Creating Informed Consent Documents That are Approachable, Readable and Brief

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Lack of CFR Requirements in ICFs #1


- Evaluated 22 requirements in 82 ICFs from 16 specialties
- 9% addressed all requirements
- 37% addressed ≥ 90%
- 22% incomplete missing ≥ 9 requirements
- Mean number discrepancies 4.7 ± 3.5
Lack of CFR Requirements in ICFs #2


• Multicenter trial with 16 sites and common protocol
• 3 out of 16 ICFs contained all of the basic elements of CFR45 Part 46
• 13 had missing elements
  – 6 missing 1
  – 4 missing 2
  – 1 missing 3
  – 2 missing 4
Reading Level of Informed Consent Forms

• 1980 Morrow JAMA
  – 60 ICFs from cancer trials only slightly less difficult than medical journals

• 1996 Golstein et.al. J Family Practice
  – 284 consent forms from 2 universities had average reading level of 12th grade and less than 10% at 10th grade or less

• 2004 Sharp. Amer J. Chn. Oncology
  – 107 ICFs None at 8th grade or below and only 10.5% at or below 10th grade
Reading Level of Informed Consent Forms

• 2003 Paasche-Orlow et. al. NEJM
  – 61 U.S. Medical School Websites provided specific readability standards which ranged from 5th – 10th grade level
  – Mean Flesch-Kincaid scores of the sample IRB provided text exceeded the stated standard by 2.8 grade levels
  – Average score was 10.6
Increasing Length ICFs

• Three studies have provided data showing that informed consent documents have increased in length over time

• The longer the document the less likely it will be read
  - time constraints
  - intimidation

• Credibility issue – long ICFs inconsistent with usual oral consent process (what aren’t you telling me?)
Results of Shortening ICFs
Epstein and Lasagna Arch Int. Med 1969

• Mock experimental situation
• Acetylsalicylic acid (fictitious name for aspirin) for headache
• Varyingly detailed descriptions of the actions and hazards, increased detail = increased length
• Comprehension inversely related to length
  - Short 67%
  - Medium 45%
  - Long 35%

• Long form- 2/22 volunteered despite contraindication
  - 5/22 missed that fatal reactions might occur
Results of Shortening ICFs

Dresden and Levit Academic Emergency Med 2001

- Standard industry consent form (IF) vs. modified (MF)
- Modification
  - Removed all information not required by regulation
  - Formatting changes
  - Simplified words
- Reading level change 12.0 to 8.7
- Significantly increased comprehension of purpose, randomization, study duration, risks, benefits, alternatives, confidentiality and voluntary participation.
- MF users: better than 85% correct on 10/12 questions vs. IF users: 85% or better on only 3/12 questions.
- Only 2% did not completely read the MF vs. 32% for the IF.
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• Goal was to develop a strategy that would lead to common use of informed consent documents that are as short and readable as possible.

• Participants included bioethicists, IRB Chairs, IRB Administrators, University Counsels, Research Deans/Vice-Presidents and representatives of OHRP, FDA, NIH, AHRQ, and AAHRPP.
Experiences Simplifying Informed Consents –
Children’s Oncology Group

• Focused consent on the research question
• Additional information on research process and standard treatment etc. contained in supplemental materials (handbook, website) and appendices.
• Created templates for different phases using junior high level language, one thought per sentence, short paragraphs.
• Most efficient and improved consistency if all consents written by a small group.
Experiences Simplifying Informed Consents – AHRQ Informed Consent and Authorization Toolkit

• Designed for low literacy audience and health services research.
• Omits all non-essential information
• Uses short words and sentences
• Uses formatting and highlighting to improve understanding
• Toolkit incorporates teach-back, question solicitation, and certification that entire process conducted.
Experiences Simplifying Informed Consents – Commercial IRB One Page Consent for Simple Procedures Research

• Avoid redundancies and include only required information
• Avoid unneeded elements
• Be concise
• Group like information into cohesive headings
Obstacles to the goal of common use of short and readable informed consent documents

- Financial costs to implement change.
- Institutions and IRBs feel isolated and in need of positive guidance and templates from regulatory agencies.
- Inertia – easiest to repeat what has worked even if deficient.
- Writing concise, simple consents is difficult and the writers lack the necessary skills and training.
- No incentive.
Potential Approach

Treat informed consent as a process with 3 parts

- Part A – Limit the informed consent document to the research question and the essential elements presented in concise easy language and format.
- Part B – Supplemental information – all additional information that a participant might want or need.
- Part C – Verification/Certification – could include teach back or testing and certification that entire process carried out.
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Next Steps

• AAMC working group to model templates for research of differing complexity and risk.
• Involve OHRP and FDA in endorsing materials as consistent with regulations including templates, best practices, and toolkits.
• Establish a website repository for endorsed materials
• Enlist pioneer institutions to implement change for investigator initiated protocols
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Next Steps (continued)

• Work with sponsors including NIH and industry.
• Liaison with SACHRP.
SACHRP Support Can Enable Change

• Change is needed and the time is now.
• Many in academic medicine are ready and eager to implement this change.
• Support positive, proactive action by OHRP, FDA, and NIH in the form of guidance and approved templates, best practices and toolkits.
• Support funding to establish and maintain a website to distribute the above materials.
• Support funding for a pilot project to implement the change at 2-4 pioneer institutions.