Challenges and Opportunities to Improve Consent Forms

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Informed Consent History

- **19th Century - The 1847 AMA Code**

" The obedience of a patient to the prescriptions of his physician should be prompt and implicit. He should never permit his own crude opinions as to their fitness to influence his attention to them."

Challenges

- Long-standing recognition that consent <u>forms</u> in research are:
  - Not evidence-based
  - Written at an educational level that is too high for most participants
  - Commonly use technical terms that are not understood by most participants
  - Too long with formatting that is too dense

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Challenges

- Long-standing recognition that the informed consent process:
  - Is not evidence-based
  - Does not ascertain whether participants understand key information elements before a decision is made
  - May be insensitive to the stressful circumstances in healthcare environments
  - May not be conducted by a person with appropriate skills, time, expertise
  - May provide limited time for decision-making
  - May provide limited opportunities for asking questions
  - May not be adequately reviewed by the IRB

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Why Have These Challenges Persisted?

- An alignment of incentives favors the current approach
- Sponsors of research
  - Seek to relay comprehensive information about procedures, risks, and benefits
  - Seek to be accurate with the use of technical language
  - Seek to reduce legal liability for inadequate disclosures
  - Lack of comprehension does not appear to reduce recruitment
  - Long/complex forms are acceptable to IRBs

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Incentives

- Investigators
  - Seek to be comprehensive with information
    - Some participants do use the form as an “owner’s manual” to complex trials
  - Seek to be accurate with use of technical language
  - Longer and more complex is easier to write than shorter and simpler
  - Lack of comprehension does not reduce recruitment
  - Liability protections
  - Acceptable to IRBs

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Incentives

- IRBs
  - No regulatory requirement that forms be shorter or simpler
  - No regulatory requirement that participants understand key information
  - Seek to be comprehensive
  - Seek to be technically accurate
  - Institutional boilerplate in legalese
  - Pushing back against complex forms entails conflict with investigators and sponsors
    - Consistency of IC forms across sites
  - Helping investigators with shorter, simpler forms requires expertise and additional work

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Incentives

- Research participants (potential participants)
  - Rely on trust of investigators, clinicians, healthcare institutions to make decisions about participation
  - Therapeutic misconception enhances trust
  - Embarrassment at revealing a lack of comprehension
  - Concerns about angering or disappointing clinicians by asking questions or declining participation

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Lack of Progress

- Enhancing informed consent is a hard problem
  - Poorly educated public with no research experience
  - Limited time for more engagement
  - The power relationship between physicians/investigators/institutions vs lay public
  - Passivity and dependence of patients/participants born of fear and anxiety
  - A strong desire to trust
- Research has not demonstrated dramatic improvements through new approaches

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Assumptions

- We know enough to improve forms and the process
- New ideas and data will not change the incentives
- Significant progress will only be made if incentives change
- New regulations or guidance from DHHS essential to change incentives

SACHRP Recommendations in 2013

- Recommendations to simplify consent forms and process by reducing the number of required elements
  - Make several elements optional
  - Give IRB's and investigators more leeway to design the form around the protocol
  - Available at: http://www.hhs.gov/ohrp/sachrp/commsec/attachmentd-sec.letter19.pdf

Current Elements of Informed Consent in Research (45 CFR 46.116)

Required Elements

1. A statement that the study involves research, purpose of the research, description of procedures
2. Reasonably foreseeable risks and discomforts
3. Benefits expected from research
4. Alternatives
5. Statement about confidentiality of records
6. Compensation, treatments if injury occurs
7. Who to contact for questions or injuries
8. Statement that participation is voluntary

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Elements of Informed Consent in Research

<u>Optional Elements</u>

- Unforeseeable risks
- Participation may be terminated by investigator
- Costs to subject
- New findings will be relayed to subject
- Approximate number of subjects in the study

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Proposed Revision: Elements of Informed Consent in Research

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Is There Regulatory Language to Support Guidance?

- **45CFR46** "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative."
- **World Medical Association Declaration of Helsinki (2000).** "In any research on human beings, each potential <u>subject must be adequately informed</u> of the aims, methods, anticipated health benefits and potential hazards of the study and discomfort it may entail… <u>After ensuring that the subject has understood</u> the information, the physician should then obtain the subject's freely given informed consent, preferably in writing."

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SACHRP Initiative

- ANPRM opened the door to potential changes in regulations
- OHRP guidance may be appropriate route to leverage changes in IRB standards for informed consent
- SACHRP may adopt an initiative to prepare recommendations to enhance the efficacy of the informed consent process

Thank You!

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