COMMENTARY

Reducing Consent Form Length: Stakeholder Support, Evidence-Based Strategies, and Regulatory Requirements

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Table 1.
Study Populations, n (%).[1]

Conference respondents	**Conference 1** **n = 233**	**Conference 2** **n = 50**	**Total** **n = 283**
IRB member	31 (13.3)	16 (32.0)	47 (16.6)
IRB administrator	39 (16.7)	19 (38.0)	58 (20.5)
Clinical investigator	8 (3.4)	4 (8.0)	12 (4.2)
Research support staff member	127 (54.5)	4 (8.0)	131 (46.3)
Research sponsor	2 (0.9)	2 (4.0)	4 (1.4)
Representative of a clinical research organization	3 (1.3)	1 (2.0)	4 (1.4)
Representative of a contract research organization	1 (0.4)	0 (0)	1 (0.4)
Government regulator	1 (0.4)	1 (2.0)	2 (0.7)
Other member of the clinical research community	8 (3.4)	0 (0)	8 (2.8)
Other	13 (5.6)	3 (6.0)	16 (5.7)
EDICT stakeholders	**First online survey** **n = 53**		
HPTN research participants	16 (30.2)		
HPTN chairs, site investigators, site staff members, core staff members	14 (26.4)		
Community representatives	6 (11.3)		
Institutional officials	4 (7.5)		
IRB members	8 (15.1)		
DAIDS representatives	5 (9.4)		

[1] Some total column percentages do not equal 100 due to rounding.
IRB—institutional review board
EDICT—Effective Delivery of Informed Consent study
HPTN—HIV Prevention Trials Network
DAIDS—Division of AIDS

Table 2.
Agreement Distribution for Statements about the Length of Informed Consent Forms, n (%).[1]

Statement 1	**Agreement**	**Conference 1 n = 243**	**Conference 2 n = 54**	**Conference Total n = 297**	**EDICT stakeholders**[2] **n = 37**
Informed consent forms [ICFs] are generally too long.	Strongly agree	138 (56.8)	39 (72.2)	177 (59.6)	16 (43.2)
	Agree	95 (39.1)	15 (27.8)	110 (37.0)	19 (51.4)
	Disagree	8 (3.3)	0 (0)	8 (2.7)	2 (5.4)
	Strongly disagree	2 (0.8)	0 (0)	2 (0.7)	0 (0)
Statement 2	**Agreement**	**Conference 1 n = 238**	**Conference 2 n = 55**	**Total n = 293**	**EDICT stakeholders n = 53**
As long as the essential information is retained, ICFs should be made shorter in length.	Strongly agree	190 (79.8)	46 (83.6)	236 (80.5)	34 (64.2)
	Agree	46 (19.3)	9 (16.4)	55 (18.8)	17 (32.1)
	Disagree	1 (0.4)	0 (0)	1 (0.3)	2 (3.8)
	Strongly disagree	1 (0.4)	0 (0)	1 (0.3)	0 (0)

[1] The total number of conference respondents who answered each question varied, as audience members could chose to answer each question individually. Some total column percentages do not equal 100 due to rounding.
[2] HPTN study participants were not asked this question.

Table 3.
Support of Strategies for Reducing ICF Length, n (%).[1]

Strategy 1	**Agreement**	**Conference 1 n = 202**	**Conference 2 n = 49**	**Conference total n = 251**	**EDICT,**[2] **stakeholders n = 53**
Grouping study procedures by frequency instead of by study visit	Strongly agree	143 (70.8)	38 (77.6)	181 (72.1)	31 (58.5)
	Agree	51 (25.2)	9 (18.4)	60 (23.9)	13 (24.5)
	Disagree	7 (3.5)	1 (2.0)	8 (3.2)	8 (15.1)
	Strongly disagree	1 (0.5)	1 (2.0)	2 (0.8)	1 (1.9)
Strategy 2	**Agreement**	**Conference 1 n = 177**	**Conference 2 n = 47**	**Conference total n = 224**	**EDICT stakeholders n = 51**[3]
Providing reference information about specific study procedures per study visit in an appendix	Strongly agree	101 (57.1)	26 (55.3)	127 (56.7)	21 (41.2)
	Agree	57 (32.2)	16 (34.0)	73 (32.6)	17 (33.3)
	Disagree	15 (8.5)	5 (10.6)	20 (8.9)	8 (15.7)
	Strongly disagree	4 (2.3)	0 (0)	4 (1.8)	5 (9.8)
Strategy 3	**Agreement**	**Conference 1 n = 198**	**Conference 2 n = 49**	**Conference total n = 247**	**EDICT stakeholders n = 44**[4]
Listing duplicative side effects once instead of for each drug	Strongly agree	64 (32.3)	26 (53.1)	90 (36.4)	22 (50.0)
	Agree	94 (47.5)	14 (28.6)	108 (43.7)	13 (29.5)
	Disagree	39 (19.7)	8 (16.3)	47 (19.0)	8 (18.2)
	Strongly disagree	1 (0.5)	1 (2.0)	2 (0.8)	1 (2.3)

[1] The total number of conference respondents who answered each question varied, as audience members could chose to answer each question individually. Some total column percentages do not equal 100 due to rounding**.**
[2] The EDICT (Effective Delivery of Informed Consent study) data presented here are from the first online survey because the first conference was held prior to the analysis of EDICT's second online survey.
[3] Data are missing from two stakeholders.
[4] Only stakeholders associated with the one HPTN study that evaluated multiple drugs were asked this question.