Reasonable People and the Three Pillars of Informed Consent

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Reasonable Person Standard

INFORMED CONSENT

Information
What would a reasonable person want to know?

Comprehension
What should we reasonably expect people to understand?

Voluntariness
How to we enable reasonable people to make voluntary decisions?
Research on Informed Consent for Biobanking

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Disclosure

What do people understand and what are their opinions about informed consent for biobanking?

What information is most important for people to know when making a decision about biobank participation?

What is an easy way to convey the information people want to know?

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Informed Consent for Biorepositories: Assessing Prospective Participants’ Understanding and Opinions
Laura M. Beskow and Elizabeth Dean
Cancer Epidemiol Biomarkers Prev 2008

Simplifying informed consent for biorepositories: Stakeholder perspectives
Laura M. Beskow, MPH, PhD; Joëlle Y. Friedman, MS; N. Chantelle Hardy, BA; Li Lin, MS; and Kevin P. Weinfurt, PhD
Genet Med 2010

Developing a Simplified Consent Form for Biobanking
Laura M. Beskow, Joëlle Y. Friedman, N. Chantelle Hardy, Li Lin, Kevin P. Weinfurt
PLoS One 2010
Comprehension

Which information in a biobank consent form must people understand to give valid consent?

Develop comprehension measure: Delphi consensus statements → quiz

Does simplified consent improve understanding?
Selected Results: National Randomized Survey

**Initial quiz scores:** Only 20% of weighted sample achieved perfect score (adequate comprehension) upon first attempt.

**After review / re-test:** 65% of weighted sample ultimately achieved perfect score.

**Profound questions** regarding the role of comprehension in informed consent:

- Whether to set a **threshold** for understanding below which the person may not be objectively “informed”
- What, if any, **consequences** should there be for failure to meet threshold?

Voluntariness

Conducted 4th round of Delphi process (n = 44, 94% of original panel)

- Presented itemized quiz responses from national survey
  - For each: What should happen when not able to answer correctly on 2\textsuperscript{nd} attempt?

| Not allowed to enroll | Additional review, re-testing | Still allowed to enroll | Other |

Follow-up interviews (n = 21)

Interviewee Characteristics

Delphi panel = Experts

Areas of expertise
- Biobanking / research (n = 7)
- Ethics /policy (n = 7)
- Community / participant perspectives (n = 7)

Years in current position:
- Mean = 12
- Range = 2 – 25
Selected Interview Results:

Role of Empirical Data

Data as a reality check

Data as an indication of educational need

“If you see a question where a large percentage of people are getting it wrong, then you think, ‘Huh. Is it really that important? Would I bounce them out of the study for not knowing this?’” (11, Biobank)

“I feel like it’s a great opportunity for education. Because if the goal is to get informed responses … then you want to know which of those questions are the ones that seem trickiest, and maybe put more resources there or more public policy efforts around those.” (07, Participant)
Selected Interview Results:
Consequence for Not Meeting Threshold

- Not allowed to enroll
- Additional review
- Still allowed to enroll

**Optimism:** “I think you can explain everything.” (16, Biobank)

**Capacity:** “If they have the capacity to consent, I think you just keep trying until they get it... I think if you make a sincere effort to somebody who’s not cognitively impaired, you can explain these things.” (17, Ethics)

**Quality:** “It depends on the quality of that remedial attempt. Is it simply restating the explanation as it appears in the consent document? Or is the consenter able to re-word the concept ... in a way that anybody with basic cognitive competency would likely get?” (18, Ethics)
Selected Interview Results:
Consequence for Not Meeting Threshold

- Not allowed to enroll
- Additional review
- Still allowed to enroll

*Meaning of consent:* “I don’t think that it’s true consent if they don’t understand deal-breakers… Consent is: ‘I understand what I have been told and read’ – and if they don’t get that, they should not be allowed to enroll.” (09, Participant)

*Meaning of consent:* “If on additional review, they still can’t get it, well then yeah, I guess they don’t get in. Because consent has really failed somehow, or this person’s ability to comprehend is impaired. And I guess if we’re going to get consent, it ought to mean something.” (14, Ethics)

Beskow LM, Weinfurt KP. The meaning and implications of “comprehension” in informed consent (publication in process)
**Selected Interview Results:**

**Consequence for Not Meeting Threshold**

- **Not allowed to enroll**
- **Additional review**
- **Still allowed to enroll**

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**Autonomy:** “There’s a tension between autonomy and paternalism. If the autonomous responder is saying, ‘You told me enough; don’t worry about it; don’t worry about what I understand or don’t understand; I believe you have told me enough; we’re done; I’m saying yes or I’m saying no,’ I can respect that the ultimate decision needs to rest with the participant.” (02, Ethics)

**Ethical value:** “I’m not so happy about saying that people have to understand the ins and outs of biobanking before they can be a participant. Because I think the result is that, in the name of a thick understanding of autonomy, we’re going to make it so that research can’t go forward. There’s value in learning things that improve human health.” (03, Ethics)

**Other protections:** “There has to be a level of trust with the research enterprise and the protections that we have in place within the enterprise... When you take that in conjunction with comprehension, comprehension doesn’t have to be perfect and our protections don’t have to be perfect.” (06, Biobank)
Selected Interview Results:
Consequence for Not Meeting Threshold

- Not allowed to enroll
- Additional review
- Still allowed to enroll

“I’m struggling here because I think valid consent is a concept people believe in, but it’s really difficult to define what valid consent means in terms of the aspects of participation that people need to understand... And what you do if they don’t understand... The whole issue is challenging... I started out thinking there’s consent and people need to understand, and you need to explain the concepts in a way that people can understand. Now I’m not sure if it’s always possible—and whether you can say, ’Okay, you don’t understand. You can’t participate.’” (19, Ethics)

Beskow LM, Weinfurt KP. The meaning and implications of “comprehension” in informed consent (publication in process)
Incorporating “Reasonable Person” Standard

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Incorporating “Reasonable Person” Standard

Expect tailored use of any templates – what is important for participants in this study?

Expect researchers to have basic knowledge of their study population: What is important to them, how to communicate in understandable way

- Research team experience with population
- Community advisory board (work needed on robust models)
- Empirical research to gather input
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