

# Informed Consent: Best Practices

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# Limitations

- Most of the empirical evidence on the consent form and the consent process comes from realm of clinical/interventional research.
  - The majority of this research has been conducted with hypothetical studies and simulated potential research subjects.
    - Most research subjects learn about the potential for enrollment from many sources prior to encounter with consent form.
    - Most research subjects are weighing actual risks and benefits.



# Overview

- Readability
- Subject Understanding
  - Interventions
- Assessment



# Readability

- Average American reads at the 8<sup>th</sup> grade level.



# Readability

- Assessment of readability of consent forms over the last 25 years indicate that they are routinely written at levels beyond the grasp of potential subjects.
  - Study teams seldom include an expert in health literacy
  - IRBs routinely approve forms submitted
    - In some cases reduce readability
    - Boilerplate fails to meet own suggested standard



# Subject Understanding

- Understanding, when assessed, is routinely found to be incomplete



# Testing Interventions

- What improves understanding?
  - Simpler and shorter consent forms
    - Receipt of forms based on NCI simplified template
  - Quality dialogue between potential subject and member of study team
    - Corrected feedback
  - Access to supplemental materials
    - Multimedia interventions minimal or no effect

# Assessment Tools

- General Format
  - Forced choice quizzes
    - Review incorrect answers, ultimate pass
  - Open-ended questions
  - Combination of closed/open-ended questions

# Assessment Tools

Tool	Population	Format
QuIC	Cancer patients	Forced choice
Q-PUR	Cancer patients	Forced choice
MacCAT	Psychiatric patients	Open-ended
DICCT	General	Open-ended
BICEP	General	Combination



## Summary

- Consent forms written at grade higher than grade at which average American can read
- Investigators rarely assess subject understanding
  - When they do, found to be incomplete
  - Assessment of comprehension or recall?
- Shorter, simpler forms and engagement with member of study team improve understanding