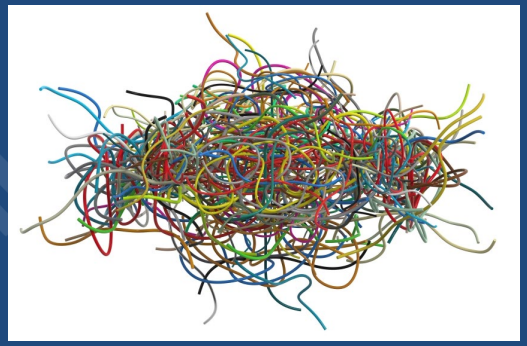

The Complexity of Informed Consent

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Improving Consent and Response
in Longitudinal Studies of Aging

September 28, 2021

Disclaimer

- The views expressed here are my own and do not represent the position or policies of the NIH, DHHS, or US government

- I have no conflicts of interest to declare

Components of informed consent

- (Capacity to consent)
- *Disclosure* of study information
- *Understanding* of that information
- *Voluntary decision* about participating or continuing to participate
- Consent *authorization*

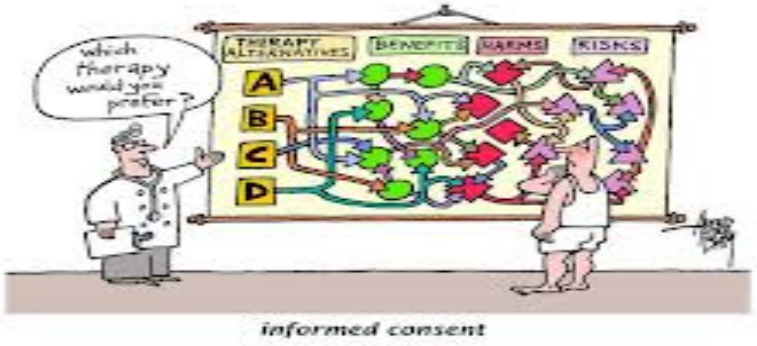
The Complexity of Informed Consent

- Why is informed consent complex?
  - Enduring challenges in disclosure, understanding, voluntary choice
  - Complicated by (and by differences in):
    - Motivations and expectations
    - Capacity
    - Tolerance for inconvenience, burden
    - Trust
    - Differential responses to incentives

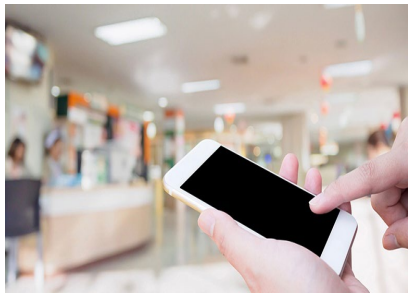
Disclosure Decisions

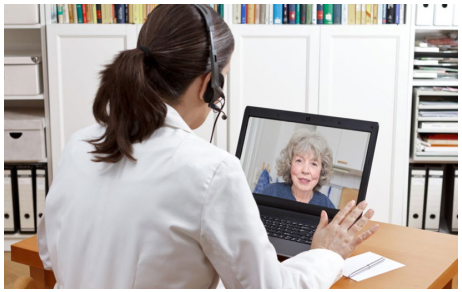
- What information should be disclosed?
- Want accessible information that explains relevant information about the study in an understandable way

- How should information be presented, considering circumstances, setting, population?



Disclosure





Elements of informed consent

- (Capacity to consent)
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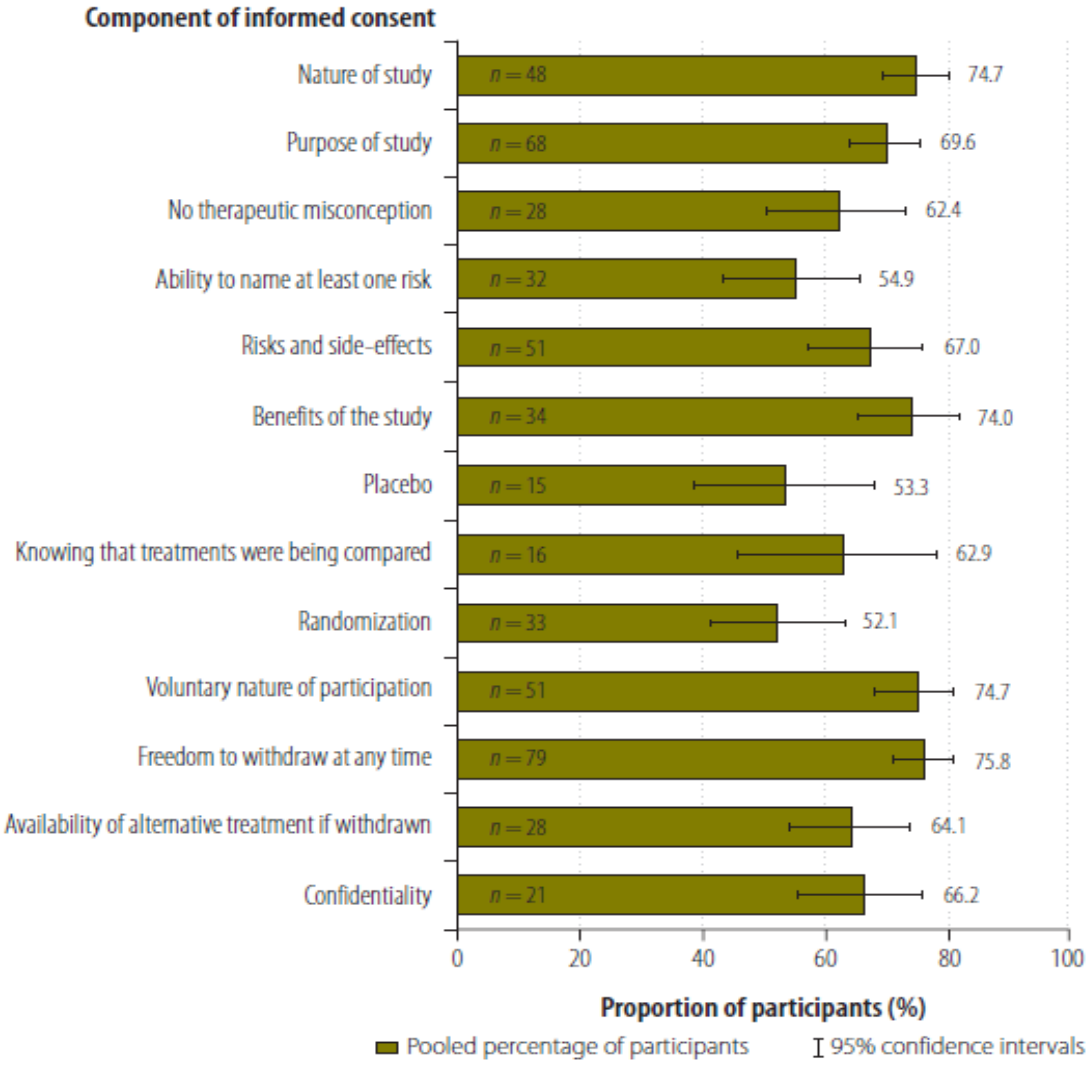
Fig. 2. **Participants' understanding of components of informed consent in clinical trials, by meta-analysis[a]**



[a] The number of studies included in the evaluation of each component is given.

Tam T et al. Bull of WHO 2015

What affects understanding?

- "Host" factors- Age, education, pain, cognitive impairment, capacity, literacy

- Expectations and familiarity
  - Trust in providers
  - Therapeutic misconception and related misunderstandings

- Process related factors
  - What is disclosed and how
  - How (and how well) the participant listens to/reads the information?

Longitudinal studies

- Limited evidence suggests that over time people forget information and want more (e.g. Smith W et al. *AIDS* 2011; Helgelsson G et al. *JME* 2005)
- Provision of information
- Ongoing consent, affirmation of consent, re-consent, dynamic consent (e.g. Smith et al *AIDS*, Resnik *JME* 2009, Wallace & Miola *BMC Med Ethics* 2021)

AMERICAN THORACIC SOCIETY DOCUMENTS

Table 4. Enhancements for Implementation by Investigators into Research Protocols to Enhance Minority Recruitment and Retention in Clinical Research

Recruitment	Retention	Overall
✓ Culturally sensitive visuals on patient-facing materials ✓ Appropriate literacy of written materials ✓ Authentic and careful recruitment language ✓ Obtain feedback on patient-facing materials from target population ✓ Allow opt out rather than opt in for contact by research team when feasible	✓ Collect multiple methods of contact (e-mail, phone numbers, texting, social media, alternate contact person) ✓ Implement follow-up data collection methods that are as low patient burden as possible (home visit, phone, community location) ✓ Patient research participation appreciation and engagement (certificates, token gift, study gatherings, birthday card, newsletter) ✓ Provide a direct connection to the study team	✓ Ensure flexible scheduling available (including evenings and weekends) ✓ Transportation assistance ✓ Train staff to use communication and interpersonal skills to establish trust and build rapport ✓ Offer meals for longer study visits ✓ Increase financial compensation if appropriate ✓ Offer childcare if target population is likely to be caring for children/grandchildren ✓ Elicit feedback from participants on their research experience ✓ Provide research in more than one language, when possible ✓ Establish standardized hard-to-reach protocol

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Understanding Challenges

- Complex Science
- Health literacy and capacity
- How much should participants understand?
- Different kinds of “mis-understanding”
  - Misconception
  - Mis-estimation
  - Optimism (Horng & Grady *IRB* 2003)

Elements of informed consent

- (Capacity to consent)
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Possible influences on voluntariness

- Dependent position, power, deference to authority
- Patterns of decision making
- Pressure from others (family, friends)
- Trust in health care provider
- Restricted choices?
- Illness?
- Incentives?

Why do people continue to participate?

- Perceived benefit (medical, personal)
- Contributions (to science, to others)
- Commitments
- Reasons differ by disease under study, prognosis, study type and phase, socioeconomic factors

(e.g. Wendler D et al 2008 *Arch Int Med*; Dainesi and Goldbaum 2014)

The Complexity of Informed Consent

Willingness to participate and continue depends on:

- Motivations and expectations
- Experience of and tolerance for inconvenience, burden
- Trust
- Differential responses to incentives

Table 2 Prevalence of participation in research and willingness to participate in research among HealthStreet participants 50 years of age and older by dementia status (n=4,881)

	Participants Reporting Dementia (n=209; 4.3%)	Participants not Reporting Dementia (n=4,672; 95.7%)	P-Value
Have you ever been in a health research study?			0.5285
Yes	45 (21.5%)	1094 (23.4%)	
No	164 (78.5%)	3578 (76.6%)	
Would you volunteer for a health research study:			
that only asked questions about your health?	201 (96.2%)	4431 (94.8%)	0.3923
if researchers wanted to see your medical records?	189 (90.4%)	4117 (88.1%)	0.3108
if you had to give a blood sample?	188 (90.0%)	4175 (89.4%)	0.7848
if you were asked to give a sample for genetic studies?	186 (89.0%)	4114 (88.1%)	0.6818
if you might have to take medicine?	132 (63.2%)	3116 (66.7%)	0.2890
if you were asked to stay overnight in a hospital or clinic?	154 (73.7%)	3712 (79.5%)	0.0444
if you might have to use medical equipment?	189 (90.4%)	4124 (88.3%)	0.3407
Would you participate in a study if you didn't get paid?			0.0557
Yes	179 (85.7%)	3751 (80.3%)	
No	30 (14.4%)	921 (19.7%)	
How much money do you think is a fair amount for participation in a study that lasts about an hour and a half and involves an interview and a blood test? (±SD)	60.2 (87.1)	88.9 (159.1)	0.0146
How interested are you being in a research study?			0.2575
Definitely	116 (55.5%)	2552 (54.6%)	
Maybe	74 (35.4%)	1817 (38.9%)	
Not at all	19 (9.1%)	303 (6.5%)	
On a scale of 1 to 10, where 1 is 'Not at All' and 10 is 'Completely', how much do you trust research? (±SD)	7.7 (7.0)	8.4 (9.7)	0.1157
On a scale of 1 to 10, where 1 is 'Not at All' and 10 is 'Completely', how much do you trust researchers? (±SD)	7.6 (7.0)	8.5 (10.2)	0.1172

Milan I S et al. Ageing International https://doi.org/10.1007/s12126-021-09441-x

Longitudinal aging studies

- Why do people want (or not) to participate?
- How can participation be made as convenient and low burden as possible?
- How is trust earned?
- What is the role for incentives?