MAKING YOUR CONSENT FORMS READABLE

The Why and the How

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Presenter

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Agenda

- What is Informed Consent?
- A bit of history: The purpose of Informed Consent
- What's required in an Informed Consent document
  - U.S. Federal regulations
- Hints and tips for making informed consent informed
  - Population considerations
  - Consent document considerations
  - Consent process considerations
- Summary

What is Informed Consent?

- Simple definition (medical): a formal agreement that a patient signs to give permission for a medical procedure (such as surgery) after having been told about the risks, benefits, etc.
- Full definition (medical): consent to surgery by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved.

Source: Merriam-Webster dictionary (http://www.merriam-webster.com/dictionary/informed%20consent)

A Bit of History
Regarding Informed Consent

- Numerous research studies either did not ask permission of the subject OR provided inadequate information for the subject to make a decision with their best interest in mind
  - Holocaust
  - PHS Syphilis Study
  - Willowbrook Study

- Led to codification of informed consent in ethical guidelines and regulations regarding human subjects research
  - Nuremberg Code: “The voluntary consent of the human subject is absolutely essential[1]”
  - Belmont Report: Respect for Persons[2]

1. The Nuremberg Code. "Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949. Credit: https://history.nih.gov/research/downloads/nuremberg.pdf
2. United States. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Bethesda, Md.]: The Commission, 1978. Credit: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#xrespect

U.S. Federal Regulations on Informed Consent

45 CFR 46.116

- Unless otherwise allowed and approved, “no investigator may involve a human being as a subject in research… unless the investigator has obtained the legally effective informed consent of the subject…”

- Unless otherwise allowed means
  - Waiver of informed consent
    - Specific criteria must be met (listed in 45 CFR 46.117)

Requirements for Informed Consent

45 CFR 46.116

- The prospective subject should have sufficient opportunity to consider whether or not to participate
- The possibility of undue influence and coercion must be minimized
- **Information provided must be in a language understandable to the subject**
- No exculpatory language which waives or appears to waive the subject's legal rights
- No language which releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence

Elements of Informed Consent (45 CFR 45.116)

Basic Elements (Required)

- Statement that the study involves research
- Purpose(s) of the research
- Expected duration of the subject's participation
- Description of the procedures
  - Identification of any experimental procedures
- Reasonably foreseeable risks or discomforts to the subject
- Benefits to the subject or to others reasonably expected
  - NOTE: Payment is NOT a benefit
- Appropriate alternative procedures or courses of treatment, if any
- Record confidentiality
- Greater than minimal risk research: Compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Contact information for research questions
- Contact information in the event of a research-related injury to the subject
- A statement that:
  - Participation is voluntary
  - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
  - Subject may discontinue participation at any time without penalty or loss of benefits to which otherwise entitled

Additional Elements (As Applicable)

- 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
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's consent
- Additional costs to the subject from participation
- Consequences of a subject's decision to withdraw from the research
- Procedures for orderly termination of participation by the subject
- 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
- Approximate number of subjects in the study

That's a lot of Information…

- Many institutions/IRBs require additional language
  - Institutional "boilerplate"

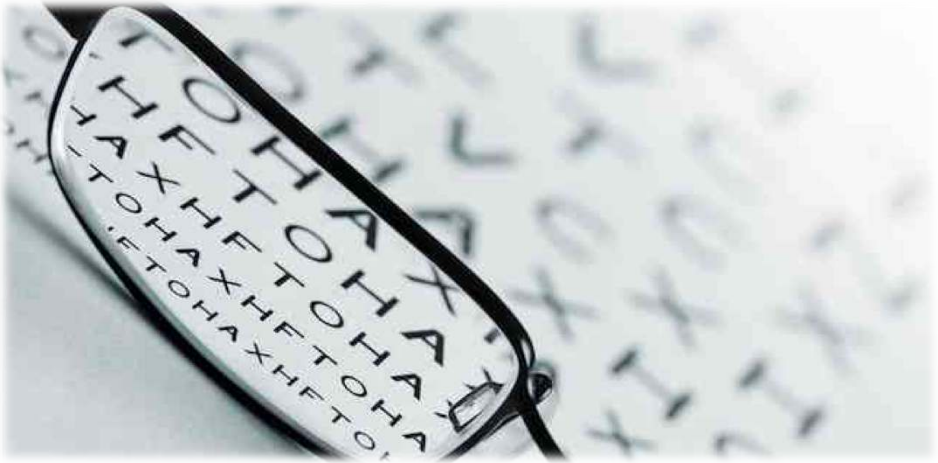
- Not uncommon to see consent form documents over 15-20 pages to fit all the "necessary" information

- Despite all this information, remember:

THE CONSENT FORM IS NOT A LEGALLY BINDING CONTRACT!

Actually…

- The consent form does not guarantee informed consent
- Consent is bigger than the document
  - Communication between the researcher and the subject
  - An ongoing process
    - Doesn't end when the document is signed
- Think of the consent form document as a reference
  - "Everything you wanted to know, but were afraid to ask"



We are still required to have a document, so how do we make it more useful to the prospective subject?

CONSENT FORM READABILITY

Know thy Subject Population!

- Consider who your target population
  - Age
    - Example: Talking to kindergarteners is much different than college students (or their parents)
  - Gender/Sex
  - Economic status
  - Culture
    - Race, ethnicity, geographic location, self-identity
  - Education level
  - Occupation
    - Example: Non-health care professionals are different than practitioners
- The average American is **not** health-literate
- The average American is **not** proficiently literate in reading and/or interpreting documents[1]
  - 50% of Americans cannot read at an 8th grade level[2]

[1] http://nces.ed.gov/NAAL/PDF/2006470.PDF
[2] http://literacyprojectfoundation.org/community/statistics/

American Health Literacy

Source: U.S. Department of Health and Human Services

- "Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." [1]
- Only 12% of Americans are proficient in health literacy[2]
  - Example: Using a table, calculate an employee's share of health insurance costs for a year
  - Additional 53% have intermediate proficiency
    - Example: Read instructions on a prescription label, and determine what time a person can take the medication
    - 35% of the population cannot even interpret a prescription label properly!
- Varies greatly based on race/ethnicity, age, insurance source, and education

[1] http://health.gov/communication/literacy/quickguide/factsbasic.htm

[2] http://health.gov/communication/literacy/issuebrief/

Take-away point

For your average study, your consent form should be understandable to a middle schooler!

Making the Actual Form Readable

That's all well and good, but how do I actually DO that?

- Write the consent form with your grandparent in mind
  - Many studies target older Americans, who, statistically, have a harder time comprehending more complex documents AND health information
- Even if it takes a few more words, replace large words with smaller ones
- Minimize acronyms
  - There is a lot of new information in a consent form, don't make more if it isn't necessary
- Use pictures to help illustrate concepts

Heart Failure

An example

- Consent form: You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE). This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.

  - Flesch-Kincaid reading level: 14.4 (College level)
  - Flesch-Kincaid reading ease: 36.6 (Difficult)

- What information are we trying to convey?

Breaking it Down

What information are you trying to convey – Main Points

- You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE).
  - A TTE is going to be done twice during the study
  - Pre- and post- treatment
- This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.
  - Minimal risk procedure (no radiation)
  - Why: measure heart function
  - Purpose: see if the intervention did anything

Breaking it Down

What words can be simplified?

- You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE). This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.

  - Undergo
  - Pre-study, post-treatment
  - Transthoracic
  - Echocardiogram
  - Ultrasound
  - Utilize
  - Radiation
  - Intervention
  - Any others?

Breaking it Down

What information is superfluous?

- You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE). This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.
  - Is transthoracic necessary?
  - What about acronym (TTE)?
  - Do we need to mention heart function twice in the second sentence?

Breaking it Down

Sentence structure

- DISCLAIMER: I am not a linguist
- You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE). This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.
  - Do we need to summarize this information in only two sentences
  - Lots of parentheses!

Heart Failure

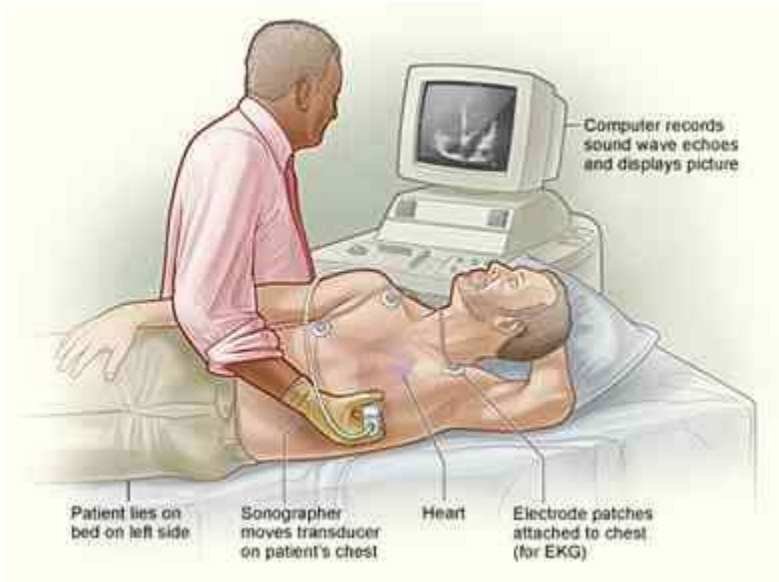
An example

- Consent form: You will be asked to undergo a pre-study (2 weeks before treatment) and post-treatment (6 weeks after treatment) transthoracic echocardiogram (TTE). This ultrasound of the heart does not utilize radiation to measure your heart function and will be used to determine whether your heart function improved after the intervention.
  - Flesch-Kincaid reading level: 14.4
  - Flesch-Kincaid reading ease: 36.6 (Difficult to read; College)

- My version: In this study, we will measure your heart function twice. This will be done 2 weeks before and 6 weeks after we give you the study medicine. The test we will use is an echocardiogram. This is also known as an TTE. This test does not use radiation and has few side effects. We want to use this test to see if your heart function changed with the study medicine.
  - Flesch-Kincaid reading level: 4.4
  - Flesch-Kincaid reading ease: 83.8 (Easy to read. Conversational English for consumers; 6th grade)

What else could we do?

In this study, we will measure your heart function twice. This will be done 2 weeks before and 6 weeks after we give you the study medicine. The test we will use is an echocardiogram. This is also known as an TTE. This test does not use radiation and has few side effects. We want to use this test to see if your heart function changed with the study medicine.



OTHER CONSIDERATIONS FOR CONSENT FORM READABILITY

Stand Up for the Subject's Understanding

- If the content does not add to the subject's understanding of the research, challenge its inclusion!
- Regardless of who is requesting the addition
  - Other investigators
  - Sponsor
  - Institution
  - IRB
- Ask for rationale to include the information
- If necessary/required, simplify the language as much as possible

Document Organization

- Place important information up front
  - People more likely to remember it
  - Easy access for referencing later
  - *Consider*: A quick reference on the front page with summary facts about the research
- What is key (my opinion only)
  - Why is this research being done?
  - What are you doing?
  - What are the risks?
  - What are the benefits?
- Appendix the “fine print” after the key components

How Do I Know My Document is Sufficient?

A few tips and tricks

- **Good:** Word processor built-in readability statistics
  - A good guide, but not sufficient in and of itself
  - Based on number of letters in a word and number of words in a sentence
- **Better:** Fellow researchers/colleagues – good for peer review
- **Better:** Ask your IRB (or English/Linguistics department, if available)
- **Best:** Focus groups – have people (not prospective subjects) read the form and comment
  - Target population
  - Middle or high schoolers – if half the population is reading at this level, why not have the real thing test it out
- Comment
  - Circle words that are unknown
  - Highlight areas that they do not understand
  - Quiz them on their understanding of the study

Consent is More Than a Document

Remember the process

- Consent conversation
  - Script out talking points
  - Ask questions of the prospective subject to gauge understanding
    - Why are we doing this study?
    - What are the possible side effects?
    - How long will you be in this study?
    - If you want to stop part way through this study, can you?
  - Include caregivers, support structure (e.g. spouse, adult children), if possible
  - *Strongly* encourage the prospective subject to take the consent form home to think about participation
    - Sometimes not possible

Other Options for the Consent Process

- Visual aids to use in-office
  - 3D structures of devices, anatomy
    - Particularly useful in surgical interventions
  - Learning videos of key procedures
  - Interactive apps for consent understanding
- Visual aids for the prospective subject to take home
  - Calendar of events
  - Reputable websites describing the research, disease, and/or procedures

Summary

- Consent is a critical component of ethical human subjects research
  - Key element in all ethical guidelines and required by federal regulations
- The average American is not health literate nor do they have a college-level reading ability
- Consent is more than a document, it is a process
  - The consent document is a powerful tool in subject understanding
- Utilize language and terms familiar to the subject, pictures, diagrams, and white space to make the consent document readable
- Minimize superfluous information
- Organize the document to put the “must-knows” up front
- Utilize supplementary aids in the consent process

THANK YOU

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