Peaels Raed Tihs

Mnay of yuor sbjuctes cnaont raed wlel euongh to uesdnatnrd yuor csneont fmros! Waht are you gniog to do aubot it?

If you hraed me tlak aubot lticarey and ifronemd cnsonet lsat yaer paesle rsiae yuor hnad (dno't wrroy I hvae ltos of new stfuf).

Informed Consent: Moving from Readability to Comprehension

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The AHRQ Informed Consent and Authorization Toolkit

D R A F T D R A F T

Subjects' Testing - 1:1 and Focus Groups:
Tucson, Boston, Waukegan, Baltimore, Atlanta

Professional Audience - Delphi Panel, interviews

Where we have come from

- “If suitably approached, patients will accede, on the basis of trust, to about any request their physician may make”

  – JAMA. 1966 Jan 3;195(1):34-5.

Current Consent Standard

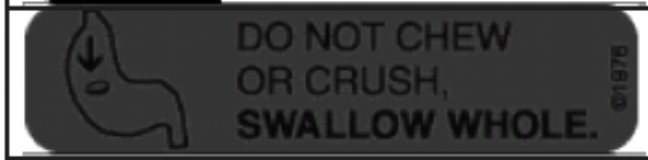
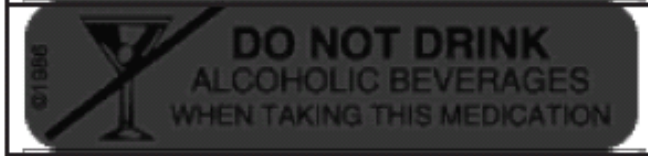
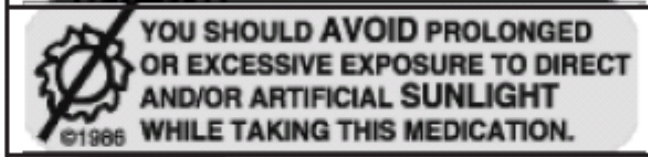
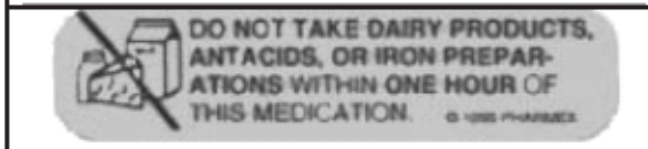
- Ethical Guidelines
- Federal Law
- And yet – consistently observed that many subjects not familiar with core principles of informed consent

Adult English Literacy in the US

- Average reading level in US: 8th – 9th grade
- National Adult Literacy Survey (NALS, 1992)
  - Over 90 million Americans had inadequate functional literacy
- National Assessment of Adult Literacy (NAAL, 2003)
- Prevalence across 85 medical studies:
  - 26% low health literacy
  - 20% marginal health literacy
  - More common among elderly, minorities, immigrants, chronic disease

– Paasche-Orlow, JGIM 2005


TRIAGE CENTER
ENTER
NEXT DOOR
⇐

Labels	Misinterpretations
	Don't take food
	Chew pill and crush before swallowing Chew it up so it will dissolve, don't swallow whole or you might choke Just for your stomach
	Don't take when wet Don't drink hot water Don't need water
	Don't drink and drive Don't drink alcohol, it's poison and it'll kill you
	Use extreme caution in how you take it Medicine will make you feel dizzy Take only if you need it
	Don't leave medicine in the sun Don't leave [medicine] in sunlight, but a cool place
	Keep medicine chilled Mix it well, discard when done
	If allergic to dairy, don't take medicine Don't eat for one hour after taking medicine

Davis et al, JGIM 2006; 21: 847-51

Focus Group Quote

- But it's like she said, there are people that show up and just want you to sign the paper, or something like that and I feel…If I'm given the opportunity to read it, and be well-informed, well, then…I would rather read it first, and know what I'm going to do, BEFORE making a mistake. Before saying yes. That is why you would probably not usually sign…But, sometimes, it's rushed, when you're being told you have to complete something, and sometimes I haven't read what I have signed.

Readability and the IRB

- Federal Statutes mandate that IRBs ensure that Informed Consent Forms are written in language subjects can understand (§**46.116, 50.20)**.
- IRBs must approve individualized informed consent forms for each study.
- IRBs often present language templates and/or sample documents to direct investigators.
- IRBs often present language standards for informed consent forms.

Readability and Liability

- **In the research setting readability has been used to negate the power of an executed ICD**
  - **In 1999, after 10 years of legal maneuvering, the University of South Florida and Tampa General Hospital agreed to a $3.8M settlement of a lawsuit brought on behalf of clinical trial subjects.**
  - **The plaintiffs maintained that the informed consent document for the study was written at a grade level that significantly exceeded the reading ability of the class – and this became a key issue in the settlement.**

Informed Consent Form Readability Standards vs. Actual Readability: A Survey of U.S. Medical School Institutional Review Boards

- Relevant data were extractable from 114/123 (93%) medical school websites examined.

  – Paasche-Orlow, NEJM 2003

Readability Standards

- Grade Level Standards in 61/114 (54%): Range 5th-10th (mode 8th) grade.
- Descriptive guidelines in 47/114 (41%): "in simple lay language"
- No language guidelines in 6/114 (5%)

Examples: Voluntary Nature of Participation

"You don't have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care." (4th)

"You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University."

(College)

Examples: Benefits (When there are none)

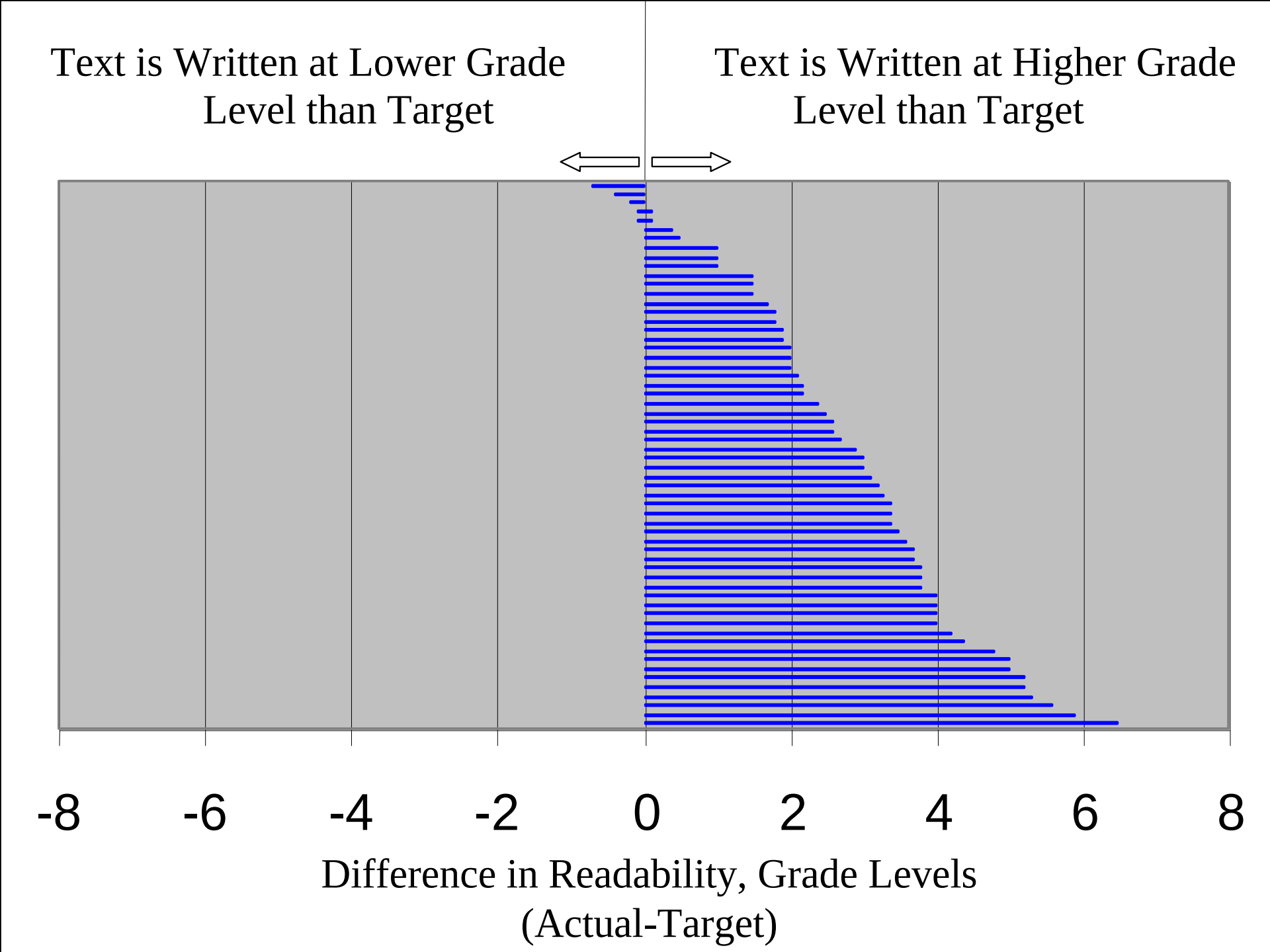
There is no benefit to you from being in the study. Taking part in this study may help patients in the future. (4th)

"There may be no direct benefit to me, however, information from this study may benefit other patients with similar medical problems in the future." (12th)

"The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study." (College)

Observed Readability of Template

- Mean Flesch-Kincaid grade level was 10.6 (95%CI: 10.3 to 10.8).
- Presence of a specified grade level standard did not influence Flesch-Kincaid grade level (10.7 vs. 10.5, P=0.10).
- In schools with specified grade level standards:
  - 5/61, 8% (95% CI: 3 to 18%) met their own standard
  - Mean of 2.8 (2.4 to 3.2) grade levels higher, P<0.001.


Text is Written at Lower Grade Level than Target
Text is Written at Higher Grade Level than Target
-8
-6
-4
-2
0
2
4
6
8
Difference in Readability, Grade Levels (Actual-Target)

IRB Readability Conclusions

- IRBs do not meet their own readability standards.

Compensation for Research Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. If your part in this study takes place at Boston Medical Center, you can get treatment for the injury at Boston Medical Center. If your part in the study is not at Boston Medical Center, ask the investigator where treatment for injury would be available locally. You and your insurance company will be billed for this treatment. Some research sponsors may offer a program to cover some of the treatment costs which are not covered by your insurance. You should ask the research team if such a program is available.

(9th grade)

Paasche-Orlow MK, Brancati FL. Am J Med. 2005 Feb;118(2):175-80.





(Cut to Ezra's room. Cameron enters.)

Ezra: What do you want?

Cameron: House wants to biopsy your skin; he sent me to get it.

Ezra: [With slight surprise.] Oh. And you agreed.

Cameron: I had nothing to do with putting you in a coma or any of the subsequent tests.

Ezra: Which brings us to now.

Cameron: I read some of your articles.

Ezra: There were a lot of them.

Cameron: 1967 Massachusetts Medical Journal. You radiated babies. Just like that. No forms, no questions, nothing. Who knows how many cancers you caused.

Ezra: I don't know. What I do know is we discovered techniques that prevent fatal kidney failures in hundreds of thousands of other kids.

Cameron: You're not sorry.

Ezra: I don't regret what I did. Informed consent, patient rights - holds back research. [Cameron takes the tool to get the sample and slices Ezra, who groans in surprise and pain.] What the hell are you doing?

Cameron: Informed consent is holding back our diagnosis.

Ezra: Good for you. Finally standing up for something; acting on what you believe.

(Cut to clinic. House pops a Vicodin.)

Readability: Text Recommendations

- Familiar Words
- Define Jargon
- Consistency
- Short Sentences
- Simple Sentences
- Line limit = 50
- One idea/paragraph
- Personal Pronouns
- Second Person
- Active voice - i.e., the subject is the doer of the act

Readability: Text Recommendations

simple outlines, flow charts, diagrams, study schemas, calendars, and other graphics

- Underline, bold, or boxes (NOT IN ALL CAPS *and not in italics*) to give emphasis.
- Layout balances white space, words, and graphics.
- Left margins are justified. Right margins are ragged.
- Upper and lower case letters are used.
- Style of print is easy to read. Only one style.
- Type size is at least 12 point.
- Readability analysis

Readability: Text Recommendations

- Logical sequence
- Visually organize
- Break up large text blocks

- Avoid when possible
  - More than 3 syllables
  - Abbreviations and acronyms
  - Long lists

Avoid writing to the formula

Subjects at all levels of literacy have better Satisfaction, comprehension, and retention with Simple ICD

Sample Introduction

- We are asking you to be in a research study.
- **You do not have to be in the study.**
- **You can quit at any time.**
- Your choice will not change your regular medical care in any way.
- Please take all the time you need to make your choice.

What happens if I say yes, I want to be in the study?

- If you say yes, we will:
  - Ask you a lot of questions.
  - The questions will be on a form you fill out.
  - If you want, we can read the questions out loud and fill out the form with you.
  - We will ask about [describe survey items, e.g., your health, what you eat, and whether you exercise, smoke, or drink alcohol, and what medicines you take].

Focus Group Quote

- That was scary. But, you prefer to be told but not using so many words.
- People can say yes or no. They're not in obligation…It's their decision…It's better than having some fine print at the bottom.
- Miniature writing is not trustworthy.

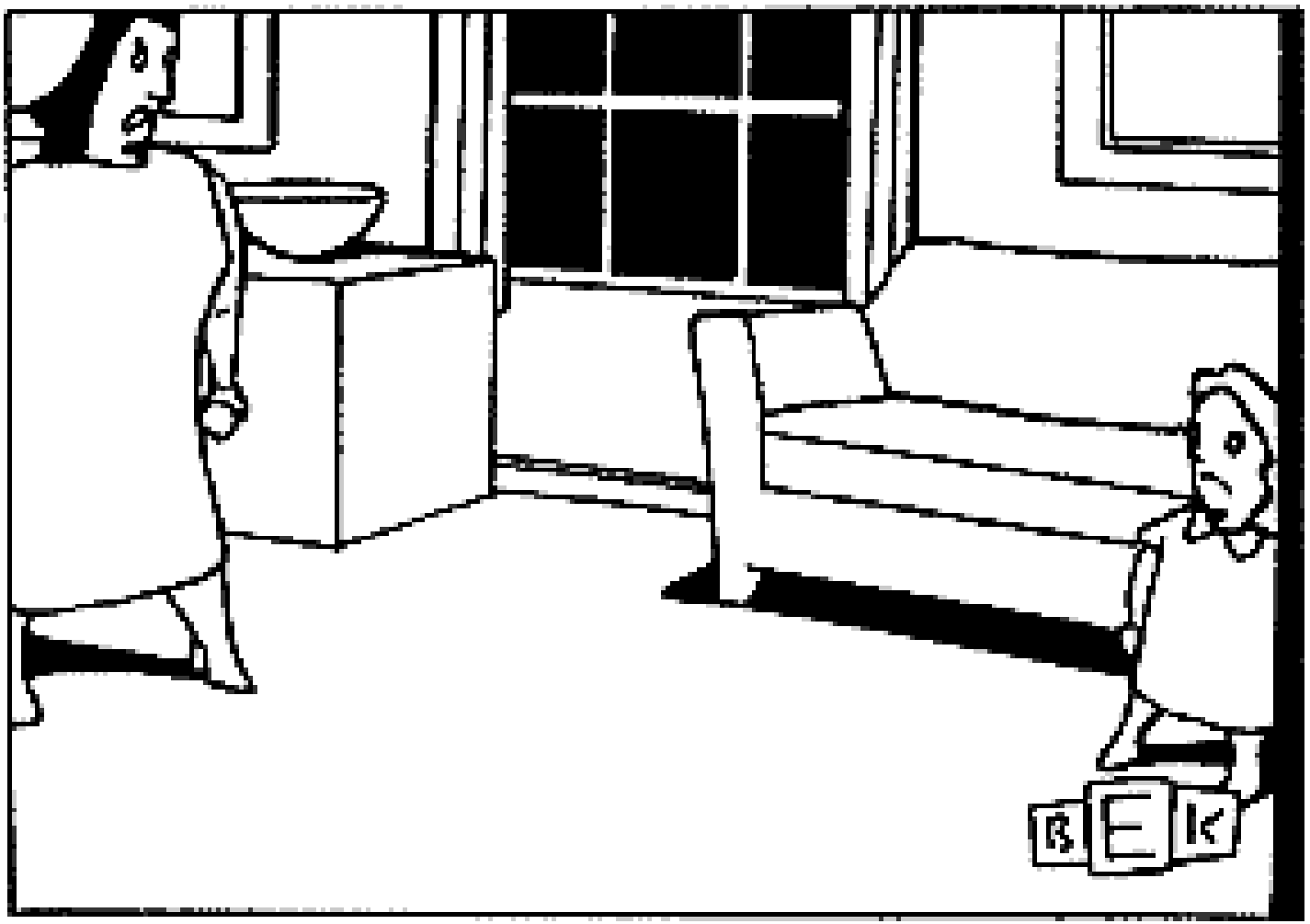
Consent Process not Consent Form

- The task is HARD
- AND Yet – cynical not to try to do better
  - Subjects do POORLY on comprehension tests
- Liability (target of private action and Regs)
- Doing a better job with the ICD can:
  - Facilitate the process
  - Cue the potential subject to engage
  - Cue the research staff to do a good job
  - Effect recruitment? Retention? Subsequent legal action – empirical questions to be sorted out

Asking Questions in a Shame Society

- Iatrocultural tendencies
  - Difficulty admitting lack of understanding
  - Subtle assertions of dominance through knowledge
- Invisibile Problem
- Give cues to not ask questions
- Make continued education contingent on asking questions

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"Someday, you'll act like you understand."

Shame Society

- Parikh 1996: Pts w/ low health literacy who admitted having trouble reading when tested:
  - 67.2% had never told their spouses
  - 19% had never disclosed to anyone
- Many patients with reading problems are ashamed and hide their inability to read. Shame is a deeply harbored emotion that plays an important role in understanding how low literate patients interact with health care providers.

Focus Group Quotes

- I think in this way it's clear because it's not using really professional, big words that you get confused that you don't know what they're talking about; all medical words that the doctors use, or professional. You know, this is our level that we can understand.
- That's what we like. Because it gets very frustrating for all of us to go into, you know, a doctor's office or…You have to read those forms over and over and over again…
- And you never get the form signed. It can be frightening. It's like what does this mean? And then some people are scared to go back, and then you're so intimidated by that.

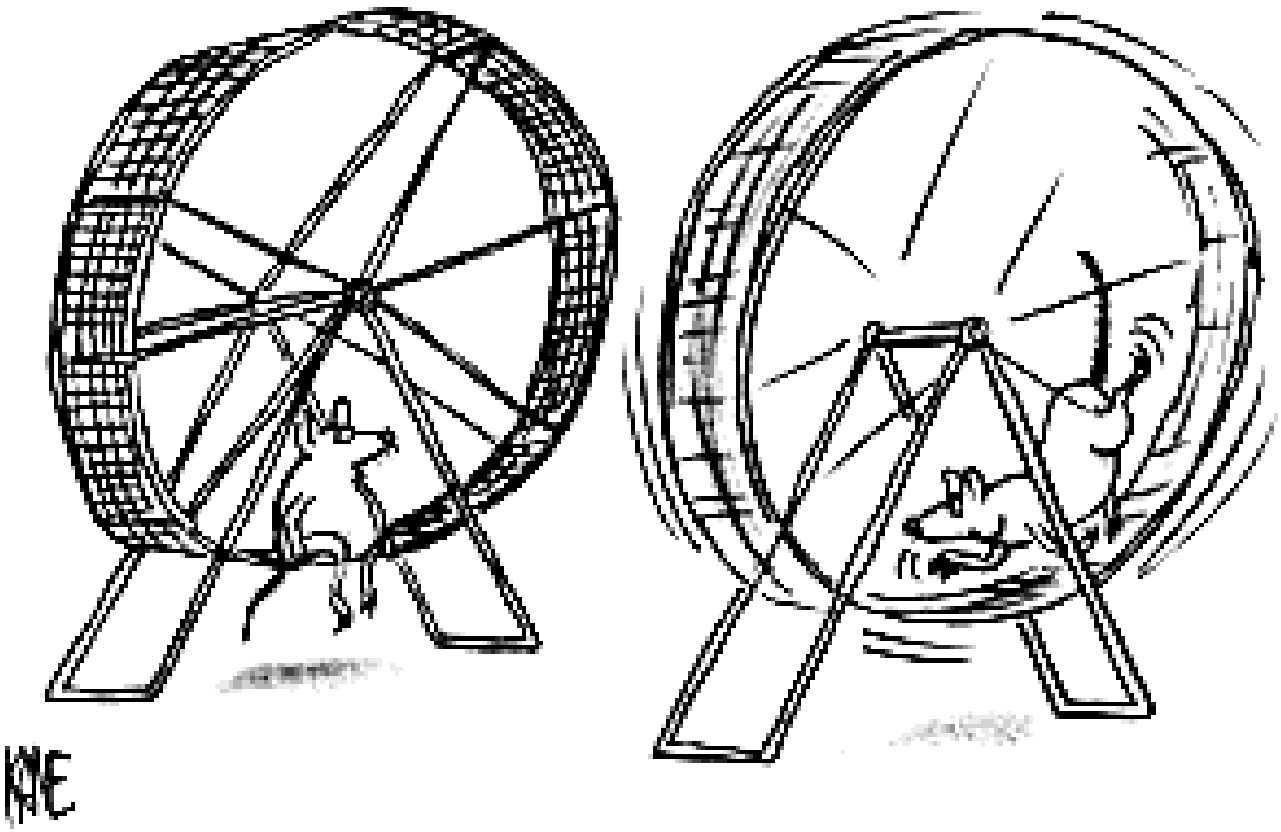
Process

- **Offer to read the document with all research subjects.**
  - Do not make any reference to reading ability. For example, the researcher could say, “Let’s read this document together,” or “If you like, I can read the document along with you to make sure all the information is clear.”

Process

- **Give the potential research subject time** to review the document. There should be no time pressure. When possible, subjects can be encouraged to take the document home and discuss their participation with family members, friends, and/or their primary care physician.

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"I had an epiphany."

Confirmation of Comprehension

- If you want a result you have to check it
- Teach-to-Goal, Teach-Back
  - Teach, assess, continue focued teaching until subject exhibits mastery.
- NQF – safety measure

Confirmation of Comprehension

- Shift goal of RA
- Shift culture of research recruitment
- Provide opportunity to monitor
- Only recruit folks who understand
- Helps shift from form to process
- Provide opportunity to revise process

Teach-Back: Part 1

- Start with phrases such as:
  - "I want to make sure we have the same understanding about this research."
  - "It's my job to explain things clearly. To make sure I did this I would like to hear your understanding of the research project."

Teach-Back: Part 2

- Make sure that the potential research subject has understood all the important elements of the study. Allow the potential research subject to consult the document when answering the questions.
- The purpose is to check comprehension, not memory.
- Listen for simple parroting; if a potential subject uses technical terms ask them to explain further.

Teach-Back: Part 2

Ask open-ended questions such as:

- **Goal of the Research and Protocol**

"Tell me in your own words about the goal of this research and what will happen to you if you agree to be in this study."

- **Benefits and Compensation**

"What do you expect to gain by taking part in this research?"

- **Risks**

"What risks would you be taking if you joined this study?"

- **Voluntariness**

"Will anything happen to you if you refuse to be in this study?"

Teach-Back: Part 2

- **Discontinuing Participation**

- "What should you do if you agree to be in the study but later change your mind?"
- "What will happen to information already gathered if you change your mind?"

- **Privacy**

- "Who will be able to see the information you give us?"

- **Contact Information**

- "What should you do if you have any questions or concerns about this study?"

Teach-Back: Part 3

- Correct any misinformation until potential research subjects indicate that they have understood by correctly answering all the questions.
- Make clear that the need to repeat is due to your failure to clearly convey the information rather than the “fault” of the potential subject.
- For example, you could say, “Let’s talk about the purpose of the study again because I think I have not explained the project clearly.”

Prior Related Studies

- Taub and Baker (1983) The effect of repeated testing upon comprehension of informed consent materials by elderly volunteers
- Embedded in a longitudinal study n=100
- 11-question test to all in EC, repeated up to 3 times w/ brief feedback on incorrect answers

The multi-trial approach improved comprehension scores at all vocabulary levels, but had no effect upon memory @ 2w.

Prior Studies

- Taub et al (1981) The elderly and informed consent: effects of vocabulary level and corrected feedback.

- Elderly volunteers Part of RCT n=87

- Research participants were given an 8-question test and received brief feedback on incorrect answers; total time for intervention was 15 min or less

Comprehension better @2w

Prior Studies

- Wirshing et al (1998) Informed consent: assessment of comprehension.

- Psychiatric patients n=49

- Research participants were tested and received brief feedback on incorrect answers until they were able to score 100%, then reevaluated for understanding 7 d later

- 31 closed and 5 open ended questions

  - 37% needed 3 or more rounds of testing
  - All improved from 1st to 7 day

Prior Studies

- Stiles et al (2001) Improving Understanding of Research Consent Disclosures Among Persons with Mental Illness.

- Mentally ill and healthy volunteers
- Simulated Randomized n=227

- Research participants were tested up to 3 times with a quiz and received brief feedback on incorrect answers

- Recall (15 point open test) as well as recognition (15 point multiple choice format)

Improved comprehension in all groups

Prior Studies

- Coletti et al (2003) Randomized, Controlled Evaluation of a Prototype Informed Consent Process for HIV Vaccine Efficacy Trials.
- Deficiencies in participant knowledge identified with Questionnaire (10 T/F items) and discussed with research participants; 3 such meetings occurred at 6-mo intervals

- Simulated Longitudinal n=3908

Participation in the prototype process was associated with substantial and sustained increases in knowledge across HIV risk groups, race/ethnicity, and educational levels

Prior Studies

- Sudore et al (2006) Use of a Modified Informed Consent Process Among Vulnerable Patients: A Descriptive Study
- Elderly volunteers n=204 part of RCT
- Simplified form, read to subject, then Teach-to-Goal
- 7 comprehension questions

28% answered questions 1st pass

80% after 2nd pass

4 subjects excluded (no mastery after 6 passes)

Questions about Confirming Comprehension

- Always? Or protocols that deserve special scrutiny?
- Nature of the Assessment:
  - Qualitative
    - standardization
    - skill set
    - time
  - Quantitative
    - Avoiding correct answers without comprehension (T/F)

Questions about Confirming Comprehension

- Test Burden
  - Subjects
  - Investigators
  - IRB Administrators
  - Specific for each protocol or generic?
- Automated creation of test?

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