okay, too. You can still participate and I will take notes instead of using a recording.

Sample text 3

You are being asked to participate in a research study. Your participation is completely voluntary. You do not have to participate if you do not want to.

Study description:

This study is using a custom built oximeter device similar to those commonly used in hospital settings. This device was built by the student principal investigator for his research. The device will use LEDs to send light into your leg and measure the levels of light that exit the leg at a fixed distance from the source.

This study is being conducted to determine how the metabolism responds to changes in elevation and moderate amounts of exercise. In order to perform these tests an experimental probe will be applied to your body.

If you agree to participate in this study you will be one of twenty individuals who will be asked to do so. You will randomly be assigned to one of two subject pools separated by whether they are performing the exercise while standing or being in a prone position.

This study will be performed in the 8th floor CEAS laboratory.

You will only be asked to perform this study a single time. The study will be conducted during an hour long period.

Examples of … less-than-fabulous consent documents

Sample text 1

Audience: Patients at a public STI clinic

The purpose of this research study is to understand patients' opinions and attitudes of partner notification for sexually transmitted infections (STIs) to develop an intervention to promote partner treatment and reduce repeat infections. Approximately 5 participants will participate in this phase of the study, all at the clinic. If you agree to participate, you will be asked to respond to questions or statements about your opinions and knowledge about potential clinical care you could receive at the STI clinic, attitudes and opinions of partner notification, and barriers and facilitators to your ability to notify sexual partners if you were diagnosed with an STI. This interview will take approximately 90 minutes of your time in a private room at the clinic.

Rewrite 1

If you have an STI (sexually transmitted infection) and take medicine for it, but your partner doesn't take the same medicine, you can get re-infected from him or her. We want to find out why people sometimes don't tell their partners when they have an STI, or why the partner doesn't get medicine. This will help doctors keep people from getting re-infected.

We will interview 5 people at the clinic. You don't have to have an STI to be in the study. The interview will be in a private room and will take about 90 minutes. We will ask you questions about:

- what you know about the medical care available at the STI clinic
- your opinions about the medical care options
- your thoughts on telling partners about having an STI
- things that made it easier or harder to tell a partner about your STI, if you've had one

Before and after 1

- Word count: 120
- Characters: 648
- Sentences: 4
- Words per sentence: 30
- Characters per word: 5.3
- Flesch-Kincaid Grade Level: 17.8

- Word count: 148
- Characters: 662
- Sentences: 6
- Words per sentence: 16
- Characters per word: 4.3
- Flesch-Kincaid Grade Level: 7.1

Sample text 2

Audience: Women about to be released from prison

The purpose of this study is to help incarcerated women with successful, supportive reentry into the community upon release. A primary goal of this project is participants' increased willingness and ability to seek services that improve their transition from jail into the community. The overall goals of the project are to reduce recidivism as well as help women find and obtain the resources they need to reestablish their lives.

Rewrite 2

The purpose of this study is to help women in jail successfully re-enter the community upon release. We will do this by supporting you in the days before and after you leave jail. We want to help you find services that improve your transition from jail back into the community.

Our overall goal is to reduce the chances of women returning to jail and to help women get the resources they need to reestablish their lives.

Before and after 2

- Word count: 69
- Characters: 363
- Sentences: 3
- Words per sentence: 23
- Characters per word: 5.2
- Flesch-Kincaid Grade Level: 13.7

- Word count: 76
- Characters: 345
- Sentences: 4
- Words per sentence: 19.0
- Characters per word: 4.4
- Flesch-Kincaid Grade Level: 9.0

Sample text 3

Audience: 3rd-5th graders

- You will fill in a questionnaire which consists of your demographic information and information resource uses (10 minutes).
- You will fill in a questionnaire which consists of questions on George Washington (10 minutes).
- You will fill in a self-assessment which consists of questions on how you are familiar with the subject of George Washington (5 minutes).
- You will conduct two search tasks including audio / video recording using Google and Kids.gov sites (40 minutes).
- You will be interviewed about your search experience and perceptions of the system features (15 minutes)

There is no serious risk occurring for you in participation in the research. You will be observed while performing searches and your search performance, computer monitor screen and voice will be recorded.

Rewrite 3

If you agree to be in this study, you will:

- Answer questions about yourself and how you find information online (10 minutes).
- Answer questions about George Washington (10 minutes).
- Tell us what you already know about George Washington (5 minutes).
- Use a computer to find out information on two different websites: Google and kids.gov. We want you to use videos and sound recordings to help find the information (40 minutes).
- Tell us how you felt about using these websites to find information online.

We don't know of anything bad that could happen if you are in this study. We will watch you and record the computer screen while you do the online searches. We will also record our conversations so we can listen to them again later.

Before and after 3

- Word count: 121
- Characters: 660
- Sentences: 6
- Words per sentence: 17.5
- Characters per word: 5.2
- Flesch-Kincaid Grade Level: 11.2

- Word count: 127 (140)
- Characters: 604 (651)
- Sentences: 9 (13)
- Words per sentence: 13.0 (10.4)
- Characters per word: 4.7 (4.5)
- Flesch-Kincaid Grade Level: 8.0 (6.1)

Sample text 4

You must agree to be audio recorded or you may not participate in the study.

Rewrite 4

We need to record everyone who is in the study. If you don't want to be recorded, you shouldn't join this study.

Your turn …

https://xkcd.com/simplewriter/