FEATURE ARTICLE

A Randomized Controlled Study Comparing the National Cancer Institute's Original and Revised Consent Form Templates

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Table 1.
Comparison of Length and Readability Statistics for Consent Documents for NSABP-C-08 Using NCI's Original and Revised Consent Form Template

Statistic	*Original form*	*Concise form*	*% of change*
# of pages:			
• Main study	13.25	11.25	-2.0 pages
• Additional study	11.25	8.75	-2.5 pages
• Difference	2.00	2.50	+0.5 pages
Word count	5294	3952	-25%
Character count	25,218	18,816	-25%
Number of paragraphs	227	244	+7%
Number of sentences	265	181	-32%
Sentences per paragraphs	2.8	1.8	-36%
Words per sentence	16.6	15.9	-4%
Characters per word	4.4	4.4	0%
Passive sentences	30%	27%	-10%
Flesch-Kincaid reading-ease level	63.1	62.9	-1%
Flesch-Kincaid grade level	8.5	8.4	-1%

Table 2.
Participant Knowledge Items Categorized by Content Domain[1]

Content Domain	*Knowledge Items*
Usual/standard of care	• People in Group 1 are at greater risk for possible side effects than people who are not in this study and given the standard treatment. (T/**F**)[2] • Patients with colon cancer who are not in this study would typically receive the same treatment as those who will be in Group 1 of this study. (**T**/F)
Purpose of study	• From what you read, the main purpose of this study is: [select from list] A: To find out if adding bevacizumab to the usual approach for colon cancer makes a difference.[3] • Adding the study drug (bevacizumab) to the chemotherapy treatment might not be any better in treating your cancer. (**T**/F)
Choice • To participate or not • To stop/withdraw • Substudy participation	• It's up to you to decide if you will be part of this treatment study. (**T**/F) • If you agree to be part of this study you must stay on the treatment until the study is over. (T/**F**) • Your study doctor can take you off the study at any time before it ends. (**T**/F) • You can say 'no' to researchers using your blood and tissues for future studies and still be part of the main study. (**T**/F)
Treatment protocol • Process • Timeline • Study groups	• How many groups are being compared in this study? [MC] A: Two • How many cancer-fighting drugs will patients in Group 1 receive? [MC] A: Three • If you were in Group 2, how long would you be taking drugs as a part of this study? [MC] A: One year • Which of the following drug(s) is the study designed to test? [MC] A: Bevacizumab • From what you read, the main difference between Group 1 and Group 2 is: [select] A: The addition of a new drug in addition to the usual chemotherapy treatment
Randomization	• If you were to agree to be part of this study, who decides what group you will be in? [MC] A: Chance (using a computer) • Your doctor can recommend which study group you will be placed in. (T/**F**)
Side effects or risks	• Stroke is a rare but serious side effect for people taking the chemotherapy drugs (5-FU, leucovorin, and oxaliplatin). (T/**F**)
Benefits	• What is learned from this study may help future cancer patients. (**T**/F) • This study is being done to find the treatment that will most benefit you. (T/**F**)
Costs	• You may be responsible for some of the treatment costs not covered by your insurance for this study. (**T**/F) • You will be paid for taking part in this treatment study. (T/**F**) • Currently the drugs bevacizumab and 5-FU will be provided free of charge to patients. (T/**F**)
Privacy	• Only your doctor can look in your medical records for information about your treatment as a part of this study. (T/**F**) • Published information about this study may include your name. (T/**F**)
Additional biobanking studies	• If you agree to participate in the additional study (discussed near the end of the document) you will be asked to provide additional tissue and blood samples. (T/**F**)

[1] The questions were adapted from Coyne CA et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: A study of the Eastern Cooperative Oncology Group. *Journal of Clinical Oncology* 2003;21 (5):836-842.
[2] For the true or false items, a bold letter indicates the correct response.
[3] For this and the following multiple choice (MC) items, only the correct answer (marked "A") is provided here.

Table 3.
Participant Descriptors by Consent Form

		Total n (%)	*Original form (n = 72)*	*Concise form (n = 81)*	*P-value*[1]
Sex	female	88 (57.5%)	43 (59.7%)	45 (55.6%)	.36
	male	65 (42.5%)	29 (40.3%)	36 (44.4%)	
Age	25-49	59 (38.6%)	31 (43.1%)	28 (34.6%)	.18
	50 or over	94 (61.4%)	41 (56.9%)	53 (65.4%)	
Race	white	136 (89%)	62 (86%)	74 (91%)	.22
	other	17 (11%)	10 (14%)	7 (9%)	
Education					
	high school or some college	59 (38.6%)	29 (40.3%)	30 (37.0%)	.40
	college graduate or beyond	94 (61.4%)	43 (59.7%)	51 (63.0%)	
Household income					
	< $74,000	79 (51.6%)	37 (51.4%)	42 (51.9%)	.54
	$75,000+	74 (48.4%)	35 (48.6%)	39 (48.1%)	
Prior clinical trial knowledge					
	low (1-2 score)	74 (48.4%)	37 (51.4%)	37 (45.7%)	.29
	high (3-5 score)	79 (51.6%)	35 (48.6%)	44 (54.3%)	

[1]Pearson chi-square test (one-sided) at the P = 0.05 level.

Table 4.
Means, t-Tests, and Regression Results for Knowledge, Satisfaction, and Change in Likelihood to Consider a Trial from Pre- to Posttest, by and Controlling for Consent Form and Participant Descriptors

Variable	*Group*	*Mean (SD)*	*P-value (t-test between groups)*	*Regression standardized beta*	*Regression p-value*[1]
Knowledge (number correct out of 24 questions)					
Consent form	original (N = 72)	19.94 (4.13)	.188	0.09	.279
	concise (N = 81)	20.73 (3.03)			
Sex	female	20.49 (3.06)	.624	0.04	.615
	male	20.18 (4.24)			
Age	25-49	19.53 (428)	.036	0.21	.011
	50+	20.88 (3.00)			
Household income[2]					
	<$75,000	19.85 (3.84)	.069	0.07	.413
	$75,000+	20.91 (3.26)			
Race	white	20.43 (3.61)	.472	0.04	.647
	nonwhite	19.76 (3.54)			
Education	high school or some college	19.32 (4.30)	.009	0.25	.003
	college graduate or beyond	21.01 (2.92)			
Prior clinical trial knowledge[3]					
	low	20.53 (3.40)	.579	-0.06	.501
	high	20.20 (3.79)			
Satisfaction (1-5 scale, 1 = not at all satisfied, 5 = very satisfied)					
Consent form	original (N = 72)	4.29 (0.72)	.228	-0.10	.216
	concise (N = 81)	4.16 (0.62)			
Sex	female	4.24 (0.67)	.598	0.05	.566
	male	4.18 (0.67)			
Age	25-49	4.12 (0.60)	.145	0.13	.122
	50 or over	4.28 (0.70)			
Household income					
	<$75,000	4.27 (0.71)	.360	0.04	.677
	$75,000+	4.17 (0.62)			
Race	white	4.22 (0.67)	.787	-0.05	.587
	nonwhite	4.17 (0.70)			
Education	high school or some college	4.34 (0.60)	.075	-0.17	.052
	college graduate or beyond	4.14 (0.70)			
Prior clinical trial knowledge					
	low	4.10 (0.71)	.033	0.23	.005
	high	4.33 (0.60)			
Change in likelihood to consider a clinical trial from pretest to posttest (1-5 scale, 1 = not at all likely, 5 = very likely)[4]					
Consent form	original (N = 72)	-0.26 (1.23)	.007	-0.22	.007
	concise (N = 81)	-0.81 (1.24)			
Sex	female	-0.64 (1.33)	.358	-0.06	.466
	male	-0.45 (1.16)			

Variable	*Group*	*Mean (SD)*	*P-value (t-test between groups)*	*Regression standardized beta*	*Regression p-value*[1]
Age	25-49	-0.39 (1.14)	.184	-0.11	.189
	50 or over	-0.66 (1.32)			
Household income					
	<$75,000	-0.61 (1.32)	.600	0.01	.871
	$75,000+	-0.50 (1.20)			
Race	white	-0.51 (1.26)	.258	0.10	.216
	non-white	-0.88 (1.22)			
Education	high school or some college	-0.39 (1.10)	.199	-0.13	.122
	college graduate or beyond	-0.66 (1.35)			
Prior clinical trial knowledge					
	low	-0.77 (1.42)	.043	0.16	.053
	high	-0.35 (1.06)			

[1] The adjusted R square for regression results for knowledge = .07; F7,145 = 2.74, p = 0.011 (using the enter method); the adjusted R square for regression results for satisfaction = .05; F7,145 = 2.19, p = 0.038 (using the enter method); the adjusted R square for regression results for likelihood to consider enrolling in the trial pretest versus posttest = .07; F7,145 = 2.64, p =.013 (using the enter method).
[2] The collapsed, two-category variable was used for the t-tests, but the categorical, incremental variable was used for the regression analyses.
[3]The collapsed, two-category variable was used for the t-tests, but the 1-5 scale variable was used for the regression analyses.
[4] The results represent the mean value when subtracting the pretest "likely" score from the posttest "likely" score. Negative numbers indicate that a score decreased from pre- to posttest. Likelihood was measured on a 1-5 scale, with higher numbers indicating greater likelihood.

Figure 1.
Participants' Likelihood to Consider a Clinical Trial in the Future, with Pre- and Posttest Mean Scores by Consent Form Group