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Standard Versus Simplified Consent Materials for Biobank Participation: Differences in Patient Knowledge and Trial Accrual

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Abstract

Replacing standard consent materials with simplified materials is a promising intervention to improve patient comprehension, but there is little evidence on its real-world implementation. We employed a sequential two-arm design to compare the effect of standard versus simplified consent materials on potential donors' understanding of biobank processes and their accrual to an active biobanking program. Participants were female patients of a California breast health clinic. Subjects from the simplified arm answered more items correctly ($p = .064$), reported "don't know" for fewer items ($p = .077$), and consented to donate to the biobank at higher rates ($p = .025$) than those from the standard arm. Replacing an extant consent form with a simplified version is feasible and may benefit patient comprehension and study accrual.

Keywords

informed consent, biobanks, biorepositories, Common Rule, tissue donors, enhanced consent form, patient comprehension, accrual

Ample research shows that patients often do not read or do not understand research consent forms they sign (Flory & Emanuel, 2004; Jefford & Moore, 2008; Joffe, Cook, Cleary, Clark, & Weeks, 2001a; Lidz, Appelbaum, Grisso, & Renaud, 2004; Montalvo & Larson, 2014; Tait & Voepel-Lewis, 2015). The possibility for inadequate or incorrect understanding may be particularly pronounced for individuals considering biobank donation, who must appreciate how biobanks collect and store remnant or other tissue samples, how data are de-identified and shared, the unique nature of future unspecified research, and special considerations related to genetic analysis (Beskow, Dombeck, Thompson, Watson-Ormond, & Weinfurt, 2015; McGuire & Beskow, 2010; Ormond, Cirino, Helenowski, Chisholm, & Wolf, 2009; Simon, Klein, & Schartz, 2016). Biobank participation typically includes few direct risks comparable with those patients might encounter in invasive clinical research, but most biobank consent forms are nonetheless long and complex. Like many research consent forms, they are responsive to the legal needs of research institutions more than the reading needs of lay participants, nearly half of whom read at or below the eighth grade level or have limited health literacy (Hudson & Collins, 2015; Jefford & Moore, 2008; Tamariz, Palacio, Robert, & Marcus, 2012). Although regulatory requirements have historically exacerbated this problem (Larson, Foe, & Lally, 2015; McCarty et al., 2011), recent changes to the U.S. Federal Common Rule have both loosened consent requirements for biobanking and encouraged an emphasis on obtaining truly informed consent ("Federal Policy for the Protection of Human Subjects," 2017). Taken together, these changes provide an opportunity for the bioethics research community to provide actionable, empirical evidence about how to improve the biobank consent process.

Researchers have developed and tested a wide range of interventions designed to improve patient understanding of consent materials. Approaches include multimedia technologies, enhanced or modified consent forms, extended discussion with educators (Flory & Emanuel, 2004), and plain language supplemental brochures (Drake et al., 2016). Some interventions include "test/feedback" or other interactive features to enhance learning (Flory & Emanuel, 2004; Simon et al., 2016). Many of these interventions have yielded modest improvements in patient comprehension of consent material in mostly simulated settings (Flory & Emanuel, 2004; Nishimura et al., 2013).

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One promising low-resource intervention is the use of a simplified version of extant standard consent forms. Considered a type of "enhanced" consent form, simplified consent materials are shorter documents that use simpler language and formatting to enhance readability (Nishimura et al., 2013). The effect of simplified consent forms on patient understanding has been tested, but mostly under simulated, rather than real-world conditions (Flory & Emanuel, 2004; Nishimura et al., 2013). In 2004, Flory and Emanuel discouraged further simulation studies because of validity concerns, yet in the following 10 years, all studies of simplified consent interventions were conducted under simulated conditions (Flory & Emanuel, 2004; Nishimura et al., 2013). As such, we know little about the effect of simplified consent forms on patient understanding or participant accrual, or the feasibility of their use, in real-world research settings.

To advance research on these topics, we investigated whether substituting a simplified consent form for the standard form of an active biobanking program would yield better patient accrual and understanding of the processes and implications of biobanking. We also investigated whether clinic staff encountered barriers to using the simplified form.

Method

Design

We conducted a sequential two-arm study at an academic medical research center in Northern California to compare the effects of standard versus simplified consent materials on patient understanding of consent and biobank accrual rates. This study was part of a parent study, EngageUC, which was a large multicampus project designed to improve biobanking systems and donor recruitment to biobanks at a large university system (Garrett et al., 2015; Dry et al., 2017).

Setting

The setting for the trial was a large breast health clinic that was actively recruiting donors for its biorepository. As part of routine care, clinic staff administered intake questionnaires to patients either via email before appointments or in-person in the clinic waiting room. The questionnaire included a question about the patient's potential interest in donating blood or saliva to the biobank. These data were recorded by clinic staff, and patients who indicated interest were targeted for recruitment. In most instances, these "interested" patients were approached by clinic study coordinators before their appointments to initiate the consent process. Patients were not approached if coordinators judged there to be inadequate time to complete the consent process before the patient's scheduled appointment or if a study coordinator was unavailable. A subset of "interested" patients therefore did not have the opportunity to join the biobank.

Intervention

The intervention substituted a simplified consent form for the breast health clinic's standard biobanking consent form, which was nearly 1,700 words and four pages long. Its reading level was estimated to be 9th to 10th grade based on the Flesch–Kinkaid readability test. See Online Appendix A for the standard consent form.

We based the simplified consent form on one developed by Beskow and colleagues that is specific to biobank participation (Beskow, Friedman, Chantelle Hardy, Lin, & Weinfurt, 2010). In keeping with their design and those of other simplified consent forms (Flory & Emanuel, 2004), we eliminated standard but unnecessary information and incorporated content headers, simplified vocabulary, and simplified sentence structure. We also consulted with a team of legal experts to ensure our form was in compliance with California law.

These simplifications were inspired by input we received in a related study, for which we engaged lay Californians in deliberations about biobanking processes (Garrett et al., 2015; Dry et al., 2017). Participants in these deliberations recommended that biobanks employ consent forms that communicate important information in simple and clear language, in a manner accessible to the average patient. Our consent form modifications advance these goals. The simplified format totaled 1,200 words in just over two pages, with an eighth-grade Flesch–Kincaid reading level, and used clear and informative headings to structure the document. See Online Appendix B for the simplified consent form.

Outcomes

The outcomes of interest were patient accrual to the clinic's biobank and patient understanding of biobanking research participation. Accrual was estimated using two kinds of clinic-based administrative data. The total number of eligible patients was based on the breast health clinic's records of which patients expressed interest in participating in the clinic biobank. The total number of participants was derived from biorepository records of which patients consented to provide a sample.

To assess patient understanding, we used a version of the self-administered Quality of Informed Consent (QuIC) instrument. Originally developed to assess understanding of cancer clinical trials (Roberts et al., 2004), the instrument was designed to assess the elements of informed consent that constitute meaningful understanding of clinical research participation as described in the Common Rule. The instrument was found to be reliable, valid, and easily administered (approximately 7 minutes; Joffe et al., 2001b). We modified the instrument to assess meaningful knowledge of biobank research participation (see Online Appendix C). The modifications were informed by items in McCarty,

Nair, Austin, and Giampietro's (2007) QuIC instrument, which was designed to measure subjects' understanding of information about participation in a genomic personalized medicine study; by literature on the critical components of informed consent in biobank research (Ormond et al., 2009); and by feedback from bioethics experts.

Our QuIC instrument contained 17 questions designed to evaluate objective understanding of biobanking processes, the handling of samples, donor rights, and related topics. Each question had the same answer choices—"true," "false," and "don't know." In keeping with other QuIC instruments, we varied the wording of the questions to avoid agreement bias so that for some questions, the correct answer was "false" and for some, the correct answer was "true" (Joffe et al., 2001b).

Due to concerns about a mismatch between one QuIC question and the consent forms, and to poor subject comprehension of two others, we chose to omit three questions from the analyses. The findings presented here are based on data from the remaining 14 questions. As assessing incorrect and inadequate knowledge is important to evaluating the simplified consent form, our analyses consider both the number of correct answers and the number of "don't know" answers.

Participant demographics were self-reported using a battery of questions modeled after 2010 Census measures.

Procedures

During the first period of this sequential two-arm study, biobank consent coordinators used their standard consent form. For the second arm, they used our study's simplified consent form. Our research staff trained the biobank coordinators in the use of the simplified form at the outset of Arm 2. During both arms, directly after the biobank consent process, the clinic's biobank study coordinators asked patients if the clinic could alert them to future research opportunities. Patients who agreed were introduced to our study's dedicated study coordinator and recruited into our consent study. Our coordinator administered the QuIC knowledge survey and demographic questions via a paper- or iPad-based questionnaire.

Analyses were conducted in SPSS version 22. Tests of significance included *t* tests for the mean numbers of total correct and "don't know" QuIC responses and chi-square tests for the remaining analyses.

All study participants provided written consent and all activities were reviewed and approved by the relevant institutional review board (IRB).

Results

The standard arm of the trial took place August through November 2014. The simplified arm took place from January through May 2015. During each arm of the trial, we recruited 65 patients who had gone through the biobank consent processes (n = 130). QuIC data are missing for three participants in the standard arm. All participants were female. The demographic characteristics of the study populations were similar across the two arms (Table 1).

Table 1. Subject Demographics.

	Standard form (baseline) sample n = 65, %	Simplified form sample n = 65, %	Probability under null hypothesis of no difference
Age			
31-44	17	14	.541
45-54	29	25	
55-64	34	30	
65+	20	31	
Partnership status			
Married/partnered	63	58	.954
Widowed	3	5	
Divorced/separated	19	23	
Never married	15	14	
Household size			
Lives alone	22	30	.350
Two persons	42	46	
Three or more	36	25	
Latino origin			
Yes	6	9	.510
No	94	91	
Education			
Less than Bachelor's	21	14	.250
Bachelor's or higher	79	86	
Race/ethnicity			
White	83	82	.818
Non-White	17	18	
Household income			
> 50K	16	12	.878
50K to <75K	13	10	
75K to <100K	15	16	
100K+	56	62	
Self-rated health			
Excellent	17	20	.604
Very good	35	43	
Good	37	26	
Fair to poor	11	11	
Self-rated stress			
No stress	17	12	.650
Very little	28	32	
Moderate	31	37	
Some to a lot	25	19	

Note. Data are complete for all respondents; all distributions sum to 100%. All subjects are female.

Patients indicated on the clinic intake form whether they were interested in potentially donating to the biobank. During the standard arm, 699 breast clinic patients indicated interest in biospecimen donation ("interested patients"), while 697 expressed interest during the simplified arm. During both arms, an unknown number of these interested patients were not offered the opportunity to participate in biobanking due to logistical problems at the clinic, for example, staff were not available or patient wait

Table 2. Accrual Rates Across Study Arms—Patients "Interested" in Contributing to Biobank.

	Number of patients who indicated interest in biospecimen donation[a]	Number (and %) of these patients who gave consent for the clinic's biobank study	Probability under null hypothesis of no difference
Standard consent period: August 8, 2014, to November 3, 2014.	699	388 (55.5%)	$p = .025$
Simplified consent period: January 26, 2015, to May 5, 2015.	697	428 (61.4%)	

[a]Subset of patients who said "yes" to this question on the clinic intake questionnaire: "We are asking our participants to donate a small sample of blood or saliva at the end of their mammography appointment for future research purposes. Are you interested? (At the end of your mammogram visit, you will be given a separate consent to sign for this and will also have a chance to ask any questions you may have.)"

times precluded recruitment. Clinic staff reported that these logistical factors did not differ systematically during the standard and simplified recruitment periods.

Increased Accrual Rates

We assessed accrual rates across the standard and simplified consent arms among patients who expressed interest in biobank donation on the intake form (the interested patient universe). During the standard consent arm, 388 (55.5%) interested patients consented to biobank donation, and during the simplified arm, 428 (61.4%) interested patients consented to donate ($p = .025$; Table 2).

More Correct Responses

Patients who reviewed the simplified consent form (Arm 2) answered more QuIC questions correctly than did patients who reviewed the standard form. Across the 14 questions, the mean number of correct responses was 8.16 for the standard consent sample and 8.89 for the simplified consent sample ($p = .064$). Patients in the simplified arm had higher rates of correct responses for nine of the 14 QuIC questions (range of increase: 2-17 percentage points). For most of these questions, the differences between Arm 1 and Arm 2 were 9 percentage points or greater (Table 3). None of these differences were significant using conventional criteria ($p < .05$), but two were marginally significant ($p < .10$). These items concerned the donor's right to remove her sample from the biobank (Item 13) and third-party access to the donor's medical record (Item 11). For the remaining five questions, three showed no change across arms in the proportion answering correctly (including Question 2, for which 100% of respondents gave correct responses in both arms), and two showed greater, though nonsignificant, proportions of incorrect answers among patients in the simplified arm.

Fewer "Don't Know" Responses

Across the 14 questions, the mean number of "don't know" responses was 3.71 for the standard consent sample and 3.01 for the simplified consent sample ($p = .077$). Compared with the patients who reviewed the standard consent form, those who reviewed the simplified form responded "don't know" to the QuIC at lower rates for 8 of the 14 questions (range of decrease: 0.1-17 percentage points). Of these eight items, four showed marginally significant differences ($.05 < p < .10$). "Don't know" response rates were higher in the simplified arm for five of the 14 questions (range of increase: 1.4-7.6 percentage points); none were significant or marginally significant. Rates were the same across arms for one item (Item 2) that received no "don't know" answers (see Table 4).

No Barriers to Implementation

The study team observed no barriers to the adoption or implementation of the simplified consent form in the second arm of the study. The clinic's staff and leadership communicated support for the modified form's content and purpose. The clinic's biobank recruiting staff were able to integrate the form into their existing practices and reported no difficulties in its use. In spontaneous comments to our study staff, several clinic staff members stated they preferred the simplified form.

Discussion

This study of a high-volume breast clinic with an active biobanking program demonstrates the feasibility of implementing a simplified consent form (shorter, more informative, more readable) in place of a standard consent form. The simplified consent form performed better than the standardized form in the domains of patient accrual and patient understanding. More patients who reviewed the simplified consent answered comprehension questions correctly, and fewer patients who reviewed the simplified form said they did not know the answer to comprehension questions. The study was small so most effect sizes are of marginal statistical significance ($p < .10$). Nevertheless, the overall results are important because this study is among the first to implement and

Table 3. Percent Correct on Knowledge Questions for EngageUC Comprehension Survey (n = 62, Standard Consent [Baseline; 3 Missing]; n = 65, Simplified Consent).

Question	Response categories	% correct for standard consent (baseline)	% correct for simplified consent	Difference % correct: simplified − standard	Probability under null hypothesis of no difference
1. A biobank, or tissue bank, is a collection of individuals' biological samples and their medical data.	Correct (true)	95	97	+2	.610
2. The main purpose of biobank (tissue bank) research studies is to advance scientific and medical knowledge.	Correct (true)	100	100	0	1.00
3. The biobank (tissue bank) will label my sample with my name to identify it.	Correct (false)	76	85	+9	.212
4. The biobank (tissue bank) will only retain my sample for a specific, limited, period of time.	Correct (false)	31	43	+12	.147
5. In the future, other researchers must get my written permission each time they want to access to my samples and data.	Correct (false)	57	57	0.0	.957
6. Some researchers may use my biobank (tissue bank) sample for genetic research, including sequencing my genome (i.e., learning my "genetic code").	Correct (true)	53	46	−7	.426
7. The biobank (tissue bank) will never report information gathered from my sample into secure government scientific databases.	Correct (false)	36	48	+12	.163
8. Biobanks (tissue banks) are not allowed to share stored samples or data with industry, such as pharmaceutical or biotechnology companies.	Correct (false)	19	19	0.0	.898
9. Some health information from my medical record could go into the biobank (tissue bank).	Correct (true)	81	85	+4	.555
10. Samples can't be guaranteed to be 100% anonymous if genetics are studied because genetic information is unique to every person.	Correct (true)	40	42	+2	.889
11. Because I am participating in a biobank (tissue bank), it is possible that a study sponsor, various government agencies, or others who are not directly involved in my care could view some of my medical record information.	Correct (true)	44	59	+15	.093
12. I can expect to receive some of the profits if any research involving my sample leads to researchers developing new tests, drugs, or other commercial products.	Correct (false)	95	92	−3	.508
13. If I change my mind, I can request any part of my sample that has not already been distributed, to be removed from the biobank (tissue bank).	Correct (true)	48	65	+17	.065
14. Before the biobank transfers any sample to a researcher, the researcher and project must undergo appropriate review by an ethics board which will decide whether or not to approve or deny the transfer.	Correct (true)	42	54	+12	.179

examine the impact of simplified consent in a real-world setting rather than asking about hypothetical situations (Kass, Taylor, Ali, Hallez, & Chaisson, 2015; Nishimura et al., 2013). Future research should investigate whether these findings stand up in larger studies and whether they are applicable in other settings.

Table 4. Percent Reporting "Don't Know" on Knowledge Questions for EngageUC Comprehension Survey (n = 62, Standard Consent [Baseline; 3 Missing]; n = 65, Simplified Consent).

Question	% DK for standard consent (baseline)	% DK for simplified consent	Difference % DK: simplified − standard	Probability under null hypothesis of no difference
1. A biobank, or tissue bank, is a collection of individuals' biological samples and their medical data.	1.6	1.5	−0.1	.973
2. The main purpose of biobank (tissue bank) research studies is to advance scientific and medical knowledge.	0.0	0.0	0.0	1.00
3. The biobank (tissue bank) will label my sample with my name to identify it.	9.7	4.6	−5.1	.266
4. The biobank (tissue bank) will only retain my sample for a specific, limited, period of time.	56.5	40.0	−16.5	.064
5. In the future, other researchers must get my written permission each time they want to access to my samples and data.	35.5	18.5	−17.0	.030
6. Some researchers may use my biobank (tissue bank) sample for genetic research, including sequencing my genome (i.e., learning my "genetic code").	37.8	40.0	+2.2	.882
7. The biobank (tissue bank) will never report information gathered from my sample into secure government scientific databases.	37.1	30.8	−6.3	.451
8. Biobanks (tissue banks) are not allowed to share stored samples or data with industry, such as pharmaceutical or biotechnology companies.	35.5	43.1	+7.6	.381
9. Some health information from my medical record could go into the biobank (tissue bank).	6.5	9.2	+2.7	.561
10. Samples can't be guaranteed to be 100% anonymous if genetics are studied because genetic information is unique to every person.	35.5	21.5	−14.0	.081
11. Because I am participating in a biobank (tissue bank), it is possible that a study sponsor, various government agencies, or others who are not directly involved in my care could view some of my medical record information.	21.0	21.5	+0.5	.937
12. I can expect to receive some of the profits if any research involving my sample leads to researchers developing new tests, drugs, or other commercial products.	4.8	6.2	+1.4	.745
13. If I change my mind, I can request any part of my sample that has not already been distributed, to be removed from the biobank (tissue bank).	40.3	24.6	−15.7	.058
14. Before the biobank transfers any sample to a researcher, the researcher and project must undergo appropriate review by an ethics board which will decide whether or not to approve or deny the transfer.	48.4	40.0	−8.4	.341

Note. DK = don't know.

Although scholars have studied the effects of many different interventions on participant understanding, information retention, and participant satisfaction, they have paid relatively little attention to the costs of the development and implementation of these interventions. Much as we and others (Flory & Emanuel, 2004) have argued that such interventions must be studied in real-world settings, so we argue that these interventions must work within "real world" constraints. Some health care institutions or research teams may have the resources to create professional multimedia consent materials and provide the devices necessary for their delivery to patients. Similarly, some clinics may be able to fund the extra staff needed to conduct interaction-heavy consent interventions such as teach-back activities. However, these types of interventions may be impractical or impossible for other institutions and research teams to implement. In these cases, a simplified consent form—which requires arguably fewer resources to develop and no changes to consent procedures—may be far more feasible to implement.

Limitations

These findings should be interpreted in light of several limitations. Our data are from female patients in Northern California receiving care at a breast health clinic; the samples do not reflect the breast health clinic's entire patient population and their generalizability to other patient populations is unknown. Another limitation to generalizability is that patients in this study expressed an interest in biobank participation on the clinic intake form. This self-selected sample may have higher-than-average interest in research participation. We note, however, that we have no reason to believe this self-selected population would respond in meaningfully different ways to standard versus simplified consent. A final noteworthy limitation of this study is our use of an imprecise measurement of study accrual. As noted above, logistical factors meant that some patients who expressed interest in biobanking were "missed" by clinic staff and never invited to participate. We have no records of which patients were missed or how many patients were missed during each arm. Our analysis of patient accrual misclassifies these "missed" patients as refusals to participate. Mitigating this limitation is that clinic staffing and procedures were consistent across both arms of the study. We have no reason to suspect that the proportion of "missed" patients differed across the study arms or that there was bias in which patients were missed in the two arms. Nevertheless, it would have been preferable to conduct accrual analyses on data from only the subset of patients who had the opportunity to review biobanking consent materials.

Best Practices

These findings suggest that simplified consent forms, which participants have preferred to standard consent forms in studies of hypothetical research, may have advantages over standard consent in practice. Biorepository and IRB leaders should consider developing and implementing simplified consent forms that are more readable and that support overall understanding of biobank participation. One limitation of the present study is that it involved a relatively small number of participants of limited diversity. Leaders who choose to implement simplified consent materials should monitor the implementation of the consent format. They should collect information on how patients respond, with an eye toward appreciating variation in responses across different patient populations and facilitating quality improvement in forms and processes.

Research Agenda

To our knowledge, this study is among the first to implement simplified consent material in a real-world biobank setting and to gauge its effects on study accrual and patient understanding of study processes. Additional research is needed on how well simplified consent forms perform logistically in diverse clinical settings, as well as how simplified forms fare among diverse patient populations. Future research is also needed to investigate barriers to and helpful resources for the simplification of existing consent forms. Can study investigators develop comprehensive and highly readable consent forms as well as teams that include, for example, legal professionals, graphic designers, or recruiters familiar with the target population? What visual or formatting layout is preferred by different patient populations? Such research can determine best practices for the development of high-quality simplified consent materials.

Educational Implications

This study adds to the growing research literature and policy consensus in support of simplified consent materials that focus on reasons why an individual might want to participate in research (Beskow et al., 2010; "Federal Policy for the Protection of Human Subjects," 2017). Educating biobank managers and IRB leaders about the advantages and acceptability of simplified consent is a priority. Professional societies such as American College of Pathologists (for biobankers) and Public Responsibility in Medicine and Research (PRIMR; for IRB professionals) should continue to develop and disseminate the educational programs they have already launched.

Conclusion

Decades of research shows that many biomedical study participants poorly understand the research in which they take part. Much of this is tied to overly long and complex consent materials. Our findings suggest that using a shortened

and simplified consent form represents a feasible, low-resources way to modestly improve both patient understanding of the target study and accrual to it. Future research should extend this research by investigating the effects of simplified forms for different patient populations in diverse real-world settings.

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Supplementary Material

Supplementary material is available for this article online.

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