Length and Complexity of US and International HIV Consent Forms from Federal HIV Network Trials

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BACKGROUND: Informed consent is required in most clinical research with humans. While federal regulations state consent information should be understandable to participants, concerns have been raised that consent forms are overly long and complex.

DESIGN: Consent forms from 2006 HIV network trials sponsored by the National Institutes of Health (NIH), Division of AIDS (DAIDS), were analyzed for complexity and length. Comparisons were made between US and international sites, template and site forms, adult and pediatric trials, and trial type. How randomization and placebos were explained was examined as these are frequently misunderstood.

RESULTS: One hundred twenty-four consent forms (21 template and 103 site forms) were reviewed. Median readability was 9.2 grade level, although confidentiality sections were 12.35 median grade level. International sites' forms had lower readability than US forms ($p=0.025$), template forms had lower readability than site forms ($p=0.046$), and adult forms were less complex than pediatric (parent) forms ($p<0.0001$). Median length of all forms was 22.4 pages; the 85 forms from adult studies had a median length of 27.4 pages. Sections describing randomization were a median length of 53 words.

CONCLUSIONS: Consent forms are extremely long, exceeding recommendations for how much information readily can be processed. Networks should consider providing shorter consent templates, consistent with federal recommendations, given that sites' forms are based on these models. Further research should examine whether forms emphasizing key information (rather than providing details about all aspects of the research) improve understanding of research.

KEY WORDS: informed consent; HIV; clinical trials.
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BACKGROUND

Informed consent generally is required in human research as a means of putting the ethical principle of respect for persons into practice.[1,2] Valid informed consent requires disclosure of information, understanding by participants, and a voluntary and competent decision.[3] The informed consent *form*, according to US federal regulations, is the means by which agreement to participate in research is documented, generally in writing through the participant's signature.[4,5] US regulations further state that information "given to the subject… shall be in language understandable to the subject."[6]

Studies conducted with research participants, however, suggest that understanding often is incomplete.[7–10] Some participants are unaware they are enrolled in research,[11–13] and others, both in US and international projects, misunderstand risks and the ability to withdraw.[8–10] Randomization and placebo, critically important concepts to understand in clinical trials, are particularly likely to be misunderstood.[7,14,15]

Concerned about inadequate understanding, studies have examined whether consent form length or complexity may hinder understanding of key information.[16,17] Data suggest consent forms are becoming longer over time,[17,18] of potential concern even if using non-technical language.[17,19–21] One study showed mean length of consent forms tripled over a 20-year period, with significant additional text related to "juridicial and financial matters, insurance, and data safety and storage."[5] This increase in length is relevant, ethically, as evidence exists that shorter forms are associated with better understanding.[17]

Many IRBs recommend that consent documents be written at or below the 8th grade level,[16] and, while almost half of Americans read at or below the 8th grade reading level,[22] this standard often is not met.[16,17,23–25] In developing countries, literacy rates can be low; literacy rates are estimated to be 62.8% in India, 55.0% in Bangladesh, and 41.9% in Senegal.[26]

In 1998, the US National Cancer Institute (NCI) recommended that informed consent forms for NCI-sponsored trials be written at no more than the 8th grade reading level, with short sentences, active voice, simple page layout, and large font.[6] NCI also emphasized minimizing the length of consent documents, suggesting investigators provide access to supplemental materials such as information sheets and videos, rather than including all details in consent forms;[6] the NCI approach achieved better participant understanding of study information.[7] In the international setting, Guidelines for Good Clinical Practice also address consent readability, urging investigators to avoid technical language.[27] Other NIH institutes have not created similar recommendations for their own networks or trials; moreover, while there is considerable literature analyzing consent documents from oncology, we are aware of no systematic analyses of consent forms from HIV trials or networks. Nonetheless, anecdotal concerns have been raised that consent forms from HIV trials and networks also

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are growing longer. HIV networks generally include participants from lower literacy backgrounds and from multiple countries. Within the US, health literacy has been shown to be an important factor in the health of people with HIV.[28] As such, and given that many trials carry high risks and uncertainties, it is particularly important that consent materials have high standards for being understandable. The objectives of this study were to determine the length and complexity of consent forms from HIV-related US and international multi-center studies sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH); to determine whether form length or complexity varied by whether forms were from US vs. international sites, adult vs. pediatric trials, and trial type; to determine the degree to which template forms were varied when reviewed by sites; and also to examine how the concepts of randomization and placebos were described in forms, as these are often misunderstood by research participants. The overarching goal was to contribute to an evidence base for potential policy changes for consent documents for federally sponsored clinical research trials.

METHODS

IRB-approved, final versions of consent forms were requested from the Division of AIDS (DAIDS), NIAID, and NIH, for all actively enrolling trials associated with DAIDS networks in 2006. DAIDS networks included the AIDS Clinical Trials Group (ACTG), Pediatric AIDS Clinical Trials Group (PACTG), HIV Vaccine Trials Network (HVTN), and HIV Prevention Trials Network (HPTN). For each network trial, consent forms requested included the template form prepared by trial leadership and every site-specific form from all US and international participating sites. Template forms are the "master" form created by each trial's leadership; these template forms are then distributed as a model for other sites. Sites are free to use the template form as originally drafted, although local IRBs also are free to require changes from the template form to be used locally. All consent forms were in English, as all templates had been written in English and all site-specific forms had an original English version. This approach allowed examination of the template models offered to sites and whether and how forms changed after IRB review at sites.

An Excel database was created, and forms were labeled with trial study number and coded as "international" or "US" based on where participants would be recruited. Forms also were coded as "drug therapy/prevention," "vaccine," "observational" or "behavioral," and "adult" or "pediatric" based on the population being recruited.

Microsoft Word readability statistics were applied to all forms, with particular attention to word count, total number of pages, and Flesch-Kincaid grade level. To standardize across different formatting and fonts across forms, the page length of each form was calculated by dividing each form's overall word length by 250, based on an existing standard of 250 words per page.[29] The Flesch-Kinkaid grade level is a standard means of assessing document readability based on number of syllables per word and number of words per sentence.[30] Readability statistics were generated for forms as a whole and for sections corresponding to topics required by US federal regulations (purpose, procedures, risks, benefits, confidentiality, voluntariness of participation, study withdrawal, and alternatives to participation).[4] If information relevant to a topic (e.g., confidentiality) was covered in more than one section, relevant text was coded as belonging to the topic, regardless of where in the form it was printed. In addition, some sentences were double or triple coded if they related to several topics, e.g., to both confidentiality and to risks. Finally, when a trial was randomized, any language related to randomization was coded and analyzed.[14,31,32]

Readability statistics were transferred to a STATA file using Stat Transfer and analyzed using STATA 10. Analyses were conducted to determine differences between template forms and site-specific forms; between US and international site forms; between drug, vaccine, observational, and behavioral trials; and between adult and pediatric trials. Median comparisons were made using a Pearson chi-squared test. Medians of readability statistics were calculated for all consent forms and sections.

Because the literature suggests that participants are particularly unlikely to fully understand consent language related to placebos and randomization, we added a textual analysis component to this project. Specifically, textual analysis was conducted for sections of consent forms related to placebos or randomization, with particular attention to analogies and phrasing. Language on forms was eligible for textual analysis if it used the words "random," "randomized," "randomization," "treatment groups," "placebo," "allocation," "groups," "lot," "coin," or "chance," or if there was an explicit section related to randomization. Any language on consent forms related to placebo or what a placebo was, including a description of a placebo as a "sugar pill," or why a placebo was included was included under the code of placebo. Sections of text related to these terms were cut and pasted into an Excel spreadsheet such that particular phrases, explanations, or analogies could be counted for frequency of use.

RESULTS

Description of Sample

A total of 124 informed consent documents from 21 different trials were included in this analysis. The data set included 21 template documents and 103 site documents, 75 from US sites, and 28 from international sites, specifically from sites in Australia, Brazil, India, Malawi, Puerto Rico, South Africa, Tanzania, Thailand, and Zimbabwe. Eight template (56 total) forms were from drug therapy/prevention trials, 8 template (45 overall) forms were from vaccine trials, 4 templates (21 overall) were observational trials, and 1 template (2 forms overall) was from a behavioral intervention trial. Sixteen templates (85 forms overall) were from adult trials, and 5 templates (39 forms) were parental forms from pediatric trials.

Complexity and Length of Forms Overall

Table 1 shows median readability statistics and page length for the total sample of forms and by subgroup. Overall, consent forms had a median readability of 9.2 grade level. Readability became more complex as forms moved from the template to the sites ($p=0.046$), domestic forms were more complex than international forms ($p=0.026$), and forms for pediatric trials were more complex than those for adult trials ($p<0.0001$).

Table 1. Median Flesch-Kincaid Grade Level and Number of Pages for Entire Data Set

	N	Median Flesch-Kincaid grade level	p-value	Median number of pages	p-value
All forms	124	9.2		22.4	
Template vs. Site forms					
Template	21	8.7		16.8	0.231
Sites	103	9.4	0.046	23.5	
US vs. International forms					
US	75	9.6		25.8	
International	28	9.1	0.025	16.4	0.087
Adult vs. Pediatric forms					
Adult form	85	8.6		27.4	
Pediatric form	39	10.5	<0.0001	15.7	<0.0001
Nature of Trial					
Drug therapy/ prevention	56	9.5	n/a	20	n/a
Vaccine	45	8.4		27.4	
Observational	21	9.8		13.3	
Behavioral	2	10.2		13.2	

Median page length of all 124 forms was 22.4 pages. The shortest forms were from observational and behavioral trials, both with a median of approximately 13 pages. The longest forms were from vaccine and adult trials, both with median page lengths of approximately 27 pages, and US sites, with a median of approximately 26 pages.

Adult trial forms were longer than pediatric trial forms (27.4 vs. 15.7 pages; $p<0.0001$). To account for possible confounding by type of trial, adult and pediatric forms were compared within the drug therapy/prevention category, the only category with both adult and pediatric trials (n=40 and n=16, respectively). Differences in length between adult and pediatric forms were sustained (median 25.9 and 17.2 pages, respectively).

Forms from US sites also were considerably longer than international sites' forms (25.8 vs. 16.4 pages, respectively), but the difference was not statistically significant ($p=0.087$). To account for possible confounding by type of trial, form lengths were compared within trial type. US forms remained longer than international site forms for drug therapy/prevention trials (21.2 vs. 16.4 pages) and observational trials (17.6 vs. 13 pages).

Complexity and Length of Sections of Forms

Table 2 shows median readability and word length for each of the eight federally mandated sections across all forms. Readability of each section was comparable to readability of documents as a whole (9.2), with the exception of confidentiality with a median readability of 12.35 across all forms. Procedures and risks were the longest sections, with procedures taking up just over six pages of text and risks just over five pages. Confidentiality sections had a median of just under two pages in length.

Explanations of Randomization and Placebo in Consent Forms

Overall, 101 forms from 16 templates had sections and/or language related to randomization. All were drug treatment, prevention, or vaccine trials. The complexity of randomization sections was generally comparable to the other sections (Table 2), and median length was 53 words total in the document related to randomization (approximately .2 pages).

Table 2. Median Flesch-Kincaid Readability Grade Level, Median Word Count, and Page Length for Individual Sections of Consent Forms

Section	Median Flesch-Kincaid Readability grade level (n=124)	Median word count (n=124)	Page length (n=124)
Purpose	9	227	0.91
Procedures	8.9	1620	6.48
Risks	9.15	1255	5.02
Benefits	7.5	61	0.24
Confidentiality	12.35	441.5	1.77
Alternatives	8.25	63	0.25
Voluntariness	6.75	135	0.54
Withdrawal	8.9	179.5	0.72
Randomization*	7.9	53	0.21

**A total of 101 forms included language regarding randomization*

Of the 101 documents that discussed randomization, all but one gave a qualitative description or analogy to help explain randomization (Table 3). An overwhelming majority (85) used the description "like the toss of a coin." None, however, explained *why* randomization is used in studies.

A total of 54 forms from 11 templates described the meaning of placebos (Table 3). Over half (40 forms) described placebo as an "inactive substance" and three described placebo as a "sugar pill." Thirty-two explained why placebos are used, such as, "we give placebos to some people, and compare the results from the people who got the experimental [drug/vaccine] with the results from the placebo group. This helps us measure the effects of the experimental [drug/vaccine]." Five documents gave neither a definition of placebo nor an explanation for why placebos are used.

DISCUSSION

This study measured readability and length of 124 informed consent documents from federally funded US and international HIV network trial sites. Consent forms had a median

Table 3. Frequency of Use of Specific Analogies or Descriptions to Explain Meaning of "Randomization" and "Placebo" in Consent Forms

Description of what randomization is	**Frequency**
"Like the toss of a coin"	84
"By lot"	6
"My group will be chosen randomly/by chance"	5
"Like rolling dice"	2
"Like choosing a number between 1 and 10"	1
"Like drawing straws"	1
"By lot or flipping a coin or rolling dice"	1
No description/analogy	1
Total	**101**

Description of what placebo is	**Frequency**
"Inactive substances that do not contain the drug/ vaccine"	40
"Looks/feels/tastes like the drug but does not have the ingredients from the drug"	6
"Like a sugar pill"	3
No description/analogy	5
Total	**54**

readability score of 9.2, only slightly higher than the recommended maximum of 8th grade level. As such, it represents some success for investigators and Institutional Review Boards, who likely have devoted attention to simplifying research information. Efforts to simplify language must continue, since target populations for HIV studies in both the US and internationally may include participants whose reading skills may be challenged even by a 9.2 grade level form. Scholars have suggested simpler alternatives to complex and commonly used phrases in consent forms.[33]

More worrisome than readability were findings about forms' length. Median length of the 124 consent documents was 22 pages, and the 85 adult forms had a median length of 27 pages. Even simply worded forms of 27 pages can pose challenges for comprehending and retaining information, and for discerning which study information is most important. Evidence exists that individuals often skim over documents longer than 1,000 words.[19,34] Also, a growing literature suggests that comprehension is higher when subjects are exposed to shorter forms. In one study, overall comprehension scores were higher on a shorter and simpler form compared with a longer, more complex form when tested in the product marketing context[35]; in another study, understanding of all subparts of consent, including purpose, randomization, and voluntariness, was higher using a shorter form for an industry sponsored clinical trial[36]; "higher objective knowledge" scores were reached in a series of cancer trials when forms were shorter than seven pages in length.[17] It was not surprising that sections related to study procedures and risks were longest. More surprising, perhaps, was that confidentiality sections had a median length of 441 words, approximately 1 1/2 pages of written text. For the 75 US site forms, median length of confidentiality text was over two pages. While HIV raises more concerns regarding confidentiality than some other conditions, protections still might be explained more succinctly.

That confidentiality sections are so lengthy was particularly striking when contrasted with the brief descriptions of randomization and placebos, topics shown repeatedly to be difficult to understand.[7,14,35] All information related to randomization from any part of the form, including analogies, was a median length of 53 words. Further, while forms described *how* participants would be randomized, none explained *why* studies randomize participants, which may help improve understanding of the concept.[14]

Finally, forms became longer and more complex when they moved from the template to individual sites. While differences were small, our findings are consistent with another study that found that US and Canadian trial sites made an average of 46.5 changes from centrally approved forms, resulting in a mean increase in grade level of 0.9.[37] That IRBs want to make minimal changes in all sections of forms may not be surprising, yet these changes consistently added rather than eliminated text.

This project had limitations. First, forms were from one division of one NIH institute. It is to the credit of NIAID officials and to their commitment to working on improving consent procedures and materials that forms were made readily available to examine trends in consent forms' readability and length. Future research should examine whether patterns observed here are replicated in other federally sponsored trials and in industry sponsored research. A second limitation is that consent forms are only one piece of the consent process. While forms were dramatic in their length, investigators may have first given concise and clear descriptions orally before introducing lengthy written material. Indeed, international sites often conduct group information sessions before reviewing forms with individual participants. Research examining the role consent forms play in participants' understanding would be valuable, given the weight put on consent form language by investigators and IRBs. Third, only English language forms were analyzed. It is fairly common for local IRBs, even in settings where consent will be conducted in other languages, to approve forms based on the English (rather than local language), even if local language forms also are submitted. Unfortunately, standard readability measures do not exist for most of the world's languages, although some evidence indicates that readability may become more complex with translation;[38] future work should compare translated forms to templates as well. Fourth, length of documents was calculated from overall words per document, using a standardized formula for page length. This standardization allows comparison of documents with different fonts, line spacing, and margins, but does not capture the "first appearance" to participants of number of pages held in their hands. Fifth, the study is not powered to examine confounding effects within and across trial types. Related, this study analyzed multiple site forms from 21 trial templates. As such, findings do not represent data from 124 independent forms, but rather they amplified the good or bad aspects of template forms. Truly independent data exist in analyses of the 21 template forms. At the same time, the 124 forms represent what was provided in ongoing trials and reveal the length and complexity of documents used with participants in the field. Finally, this study was limited to consent forms from HIV trials. It is our speculation that many of the findings—from dramatic overall length, to segments such as confidentiality being so much longer than important, challenging concepts like randomization, to the increase in complexity when templates are modified from local review—would likely be replicated in examinations of forms from other trial networks for other very different types of medical conditions.

As implied throughout this paper, long consent forms pose serious detriments to participant understanding in human subject research. Doctors, IRBs, researchers, and others involved in writing consent documents must work to shorten and simplify consent forms in order to allow for genuine, reliable consent to happen with human subjects. The findings from our study and subsequent recommendations we have made in this paper serve to support the principle that the consent process is critical in respectful treatment of research participants and the public perception of medical research as a whole.

Additional research should examine whether length results from extensive study detail, significant redundancy, or both. Related, experimental research should measure not only the impact of shorter vs. longer forms on understanding, but also whether studies that emphasize what are thought to be the most important concepts improve understanding. Informed consent requirements were introduced as part of our federal regulatory structure more than 30 years ago. Consent forms of greater than 20 pages beg a question of whether current norms, at least in some contexts, of extremely lengthy consent forms fulfills the foundational moral goals of our regulations—to respect and protect the individuals who join and ensure they

are equipped to make decisions themselves based on a good understanding of proposed research.

This study found that consent forms from federally funded HIV trials have lower readability scores than found in previous studies, likely a result of the attention investigators and IRBs have devoted to this goal. Given recent data that shorter forms provide comparable understanding to longer ones,[39] the same attention should be dedicated to shortening forms. Finally, in keeping with federal recommendations, trial networks should consider providing shorter templates, especially since site forms are based on their models.

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