Creating Informed Consent Documents That are Approachable, Readable and Brief

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Tomorrow's Doctors, Tomorrow's Cures

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Lead

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Lack of CFR Requirements in ICFs #1

White et.al. Academic Emergency Medicine 1996 3(5): pg. 745-50

- 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

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Lack of CFR Requirements in ICFs #2

Silverman, Hull, and Sugarman. Critical Care Medicine 2001. 29 (2) pg. 235-41

- 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

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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

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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

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Increasing Length ICFs

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

Baker and Taub, JAMA 1983; LoVerde et al J Gen Int Med 1989; Tarnowski et al Pediatrics 1990

- 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?)

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Results of Shortening ICFs

Epstein and Lasagna Arch Int. Med 1969

- Mock experimental situation
- Acetylhydroxybenzoate (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

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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.

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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.

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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.

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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

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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.

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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.

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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.

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