JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

JOHNS HOPKINS | BERMAN INSTITUTE OF BIOETHICS

Informed Consent: How is it done and what works best?

Nancy Kass, ScD
Berman Institute of Bioethics and
Bloomberg School of Public Health
Johns Hopkins University

Introduction

- **The FDA and other federal agencies have regulations governing most human research**
  - Most research must be reviewed by an IRB
  - Most studies will require the voluntary informed consent of participants before enrolling
- **Informed consent regulatory requirements:**
  - *Disclosure:* Specific topics must be included in an informed consent disclosure/form (e.g., purpose, risks)
  - *Documentation:* The participant's willingness to enroll must be documented (usually through signed form)

Good news and bad news

- **Good news:**
  - Researchers know about informed consent requirements
  - A large body of research demonstrates what works and what doesn't work to improve understanding
  - Both NIH and FDA want informed consent to be in place and be meaningful; FDA guidance expressly encourages best practices
- **Bad news:**
  - There has not been much uptake of best practices in informed consent
    - This is an example of an "evidence to practice gap"

What do we know about how consent is done now?

- Consent forms have grown longer and longer
  - Lung cancer forms median 21 pages
  - Covid trial forms average 8333 words (± 17-18 pg)
- Length and complexity of forms *increases* for higher risk research studies

Understanding?

- Many participants do not understand *why* a study is being done or key procedures
- Sometimes not clear to people that they are in research (rather than receiving regular care)
- Three systematic reviews found that one of the **most challenging** concepts to understand is **randomization**

Empirically, what helps with understanding?

- Studies demonstrate ways to improve the consent **form**
- Studies demonstrate ways to improve the consent **process**
- **Bottom line:**
  - Research shows that simpler and shorter *consent forms* along with *more back and forth dialogue* improve understanding

What changes to consent forms improve understanding?

- Simpler language; using pictures to illustrate
- Shorter sentences; shorter forms
- Better formatting:
  - More bullets
  - More white space
  - Headers (including as questions)
- Summaries at beginning and end
- Emphasizing what is most important

7. Will my taking part be kept confidential?

- I will not use your real name in my work.
- I will lock the information away.
- This is to keep your information safe so that others can't take it.

Videos are helpful (and don't require clinician time!)

- Pre-appointment videos can help improve understanding
- Interactive phone or tablet presentations can improve understanding
- Participants have said they prefer video presentations to reading long forms
- One study found that consent information presented through a video results in more participants from underrepresented backgrounds, including those who are older, Black, or had lower education, being recruited and retained.

Helpful: More discussion and assessing what participants understand

- **More discussion consistently improves understanding**
- **"Corrected feedback": Ask participants a few questions and correct misunderstandings**
  - Quiz with immediate correction
  - Simple conversational questions (requires no preparation!)
    - "I've just given you a lot of information. Can you tell me yourself what will happen if you join the study, just so I know we've explained this well?"
  - Oral/open-ended even better than "quiz"

Evidence to Practice Gap in informed consent

- **Challenge:** We have known for decades that shorter and simpler forms, and more discussion, improve understanding
  - **And yet forms are getting longer and more complex**

- **Challenge: Why does that persist? What could help?**

Federal policy updates

- 2018: The Common Rule revision now requires "Key Information" to be presented at the top of all consent forms they regulate
- FDA has published guidance:
  - 2016: electronic consent guidance included language "may include diagrams, videos, narration…may contain methods to help…assess…understanding [such as] optional questions…to gauge subject comprehension of key study elements and highlight areas where the subject might need further explanation and discussion"

- FDA 2024: draft guidance on key information
  - Interested parties could consider developing alternate ways to present key information that would facilitate understanding by prospective subjets by, for example, consulting in advance with patient advocacy groups or prospective subjects…The key information could also be presented using alternative media, such as illustrations, video, and electronic tables, to meet the goals of improving clarity and increasing prospective subjects' understanding of consent information.

Considerations

- There seems to be agreement among participants, regulators, and professionals that current approaches are too long and complex. Consent is “broken”.
- Also agreement that simpler approaches work better.
- Why does this *still* not happen?
  - Does guidance need better dissemination that outlines that simpler approaches are allowable?
  - Do we need requirements rather than guidance?
  - Do we need more advocacy from patients or others?
- What other ideas might be helpful?