

UNIVERSAL USE OF SHORT AND READABLE INFORMED CONSENT DOCUMENTS: HOW DO WE GET THERE?

Summary of Strategic Planning Meeting May 30, 2007

Division of Biomedical and Health Sciences Research

August 2007

Introduction:

The Association of American Medical Colleges convened this meeting to follow-up on Recommendation 9 of the AAMC Clinical Research Task Force II (2006):

Human Research Protection Programs should be made more effective and efficient by (a) trans-agency harmonization of federal regulations, (b) accreditation of Human Research Protection Programs, (c) *simplification of institutional regulatory compliance processes* (italics added), and (d) expanded use of central IRBs in multi-site research.

Specifically the goal was to develop a strategy that would lead to common usage of informed consent documents that are both short and written in simple and comprehensible language so that they facilitate a greater level of understanding and enable potential subjects to make truly informed decisions about research study participation. For this purpose the AAMC invited individuals with a variety of perspectives and backgrounds all of whom possessed great expertise and experience in human research protection. The group included bioethicists, IRB Chairs, IRB Administrators, University Counsels, and Research Deans/Vice Presidents, as well as representatives of various government agencies including the Office of Human Research Protection (OHRP), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality (AHRQ), and the Association of Human Research Protection Programs (AAHRPP). A list of the participants is provided in *Appendix A*. Presentations included an informed consent literature review, reports on 4 different efforts to use short informed consent documents, and a review of efforts to measure effectiveness. There was then group discussion of the obstacles and potential approaches to reaching the goal. The agenda can be found in *Appendix B*.

Informed Consent Literature Review (Dr. Dickler):

A comprehensive review of the literature on informed consent documents was undertaken and the review with complete referencing is provided in *Appendix C*. Deficiencies in informed consent documents have been identified in 3 main areas:

- Informed consent documents frequently do not contain all of the basic elements of informed consent required by the Code of Federal Regulations (CFR) Title 45, Part 46, Section 46.116. This shortfall was identified in informed consent documents for research in various medical specialties. Particularly striking was the report that in a 16 site multicenter trial using the same protocol only 3 of the sites had consents containing all of the basic elements, and 7 were missing multiple elements.
- Three studies have presented data that show that the length of informed consent documents has increased over time. The longer the consent document the less likely it will be read due to both time constraints and intimidation. One study has shown an inverse relationship between comprehension and the length of the consent. A second study compared a standard industry consent form to a modification which was shortened by taking out all text not related to the basic elements, decreasing reading level from 12.0 to 8.7 and improving formatting. There was

significantly increased comprehension of nearly all of the elements including purpose, randomization, risks, benefits, and voluntary participation.

- The National Adult Literacy Survey of 1992 found that nearly half of the adult population is functionally illiterate at the 8th grade level. Yet study after study reveals that fewer than 10% of informed consent documents are at the 10th grade level or below. Even more striking is a 2003 study that showed that the IRB approved consent template text found on the websites of 61 U.S. medical schools had an average reading grade level of 10.6.

Experiences Simplifying Informed Consent Documents:

Childrens Oncology Group (Dr. O’Leary):

A Task Force began work in 2004 to address issues that included length (commonly over 20 pages), complexity and difficult language (grade 14), failure to distinguish standard of care from research, and lack of consistency. The task force used an iterative consensus process involving the COG membership, the Pediatric Central IRB, local IRBs and the patient advocacy committee. New informed consent document templates were developed for Phases I, II, and III which focused on research and were developed as part of a larger process that utilized a host of educational supplemental materials (handbooks, websites) and appendices (standard treatment, diagrams, risk table, certificate of confidentiality). The consents use simple language (Junior High level), one thought per sentence, short paragraphs, a template table of standard treatments in an attachment, and short, simple templates for concepts used repeatedly (randomization, dose escalation, and standard therapy phrases like induction and consolidation). It is found to be more efficient to use a small group to create all the consents because this improved consistency and also fostered improved consent writing skills over time. This also helped to prevent template “creep”.

AHRQ’s Informed Consent and Authorization Toolkit (Ms. Brach):

This toolkit was developed to provide simple and understandable informed consent and HIPAA authorization documents appropriate for low literacy audiences and designed for health services research. Development used an iterative process starting with drafts from a contractor, revision by AHRQ, and review by OHRP as well as health literacy and consent experts. Simplification involved the use of short words and sentences, elimination of jargon and irrelevant information, and formatting, organization and highlighting designed to assist understanding. The toolkit provides a process which involves not just forms but also recommendations for how to present the information including use of interpreters, teach-back, soliciting questions, and certification that all parts of the process were conducted. AHRQ has awarded a contract for testing with subjects, health services researchers, and IRB officials.

Commercial IRB: A One Page Informed Consent for Simple Procedures Research (Ms. Heath): A simple, one page (long form) informed consent document is possible primarily for studies with simple procedures. (This category may or may not relate to the risk level.) The principles for writing a one page form included (a) avoid redundancies, (b) include only required information and avoid unneeded additional elements, (c) group like information into more cohesive headings, (d) be concise, and (e)

remember the needs of your audience. Starting with a template with all possible elements each with its separate heading is guaranteed to produce a long consent form with some useless information.

Duke University Medical Center Survey on Short Form Use (Ms. Mosher): Regulations permit the use of the “short form” process for non-English speaking participants. This consists of a translated document listing the generic elements of consent supplemented by oral translation of an IRB-approved written summary. IRB Administrators at 140 institutions were surveyed about their policies regarding non-English speaking participants. Of the respondents (47/140; 34%) 50% allowed use of the short form, 39% did not allow use, and 11% indicated no knowledge of the short form.

Measuring Effectiveness of Informed Consent (Dr. Sugarman):

The Brief Consent Evaluation Protocol was developed to evaluate the quality of the informed consent process. It is a short answer and yes/no orally administered questionnaire comprised of 12 questions that was field tested with 8 different “parent” protocols at 14 institutions. Disruption of the parent study was negligible and there was only a minimal incremental time burden (14 minutes for coordinators, 11 minutes for subjects). Respondents were highly satisfied with the parent study informed consent process but answers to verbatim questions (coding for which was verified to be reliable), indicated some confusion about the primary purpose of the parent study (only 80% correctly identified research) and about voluntariness (only 55% clearly indicated appreciation of the voluntary nature of participation).

Keeping Informed Consents Short and Simple (Group discussion led by Dr. Gordon):

There was consensus that reaching the goal of keeping all informed consent documents as short and simple as possible would improve human subject protection. The discussion then focused on a number of obstacles that must be addressed in order to reach this goal.

- There is significant financial cost to an institution of implementing a change to short and simple informed consent documents including development of templates, development of the other elements of the informed consent process, and education of protocol and consent writers, investigators, and IRB members. Two approaches to managing such costs were discussed. First, centralization at the level of the institution and/or the trial group of the writing of protocols, consent documents and the other elements of the process would produce efficiencies and might even be cheaper in the long run. Second, the general availability of templates, sample documents, and best practices (from either the regulatory agencies or organizations such as AAMC or PRIM&R) would greatly reduce costs.
- Institutions and IRBs feel that they work in isolation and each has to reinvent the wheel on its own. There is no forum for communication between IRBs even when they are dealing with the same protocol such as in a multi-site trial. Guidance and templates and positive reinforcement from the regulatory agencies would be welcome. However, there is the feeling that even when an IRB or institution tries to improve things there is pushback from the agencies. There is little of a positive and proactive nature issuing from the agencies regarding consent, only warning letters. However, it was noted that OHRP, while it has not issued templates, is willing to review

templates and make a determination as to whether they are consistent with regulations and guidance.

- Inertia is present for institutions, investigators and sponsors. The easiest thing to do is to mimic what has worked in the past even if it has deficiencies. Moreover, there is no incentive to change. This is especially true for industry sponsored studies because industry is particularly risk adverse. This inertia can only be overcome if there is leadership at the level of the institution, the regulatory agencies, and from organizations like AAMC and PRIM&R.

Potential Approaches (Group discussion led by Dr. McKinney):

There was a strong consensus that informed consent is a process that involves considerably more than the informed consent document itself, and that the various components *in toto* can be considered a toolkit. It is also self evident that research varies from simple to very complex and from minimal to high risk and everywhere in between and that the process cannot be one size that fits all. It was suggested that the different parts of the toolkit could be grouped into 3 categories, A, B, and C. Disaggregating the parts removes the necessity for the informed consent document itself to fulfill multiple roles.

Part A. The Informed Consent Document: The document itself should focus on the research question and the essential elements of consent as prescribed by regulation. Many consent forms, e.g. in oncology, include the procedures, risks and benefits of the standard treatment without differentiating the line between research and practice. The baseline practice information should be excluded from the research discussion and should be assigned to part B. The line drawn between A and B was considered “where the rubber meets the road” and templates for various kinds of research and different degrees of risk and complexity will need to be created. Unnecessary language, e.g. exculpatory language, as well as jargon and abbreviations should be omitted. The document should be written using short words, sentences that express a single idea, and short paragraphs, and the target grade level should be 8 or less.

B. Supplemental Information: For very simple procedure research such as providing a venous blood sample, no part B will be necessary. For very complex and high risk research, e.g. a pediatric oncology protocol, multiple additional sources of information can be utilized. For example, the Children’s Oncology Group uses both supplemental materials such as handbooks and websites, and appendices for information on standard treatment, diagrams of treatment schedules, risk tables, etc. The amount of supplemental information that individual subjects may want will, of course, vary, but should always be available. An IRB, knowing that supplemental information is available, might be more likely to agree to deletion of background information from Part A.

C. Verification/Certification: Various types of materials whose purpose is to strengthen the process may be included here. Examples would include teach back or using a test to determine understanding of the essential elements, and a check list or certification that all aspects of the process were carried out.

Next Steps (Group discussion led by Dr. Schwetz):

It was acknowledged that considerable effort on a number of fronts would be necessary to reach the goal of universal use of short and simple informed consent documents. Nevertheless, the group expressed considerable enthusiasm for taking the next steps towards that goal and encouraged AAMC to take the lead wherever possible.

- Establish a working group to model short and simple informed consent templates for research of various degrees of complexity and risk using the A, B, C format described above. Several of the participants volunteered for the working group and AAMC plans to convene the group by conference call in the near future.
- Involve OHRP and FDA in all efforts from the beginning. OHRP is willing to review templates for consistency with the regulations. OHRP can also provide endorsed examples of templates, best practices, and toolkits that can be made available to the research community. FDA should be encouraged to follow suit.
- Establish a website as a repository of OHRP and FDA vetted informed consent templates, supplementary materials, toolkits and best practices. Hopefully, these will include innovative designs and approaches. AAMC will consult with various organizations as to the best host for such a website.
- Enlist pioneer institutions to implement use of short and simple informed consent templates, supplemental materials, and toolkits, particularly for local investigator initiated protocols.
- Work with NIH and central IRBs and sponsors to implement use of short and simple informed consent templates, supplemental materials, and toolkits in multicenter trials.
- Work with the Chief Scientific Officers of Pharmaceutical and Biotechnology companies towards the same goals. It was suggested that this might be most productive after positive outcomes are obtained in other arenas.
- Establish contact with the Secretary's Advisory Committee on Human Research Protection. Dr. Dickler has been invited to present a summary of the informed consent literature and the results of this meeting to SACHRP on July 31, 2007.

{APPENDIX A}

UNIVERSAL USE OF SHORT AND READABLE INFORMED CONSENT DOCUMENTS: HOW DO WE GET THERE?

Wednesday, May 30, 2007
The Fairmont Washington, D.C.

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{APPENDIX B}

UNIVERSAL USE OF SHORT AND READABLE INFORMED CONSENT DOCUMENTS:
HOW DO WE GET THERE?
Wednesday, May 30, 2007

AGENDA

The Fairmont Washington, D.C.
(Sulgrave Suite – 2nd Floor)
2401 M Street, NW, Washington, DC 20037

7:15 AM	Breakfast	
7:45	Introduction and Charge	Drs. Schwetz and Korn
8:00	Problems with ICFs, A Literature Review	Dr. Dickler
8:30	<u>Examples of Short & Simple ICFs</u>	
	Childrens Oncology Group	Dr. O'Leary
	AHRQ	Ms. Brach
	Low Risk One Page	Ms. Heath
	Short Form	Ms. Mosher
10:00	Break	
10:15	<u>Keeping it Short – Group Discussion</u>	Leader – Dr. Miles
	Sticking to Required Elements Focusing on the Intervention How Much About Risk?	
11:15	<u>Measuring Effectiveness? – Group Discussion</u>	Leader – Dr. Sugarman
12:00 PM	Lunch	

AGENDA (continued)

12:30	<u>Potential Approaches – Group Discussion</u> Use of Pilot Institutions Support from OHRP Templates vs. Short Form Approaches Obstacles	Leader – Dr. McKinney
2:00	<u>Next Steps – Group Discussion</u>	Leader – Dr. Schwetz
2:30	Adjourn	

{APPENDIX C}

**Creating Informed Consent Documents That Inform:
A Literature Review**

February 2007

Kim M. Wittenberg, M.A.

Howard B. Dickler, M.D.

Goal

In "A History and Theory of Informed Consent," Faden and Beauchamp [1] concluded that a truly informed consent "must be an authorization that is intentional, substantially non-controlled, and based on substantial understanding." They specifically noted that substantial understanding should be attained for the act of authorization, as well as for the nature of the study and its potentially associated consequences and risks. If substantial understanding is achieved, then the participant's authorization is usually autonomous and intentional. The authors explain that "substantial" understanding is a subjective level of understanding that is between complete understanding, which requires so much information that it would possibly overwhelm and confuse, and insufficient understanding, which would not provide the amount of information necessary to make an informed decision about participating. Achieving understanding is not only important ethically, but also legally. In 1994, the *Butler v. South Fulton Medical Center* case resulted in the following ruling: "even if the patient is provided proper and legal disclosure, he or she also must comprehend what the physician is saying and understand the information on the consent form so that he or she gives permission for treatment or surgery voluntarily" [2, 3].

Does the average informed consent form (ICF) achieve the goal of substantial understanding? Unfortunately, much evidence suggests a resounding "no." Studies have shown that participants often have therapeutic misconceptions, believing that they will receive the treatment best suited for them [4-9], and often misunderstand the nature or purpose of the study or fail to retain the information they do understand [5, 6, 10-18].

❖ Impediments

What is the root of the therapeutic misconceptions and lack of understanding and retention? Below is a list of factors which obstruct sufficient understanding.

- **Missing Required Elements**

Many ICFs do not contain all of the required elements [19-22]. For example, Silverman et al. [22] discovered that out of 16 ICFs, each derived from the same protocol within a multi-center trial, only three contained all required elements.

- **Literacy and Readability**

In 1993, the National Adult Literacy Survey determined that 21-23 percent of the U.S. population possesses the lowest level of literacy [23]. At this level, one is unable to process even a short brochure or a sports article. On average, the nation is only able to read at an 8th- or 9th-grade level [24]. This falls short of the average ICF reading level – 11th-grade or higher [21, 22, 25-39]. Indeed, Morrow [39] found that 60 ICFs from cancer trials were just slightly less complex than medical journals.

This incongruence between the national literacy level and the average ICF reading level occurs despite the CFR requirement that ICFs be composed in "understandable" language [40]. It is also despite the recommendation issued in 1998 by the Informed Consent Working Group (formed by the National Cancer Institute [NCI], the Office of Human Research Protections [OHRP], and the U.S. Food and Drug Administration [FDA]) to keep language at or below an

8th-grade reading level, and evaluate and guarantee this level by software programs or other methodology [41]. A study conducted in 2004 demonstrated that, of the 107 oncology ICFs it analyzed, *all* were written above the recommended reading level [42]. The authors concluded that Institutional Review Boards (IRBs) may approve such non-complying ICFs which are not written in understandable language, because the legal aspect of ICFs is more heavily emphasized than the communicative aspect. Others hypothesize that IRB committee members may actually judge the language to be acceptable simply because the majority of such members are usually professionals who understand the language, and the minority who are not find the language more acceptable over time with repeated exposure [38]. Unfortunately, when Paasche-Orlow et al. [43] studied ICF templates and sample text on 61 U.S. medical school IRB Web sites, they generally failed to meet their own reading level requirements.

- **Excessive Length and Inadequate Time**

Most potential participants are not given enough time to carefully read an ICF [44]. This time deficit is almost wholly due to the exorbitant length of the average ICF. The length of ICFs has steadily increased over time [25, 35, 38] and often goes hand-in-hand with complexity. ICFs are so long that they are usually not read completely [19]. Moreover, the longer the document, the lower the chance it will be read [42]. This unfortunate fact is especially alarming because longer and more complex ICFs are usually associated with studies involving greater risk [45]. The failure to read lengthier documents may be due not only to time constraints, but also to a threatened feeling, especially experienced by those who are less educated [42].

❖ Potential Solutions

- **Improve Readability Via Reducing Reading Level**

As the national average reading level is below that of the average ICF text, it is logical to assume that simplifying language may increase comprehensibility. Strategies to simplify language include using short, familiar, concrete, and simple words; using proportionately more content words than function words; limiting the use of polysyllabic words; keeping sentence length below 12 words and paragraph length below seven lines; making sentences declarative and, when possible, affirmative, and minimizing embedding; ensuring each paragraph only conveys one idea; and using active voice, personal pronouns, and simple language [21, 46]. Notably, many short words are complex and/or unfamiliar [36, 47], and these words should be avoided when possible. The University of Michigan [48] has created a list of simple words to be used in lieu of complicated medical terms. This list is available online at <http://www.med.umich.edu/irbmed/guidance/guide.htm>. Similarly, Hochhauser [32] and Meade and Howser [36] have suggested simple alternatives for complex words often used in ICFs (See Appendices B1 and B2.) Readability can also be improved by avoiding the use of acronyms [41], symbols (e.g. "<" and ">") [49], and abbreviations (e.g. "lb") as much as possible, and by substituting measurements that are commonly known for those which may not be known, such as "teaspoon" for "5 milliliters". The resulting reading level can be approximated via a computational readability formula. It is important to note that readability formulas are purely quantitative *estimates* and not without flaws [50]. When assessing reading level, the text should also be manually checked for uncommon words, sentence flow, and anything that does not make sense or is complex. In addition, the text should be checked to confirm coherence, as coherence

is also important in comprehension and learning [51]. Coherent text contains clear connections between ideas, facilitating integration into a single unit.

Numerous studies have tested the hypothesis that reducing the reading level improves comprehension. Some studies involving materials other than ICFs, such as medical information leaflets and a Bill of Rights in a long-term care facility, have demonstrated improved comprehension with reduced reading level [52-54]. The results of studies testing ICFs, however, have been mixed. Whereas some studies have found that simpler ICFs result in better comprehension [19, 55-58], others have found that simpler ICFs are preferred by potential participants, but do not improve comprehension level [59-61], and yet another found that simplifying the ICF improved comprehension for men, but not for women [62]. Upon closer examination, it becomes apparent that each study involved several variables, many of which were uncontrolled and may have confounded the results. Examples of variables included "people" variables, such as educational level, background knowledge, motivation, and age; "task" variables, such as the amount of reading time allowed and the amount of discussion and feedback; and "text" variables, such as vocabulary, syntax, conceptual load, cohesiveness, formatting, layout, and length. Moreover, another aspect of study design that may have affected the results was the focus on the *correlates* of increased comprehensibility, rather than the direct *causes* of increased comprehensibility. This aspect is due to the fact that reading comprehension is currently not fully understood, and no causative factors have been identified thus far [63].

▪ **Improve Readability Via Improving Formatting and Layout**

Although most ICF studies have focused on the benefits of lowering the reading level, many of these studies have also incorporated formatting and layout modifications, and numerous authors have made formatting and layout recommendations aimed at improving. Significantly, Hochhauser [47] noted that "document design and layout are at least as important, perhaps more important" than reading level estimates. For example, Tymchuk and Ouslander [64] examined layout by studying the effect of order on comprehension. While studying a group of elderly subjects, they noted the primacy effect – subjects exhibited better comprehension of information located at the beginning of the ICF. Moreover, it is important to note that readability researchers have found that formatting features such as titles and graphics can facilitate coherence on a global level [51]. Thus, such formatting can aid the integration of "high-level" ideas throughout the whole document and, consequently, aid comprehension.

▪ **Decrease Length**

A study conducted in 2004 recommended that ICFs be limited to 1250 words [42]. This shorter length would reduce the necessary reading time to about 5 to 7 minutes, well within the duration allowed by most studies. How can ICFs be shortened? One way is to remove all information not required by [45 CFR 46.116](#). Dresden and Levitt [19] constructed a shortened ICF in such a manner. In addition, they improved readability via some of the methods listed above, including shortening headings, simplifying syntax and vocabulary, and adding formatting such as bullets, underlining, bold, italics, and increased font size. Potential research participants were randomly assigned to either the shortened, simplified ICF with an 8.7 grade level (MF), or to a standard, IRB-approved ICF with a 12.0 grade level (IF). Subjects were allowed as much time as they needed to read the entire form. After verbally confirming they had finished reading, they

decided if they wanted to sign the ICF. If they signed the form, their comprehension of the ICF was tested via a brief questionnaire, and then they were informed of the actual purpose of the study. The questionnaire queried whether they had read the entire ICF and whether they had comprehended topics relating to the required elements of consent. Only 2% of the MF group failed to read the entire ICF, compared to 32% of the IF group. Moreover, the average MF group member answered 83% of the questions correctly, whereas the average IF group member only answered 25% correctly.

Epstein and Lasagna [65] also studied the effect of length on comprehension. They compared three forms, each differing in the amount of detail included and, consequently, in length. Those receiving the short, less detailed form scored the highest on comprehension (67%); those receiving the medium length form scored the next best (45%); and those receive the long form scored the lowest (35%). Therefore, additional detail seemed to have a confusing effect. This study reinforced the concept that ICFs are most comprehensible when they are as concise as possible.

- **Dispel Therapeutic Misconceptions**

Lidz and Appelbaum [8] recommended that, before an ICF delves into study details, potential participants should have a firm grasp on the differences between regular treatment and a research study. They should understand, for example, that treatment type and dosage are not based on improving his/her well-being. Topics such as randomization and placebos should be discussed. The authors suggested that *randomization* could possibly be explained by saying that “the intervention you receive will be selected by chance, like a flip of a coin, not because we believe that one or the other will be better for you in particular.” Horng et al. [66] suggested that modifying terms used could also help. For example, 'experimental,' 'investigational,' or 'research drug or agent' could replace 'treatment,' so that established effectiveness is not implied.

- **Verify Comprehension Before Signature is Attained**

As noted earlier, readability formulas are imperfect. Moreover, potential study participants possess varying degrees and types of educational backgrounds and abilities. To determine if substantial understanding is achieved, a measure of a subject's comprehension level is ultimately necessary [47, 67]. It is insufficient to simply ask subjects if they understand the ICF, as Tait et al. [58] found that subjects significantly overestimate their level of understanding. One group, the National Quality Forum [68, 69], encourages a “teach back” method to test understanding. It involves asking the participant to summarize what has been learned during informed consent. More commonly, however, questionnaires are used to test ICF understanding. A wide variety of questionnaires have been employed, including those containing questions of the following types: yes/no [19, 44, 70], disagree/agree/unsure [6], short answer [19, 71, 72], fill-in-the-blank [73], open-ended [16, 74, 75], and/or multiple-choice [73, 75-79]. The information tested has also varied. Minimally, the questions should verify comprehension of the required elements. The Deaconess Informed Consent Comprehension Test (DICCT) is a short answer questionnaire that succeeds at this goal [80]. Another test is the Brief Consent Evaluation Protocol (BICEP), a short answer and yes/no questionnaire [81]. It is composed of 12 orally asked questions and requires less than 10 minutes. Other common examples are the Cloze test [32, 82-84] and the Quality of Informed Consent (QuIC) [85]. Some investigators have chosen to provide corrected

feedback while testing comprehension, giving the subjects a second chance to understand the information. For example Taub and Sturr [73] orally corrected any incorrect answers and directed participants to the corresponding section in the ICF. At the completion of the questionnaire with feedback, the questionnaire was repeated, again with feedback. Whichever comprehension testing method is employed, one can help ensure that comprehension is being verified, rather than recall, by allowing participants to refer to the ICF while being tested [86]. Wager et al. [87] went one step further, suggesting that some of the comprehension questions be incorporated directly into the ICF, preceding the signature lines.

- **Develop Templates and a Checklist**

Implementation of an improved standard could be aided via the creation of an ICF template(s) and checklist. Some resources that propose templates and/or checklists include an article by Silverman et al. [20], a tutorial by Grundner [88], and the National Cancer Institute's [41] report entitled "Simplification of informed consent documents."

- **Accommodate Special Needs**

Special considerations should be taken into account for individuals with decreased capacity, such as children, seniors, non-English speaking individuals or individuals with limited literacy, individuals in emotional or physical distress, and individuals with mental illness or cognitive impairment. For example, in the case of a participant who seems to be struggling due to low literacy, it may be beneficial to assess reading skills. Examples of assessment tools include the Wide Range Achievement Test-Revised (WRAT-R-III) and the Rapid Estimate of Adult Literacy in Medicine (REALM). Both tests are word recognition tests and require less than 5 minutes to administer and score. (Refer to Doak et al. [82] for a more detailed description of these tests.) REALM may be preferable because it specifically tests medical terms [89]. If the participant scores poorly, ensuring comprehension is challenging. For subjects who do not speak English, the OHRP has developed a special ICF called the "[short form](#)" [90]. The regulations permit oral presentation of informed consent information in the language of the subject in conjunction with a short form consent document written in the language of the patient stating that the elements of consent have been presented orally. There is also an IRB approved written summary in English. The process is observed by a witness fluent in both English and the language of the subject. The short form is signed by the subject and the witness while the summary is signed by the individual obtaining consent and the witness. . Regardless of which document type is employed—a short form or a standard ICF—it may be especially crucial to verify comprehension before receiving signatures from individuals with special needs.

- **Employ Supplemental Strategies**

Numerous studies have explored the effects implementing strategies to supplement the ICF document. Some studies, for example, have researched the effects of verbal explanation or discussion [92-94], videos [54, 56, 92, 94-98], pamphlets [92, 96, 99], and computer presentations [10, 56, 96, 98, 100]; however, these methods are not within the scope of this review, which is focused upon improving the informed consent document itself.

❖ Summary

Informed consent documents are generally not sufficiently comprehensible for the general population to achieve substantial understanding. The legal and scientific nature of ICFs makes it difficult to achieve this level of comprehensibility. Until cognitive psychology and linguistic research unravels the many facets involved in the reading comprehension process, one cannot hope to create ICFs that will achieve perfect comprehension for individuals of a particular age and a particular level of education, reading ability, and background knowledge. However, one *can* hope to improve comprehensibility by eliminating factors known to complicate ICFs, some of which include long overall document length due to the inclusion of information not related to the Code of Federal Regulation's required elements; long sentences and paragraphs; high reading level; polysyllabic and unfamiliar words; small font; single spacing; lack of graphics, summaries, lists, tables, or clear headings; and passive voice. Templates may help guide investigators in succeeding at such efforts. Whatever the type and magnitude of efforts employed, testing a subject's comprehension of the required elements is ultimately necessary to determine if substantial understanding is achieved [47, 67].

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