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Research and Applications

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Does an interactive trust-enhanced electronic consent improve patient experiences when asked to share their health records for research? A randomized trial

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ABSTRACT

Objective: In the context of patient broad consent for future research uses of their identifiable health record data, we compare the effectiveness of interactive trust-enhanced e-consent, interactive-only e-consent, and standard e-consent (no interactivity, no trust enhancement).

Materials and Methods: A randomized trial was conducted involving adult participants making a scheduled primary care visit. Participants were randomized into 1 of the 3 e-consent conditions. Primary outcomes were patient-reported satisfaction with and subjective understanding of the e-consent. Secondary outcomes were objective knowledge, perceived voluntariness, trust in medical researchers, consent decision, and time spent using the application. Outcomes were assessed immediately after use of the e-consent and at 1-week follow-up.

Results: Across all conditions, participants (N = 734) reported moderate-to-high satisfaction with consent (mean 4.3 of 5) and subjective understanding (79.1 of 100). Over 94% agreed to share their health record data. No statistically significant differences in outcomes were observed between conditions. Irrespective of condition, black participants and those with lower education reported lower satisfaction, subjective understanding, knowledge, perceived voluntariness, and trust in medical researchers, as well as spent more time consenting.

Conclusions: A large majority of patients were willing to share their identifiable health records for research, and they reported positive consent experiences. However, incorporating optional additional information and messages designed to enhance trust in the research process did not improve consent experiences. To improve poorer consent experiences of racial and ethnic minority participants and those with lower education, other novel consent technologies and processes may be valuable. (An Interactive Patient-Centered Consent for Research Using Medical Records; NCT03063268)

Key words: e-consent, broad consent, Common Rule, research informatics, electronic health record, information systems design

INTRODUCTION

The widespread implementation of electronic health record (EHR) systems in the United States has created new opportunities for research data repositories,[1–3] quality assurance,[4,5] targeted research recruitment,[6] and cross-institutional data sharing networks such as the Patient-Centered Outcomes Research Network (PCORnet).[7,8] In addition, recent updates to the Federal Policy for the Protection of Human Subjects (Common Rule) allow researchers and their institutions the option of seeking broad consent from patients for future research uses of their EHR data.[9] In contrast with study-specific consent, broad consent allows institutions to consent patients to future, yet-to-be-specified research uses of their individually identifiable EHR data.

Broad consent for research use of EHR data has both ethical and operational implications. Ethically, broad consent must be implemented in a way that reflects patients' rights to be informed about and choose how their health information is used, while also considering the good (beneficence) that may result from the knowledge obtained from research using information found in EHRs. Operationally, broad consent may provide a less burdensome option than study-specific consent while also giving patients more information and autonomy than using waivers of informed consent. Indeed, many patients want to be asked about using their personal data and want some control over its research uses.[10–13] Furthermore, EHRs contain an ever-increasing volume and scope of data, including genetic data and linked data that span care systems and settings. These important and emergent complexities underscore the ethical, operational, and scientific need to examine approaches to using broad consent to ask patients to use their EHR data in research.

Interactive electronic consent (e-consent) applications offer a promising but understudied informatics solution to conducting broad consent that is operationally feasible and ethically appropriate. E-consents that deliver consent information via computer and collect digital signatures are typically lower cost and more scalable than in-person consents.[14,15] E-consents can present federally required consent information as well as additional information that patients may want to know. Such additional information may include examples of study risks, definitions of key terms, or descriptions of technologies and processes that research institutions employ to protect research data.[16] However, simply providing more information during the consent process does not necessarily improve the consent process.[17,18] In some cases, providing more information may produce unintended effects, such as inconsistent decision making, perceived coercion, mistrust, decreased understanding, and less time spent reviewing the information.[19] To combat potential unintended effects, e-consents can be designed to allow patients to interactively explore information in a self-guided process that best meets their individual needs. Indeed, e-consent applications have shown promise in accommodating the information needs of users at different levels.[16,20] Some evidence also suggests that multimedia tools allow patients to better control the pace of information delivery.[21,22] Finally, processes that provide objective information designed to enhance trust in research, an important factor in consent,[23,24] can also be easily incorporated into e-consents. Rather than manipulating patients into making a consent decision, trust enhancements are intended to underscore factual information and legal protections and to address patient concerns related to consent processes. Therefore, in the context of broad consent for patient EHR data sharing for research, there is value in understanding how different e-consent designs affect the quality of the consent process. Specifically, previous studies have not compared e-consents with and without interactive capabilities that deliver additional information that some patients prefer. Similarly, previous studies have not compared e-consents with and without messages designed to enhance trust in researchers.

OBJECTIVE

The purpose of this study was to compare the effectiveness of an interactive trust-enhanced e-consent with an interactive-only e-consent (no trust enhancement) and a standard (no interactivity, no trust enhancement) e-consent that asked patients to give broad consent for future research uses of their EHR data. This study provides a novel contribution to the biomedical informatics literature in 2 primary ways. First, this study improves understanding of how different systems design features affect people's understanding of and satisfaction with electronically delivered health information. Second, given increased use of broad consent and increased complexity of a patient's health record content, this study provides a more current understanding of how patients perceive organizational systems and processes that request access to their health records.

MATERIALS AND METHODS

Procedure

We conducted a randomized trial among a convenience sample of adults in 4 family medicine practices associated with the University of Florida academic health center in north-central Florida, United States. Eligible participants were English-speaking patients 18 years of age and older making a regularly scheduled medical visit. A research assistant approached eligible participants in clinic waiting areas and asked patients to consider participating in the study either before or after their visit. Patients who agreed were given a tablet computer on which they completed an e-consent that asked them to include their identifiable EHR data in a "Family Medicine Research Database" for future, yet-to-be-specified research studies. As required by our institutional review board to minimize deception, patients saw an initial screen that indicated the consent process itself was being studied in addition to the creation of the research database. To maintain realism and minimize participant confusion from signing multiple consents, the initial screen's information was brief and did not require a signature to continue. The research assistant asked participants to use the tablet independently, though he was available to assist if patients experienced difficulties using the technology. Using a prespecified block randomization schedule, the research assistant randomized patients in a 1:1:1 ratio to each of the 3 conditions. Patients were blind to the content and functionality of the 3 conditions, and thus blind to their assignment.

The research assistant randomly assigned each participant to 1 of 3 e-consent application conditions: standard (no interactivity, no trust enhancement), interactive only, and interactive trust-enhanced (Table 1). The e-consent was developed using an iterative design process involving think-aloud interviews with a community-based sample of adults to elicit feedback and preferences related to usability, content, and potential ethical and privacy concerns.[16] The standard e-consent contained the federally required elements of informed consent, including an explanation of the purposes of the research, description of procedures to be followed, descriptions of any reasonably foreseeable risks or discomforts and benefits, a statement describing the extent to which confidentiality of records will

Table 1. Comparison of content elements between e-consent versions

E-consent element	Consent version		
	Standard	Interactive only	Interactive trust-enhanced
Federally required elements of informed consent • Explanation of the purposes of the research; a description of procedures to be followed; a description of any reasonably foreseeable risks or discomforts to the subject; a description of any benefits to the subject or to others which may reasonably be expected from the research; a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; a statement that participation is voluntary.	✓	✓	✓
Interactive information exploration • On-demand content including research study examples, explanations of EHR content, and terminology definitions, delivered interactively via hyperlinked text box call-outs. • Example text: "Medical Record Number (MRN) Your Medical Record Number or MRN is a unique number that the University of Florida uses to identify you when you go to the doctor or other healthcare provider."		✓	✓
Trust-enhanced messages • Factual messages designed to accurately portray trust-relevant attributes of medical researchers. Message content includes information such as details on research regulations, researcher training, and data protections. • Example text: "The computer system that contains your health record here at the University of Florida has many levels of security and safeguards to keep unauthorized people from seeing your information."			✓
Consent task (yes or no) Consent for identifiable past and future medical or health record data to be shared for family medicine research studies.	✓	✓	✓

EHR: electronic health record.

be maintained, and a statement that participation in the research database is voluntary. The interactive-only e-consent included all information provided in the standard e-consent as well as clickable links to additional content that our development process suggested some participants may want to obtain. This content included examples of possible future studies, explanations of types of data contained in EHRs, and definitions of research- or EHR-related terminology. Upon clicking these links, the additional information was presented on the same screen via expanded text boxes that could subsequently be closed (Figure 1). The interactive trust-enhanced e-consent included all elements of the standard and interactive-only e-consents as well as trust-enhanced messages designed to convey trust-relevant attributes of medical researchers and content related to details on research regulations, researcher training, and data protections both generally and specific to the health system (Figure 2).

After reviewing the consent information presented in 1 of the 3 randomly assigned e-consent conditions, each participant agreed or did not agree to allow researchers to access their identifiable past and future medical or health record information in a Family Medicine Research Database. Immediately after consenting, participants completed a follow-up survey to assess outcome measures and demographic characteristics (including gender, age, race, ethnicity, and education).

Participants also completed 1-week and 6-month follow-up surveys with the outcome measures repeated. Outcomes from the 6-month follow-up surveys will be reported once completed. Patients were compensated $25 for participating in the initial consent process and immediate follow-up survey, and $15 for each subsequent follow-up survey. The procedure was approved by the University of Florida Institutional Review Board.

Outcome measures

The primary outcomes were satisfaction with the consent decision and subjective understanding of the consent content. We assessed participants' satisfaction with the consent decision using the Satisfaction with Decision scale, a previously validated assessment of patient satisfaction with a health care decision.[25] The Satisfaction With Decision scale has been used previously to assess patient satisfaction with informed consent decisions related to participation in health research.[26–28] We measured participants' subjective understanding of the content presented in the consent application using a subscale of the Quality of Informed Consent instrument, which was originally developed to assess subjective and actual understanding of informed consent in cancer trials.[29] The subjective understanding subscale is intended to measure the degree to which research participants believe that they are informed about the study, including the purpose of, risks and potential benefits of, and duration of involvement in the research. The item wording was modified slightly from the original instrument to reflect the context of consenting to participate in a research database. For example, the original item "What the researchers are trying to find out in the clinical trial" was modified to read "Why the researchers want to use your medical record information." Response options remained the same as in the original instrument and ranged from "I understood this very well" to "I didn't understand this at all" on a 5-point Likert-type scale ranging from 1 ("I didn't understand this at all") to 5 ("I understood this very well").

Secondary outcomes were objective knowledge of the informed consent, perceived voluntariness, trust in medical researchers, consent to EHR research uses (yes/no), and engagement with the consent information. We measured objective knowledge by asking participants to agree or disagree with statements based on factual information included in all 3 e-consent conditions. We assessed perceived voluntariness using the Decision-Making Control Instrument, a previously validated tool designed to measure the extent to which participants view treatment and research decisions as voluntary in medical settings.[30] We measured participants' attitudes toward researchers using the Trust in Medical Researchers Scale, a

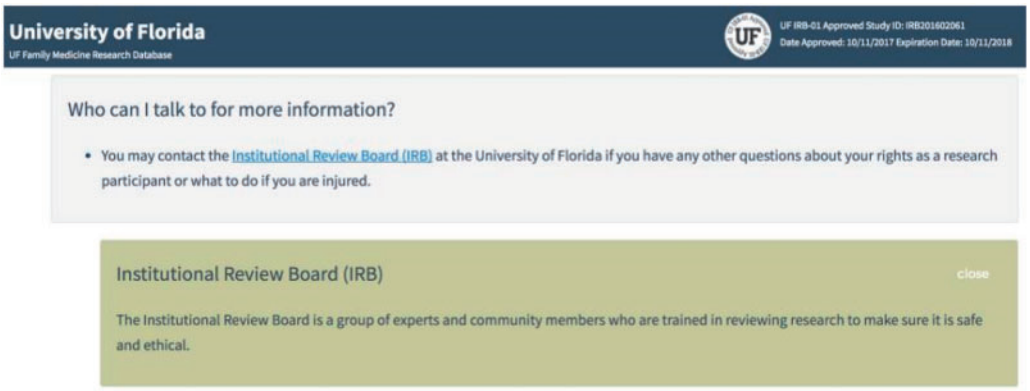

Figure 1. E-consent example of an opened hyperlink for additional information.

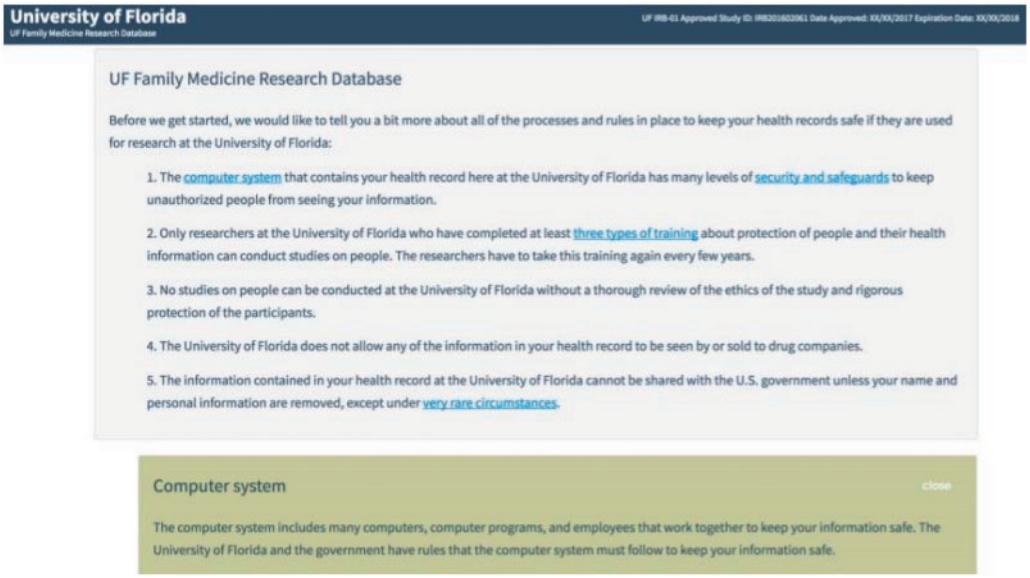

Figure 2. Example of one trust-enhancing message in the interactive trust-enhanced consent application. UF: University of Florida.

previously validated, 12-item instrument with subscales related to participant deception and researcher honesty.[31] We assessed engagement with the consent application by capturing time spent using the e-consent. We also measured users' click activity within the application.

Other measures

In addition to measuring the outcomes described previously, the participant surveys assessed demographics (age, education, gender, race, and ethnicity).

Sample size

We initially planned for an enrollment of 200 participants per consent condition, for a total of 600 participants. We designed the study to have 85% power to detect a difference between conditions of 1.1 units for the decisional satisfaction outcome and 2.8 units for the consent understanding outcome using a 2-sided .025-level test. For sample size calculations, we defined satisfaction and understanding as the average of immediate and 1-week follow-up responses.

Statistical analysis

We conducted bivariate analyses to assess relationships between participant characteristics and outcomes using chi-square tests for categorical data and 1-way analyses of variance for continuous variables. For each outcome measured at immediate and 1-week follow-up (satisfaction, subjective understanding, objective knowledge, perceived voluntariness, and trust in medical researchers), we used linear mixed models to assess the relationship between consent condition assignment and the outcome. Each model included a participant random effect and fixed effects for consent condition, time (immediate or 1-week follow-up), participant age, education level, gender, race, and ethnicity. For outcomes measured only once (consent decision and time spent using the application), we used logistic and linear regression, respectively, to assess the relationship between consent condition assignment and these outcomes, controlling for participant age, education level, gender, race, and ethnicity.

RESULTS

A total of 1242 patients were approached, with 750 (60.4%) agreeing to participate. Figure 3 provides an overview of the participant

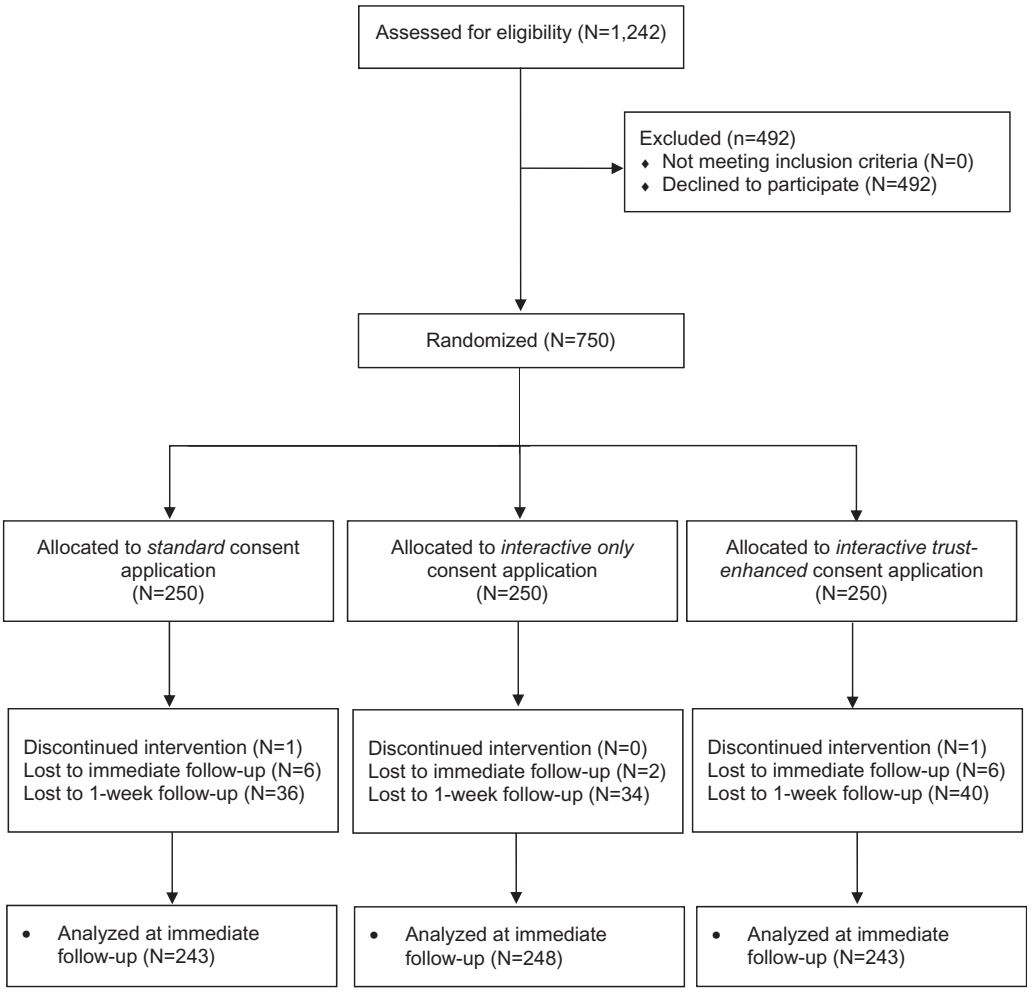

Figure 3. Trial flow diagram describing randomization, allocation, follow-up, and analysis.

flow. Patients who declined to participate stated either that they were not interested (n = 387) or that they did not have time to participate (n = 105). Additionally, 16 patients either failed to complete the e-consent or did not complete the immediate follow-up survey and were excluded from analysis.

The patients included in the analysis were demographically similar to the underlying population of clinic patients (Table 2). This included the percentage female (68.4% in study vs 62.5% in population), percentage Hispanic or Latino (9.0% vs 5.4%), and percentage 18-34 years of age (31.7% vs 26.8%), 35-44 years of age (15.4% vs 16.4%), 45-54 years of age (16.7% vs 16.8%), 55-64 years of age (23.9% vs 19.4%), 65-74 years of age (10.0% vs 13.7%), 75-84 years of age (2.2% vs 5.5%), and 85 years of age or over (0.1% vs 1.4%). Our study had a higher proportion of patients who identified as black (43.3% vs 30.6%). Randomization resulted in a similar distribution of participant demographic characteristics across the 3 conditions (Table 2).

Across all versions, participants reported moderate to high satisfaction with consent (mean 4.3 of 5), subjective understanding (79.1 of 100), voluntariness of consent (38.2 of 45), objective knowledge of the consent (3.5 of 5), and trust in medical researchers (31.9 of 48). On average, participants spent 4.9 minutes reviewing the consent application (median = 2.71 minutes), and 94.3% agreed to share their health record data. Across the interactive-only and interactive trust-enhanced versions, 20 (4.1%) participants clicked at least 1 link for additional information.

In bivariate analysis of immediate follow-up (Table 3), mean satisfaction with consent was similar across all 3 conditions (standard = 4.2, interactive only = 4.2, interactive trust-enhanced = 4.3; $P = .217$), as was mean subjective understanding of consent (80.2, 77.0, and 80.1, respectively; $P = .174$). Similarly, objective knowledge of consent (3.6, 3.4, and 3.6, respectively; $P = .376$), perceived voluntariness of consent (38.3, 37.7, and 38.6, respectively; $P = .213$), trust in medical researchers (31.8, 31.6, and 32.3, respectively; $P = .661$), consent rate (94.6%, 93.6%, and 94.6%, respectively; $P = .845$), and time spent reviewing the consent (5.23, 4.20, and 5.29 minutes, respectively; $P = .679$) did not significantly differ between conditions (Table 3). In bivariate analysis of 1-week follow-up for the 624 participants who responded, there were also no between-condition differences in satisfaction with consent (4.5, 4.4, and 4.5, respectively; $P = .354$), subjective understanding of consent (84.0, 83.4, and 83.2, respectively; $P = .885$), objective knowledge of consent (4.1, 4.0, and 3.9, respectively; $P = .503$), perceived voluntariness of consent (38.2, 37.9, and 38.2, respectively; $P = .830$), and trust in medical researchers (33.0, 33.8, and 33.8, respectively; $P = .480$).

Differences between conditions were estimated using a chi-square test for consent decision and analysis of variance for all other outcomes.

Table 2. Participant demographic characteristics by e-consent condition (N = 734)

	Standard (n = 243)	Interactive Only (n = 248)	Interactive Trust-Enhanced (n = 243)	*P* Value
Age, y[a]	46.3 ± 16.8	45.2 ± 15.3	45.4 ± 16.0	.716
Gender				.486
Female	161 (66.3)	168 (67.7)	173 (71.2)	
Male	82 (33.7)	80 (32.3)	70 (28.8)	
Race				.309
White	123 (50.6)	115 (46.4)	100 (41.2)	
Black or African-American	96 (39.5)	109 (44.0)	113 (46.5)	
Asian	3 (1.2)	3 (1.2)	9 (3.7)	
American Indian or Alaska Native	1 (0.4)	2 (0.8)	1 (0.4)	
Native Hawaiian or Pacific Islander	0 (0.0)	1 (0.4)	1 (0.4)	
Other single race	10 (4.1)	9 (3.6)	7 (2.9)	
Multiple race	10 (4.1)	9 (3.6)	12 (4.9)	
Ethnicity				.402
Hispanic	25 (10.3)	24 (9.7)	17 (7.0)	
Not Hispanic	218 (89.7)	224 (90.3)	226 (93.0)	
Education				.127
Less than high school	23 (9.5)	20 (8.1)	29 (11.9)	
High school graduate or GED	85 (35.0)	98 (39.5)	66 (27.2)	
Some college	77 (31.7)	68 (27.4)	89 (36.6)	
Bachelor's degree	37 (15.2)	38 (15.3)	31 (12.8)	
Master's, professional, or doctorate degree	21 (8.6)	24 (9.7)	28 (11.5)	

Values are mean ± SD or n (%). Differences between conditions were assessed using analyses of variance for age and chi-square tests for all other variables.
[a]n = 732 due to missing data.

Table 3. Outcomes at immediate follow-up by e-consent condition

	Standard (n = 243)	Interactive Only (n = 248)	Interactive Trust-Enhanced (n = 243)	*P* Value
Primary outcomes				
Satisfaction with consent (1-5)	4.23 ± 0.74	4.23 ± 0.69	4.33 ± 0.66	.217
Subjective understanding of consent (0-100)	80.23 ± 20.92	76.96 ± 23.73	80.11 ± 21.13	.174
Secondary outcomes				
Objective knowledge about consent (0-5)	3.58 ± 1.31	3.42 ± 1.49	3.56 ± 1.31	.376
Perceived voluntariness of consent (9-45)	38.29 ± 5.45	37.65 ± 6.91	38.58 ± 5.68	.213
Trust in medical researchers (0-48)	31.75 ± 8.32	31.60 ± 8.59	32.27 ± 8.69	.661
Consent decision (agree/disagree)[a]	229 (94.6)	232 (93.6)	227 (94.6)	.845
Time spent reviewing the consent, min	5.23 ± 9.37	4.20 ± 6.67	5.29 ± 8.43	.679

Values are mean ± SD or n (%).
[a]n = 730 for consent decision due to missing data (242 for standard, 248 for interactive only, and 240 for interactive trust-enhanced).

Our multivariable modeling also indicated no between-condition differences in the primary or secondary outcomes (Table 4). However, we did observe statistically significant relationships between several demographic characteristics and the consent outcomes. In particular, when compared with participants with less than a high school education, participants with some college education (B = 0.16, P = .011) or a bachelor's degree (B = 0.21, P = .004) reported significantly higher satisfaction with the consent. Also, when compared with participants with less than a high school education, participants with some college education (B = 4.88, P = .03) or a bachelor's degree (B = 5.11, P = .045) reported significantly higher subjective understanding of the consent. Similarly, participants with some college education (B = 0.49, P = .0002), a bachelor's degree (B = 0.86, P < .0001), or a master's, professional, or doctorate degree (B = 1.03, P < .0001) reported significantly higher objective knowledge of the consent compared with participants with less than a high school education. Also, participants with some college education (B = 3.50, P < .0001), a bachelor's degree (B = 4.69, P < .0001), or a master's, professional or doctorate degree (B = 5.68, P < .0001) each reported significantly higher perceived voluntariness compared with participants with less than a high school education. Similarly, when compared with participants with less than a high school education, participants in higher education groups, including some college education (B = 2.03, P = .031), a bachelor's degree (B = 2.82 P = .009), or a master's, professional or doctorate degree (B = 3.98, P < .0001), reported higher trust in medical researchers. Compared with those with less than a high school education, participants in higher education groups, including some college education (B = –66.32, P = .020), a bachelor's degree (B = –87.94, P = .007), or a master's, professional or doctorate degree (B = –129.94, P = .002), spent less time reviewing the consent application.

Table 4. Regression analysis of outcomes at immediate and 1-week follow-up

	Satisfaction With Consent (n = 732)	Subjective Understanding of Consent (n = 732)	Objective Knowledge About Consent (n = 732)	Perceived Voluntariness of Consent (n = 732)	Trust in Medical Researchers (n = 732)	Consent Decision (n = 728)	Time Spent in Application (n = 722)
Condition							
Standard [reference]							
Interactive only	−0.04 (0.04), .383	−1.04 (1.48), .483	−0.09 (0.09), .279	−0.29 (0.40), .476	0.61 (0.62), .327	0.85, .610	−14.59 (18.97), .442
Interactive trust-enhanced	0.03 (0.04), .496	−0.17 (1.51), .912	−0.06 (0.09), .519	0.15 (0.41), .717	0.85 (0.63), .180	1.01, .791	32.95 (19.28), .088
Follow-up time							
Immediate [reference]						N/A	N/A
1 week	0.19 (0.02), <.0001	4.08 (0.83), <.0001	0.46 (0.05), <.0001	−0.14 (0.20), .500	1.61 (0.29), <.0001	N/A	N/A
Age	−0.00 (0.00), .045	0.02 (0.04), .657	0.00 (0.00), .059	−0.03 (0.01), .010	0.00 (0.02), .761	0.99, .504	5.96 (0.50), <.0001
Education							
Less than high school [reference]							
High school graduate	0.08 (0.06), .234	1.47 (2.22), .501	0.13 (0.13), .318	1.01 (0.60), .094	0.71 (0.93), .448	0.59, .075	−7.99 (28.32), .778
Some college	0.16 (0.06), .011	4.88 (2.24), .030	0.49 (0.13), .0002	3.50 (0.61), <.0001	2.03 (0.94), .031	0.71, .244	−66.32 (28.54), .020
Bachelor's degree	0.21 (0.07), .004	5.11 (2.55), .045	0.86 (0.15), <.0001	4.69 (0.69), <.0001	2.82 (1.07), .009	1.04, .967	−87.94 (32.45), .007
Master's, professional, or doctorate	0.14 (0.08), .068	3.87 (2.74), .159	1.03 (0.16), <.0001	5.68 (0.75), <.0001	3.98 (1.15), .001	3.07, .198	−129.94 (34.93), .0002
Gender							
Male [reference]							
Female	0.09 (0.04), .025	3.84 (1.34), .004	0.40 (0.08), <.0001	0.58 (0.36), .112	0.94 (0.56), .096	0.66, .288	−7.87 (17.09), .645
Race							
White [reference]							
Black	−0.24 (0.39), <.0001	−6.32 (1.35), <.0001	−0.66 (0.08), <.0001	−3.35 (0.37), <.0001	−5.58 (0.57), <.0001	0.49, .434	38.62 (17.36), .026
Other race	−0.09 (0.06), .117	−5.20 (2.11), .014	−0.55 (0.12), <.0001	−1.85 (0.57), .001	−4.22 (0.88), <.0001	0.41, .276	77.20 (26.84), .004
Ethnicity							
Non-Hispanic [reference]							
Hispanic	−0.11 (0.06), .105	−2.75 (2.25), .222	−0.11 (0.13), .413	−0.79 (0.61), .194	−2.33 (0.93), .013	1.19, .792	66.43 (27.88), .018

Values are *B* (SE), *P* value or odds ratio, *P* value. *B* values are from linear mixed models for satisfaction, subjective understanding, objective knowledge, perceived voluntariness, and trust outcomes. Estimates are odds ratios from logistic regression for the consent decision outcome, and *B* values are from linear regression for the time spent in application outcome. For the analysis of time spent in application, 12 observations with outlying time values (studentized residuals >3 and Cook's D > 4/n [0.0005]), were excluded from analysis. In other models, the n values vary due to missing data.

When compared with white participants, black participants reported significantly lower satisfaction ($B = -0.24$, $P < .0001$), lower subjective understanding ($B = -6.32$, $P < .0001$), lower objective knowledge ($B = -0.66$, $P < .0001$), lower perceived voluntariness ($B = -3.35$, $P < .0001$), lower trust in medical researchers ($B = -5.58$, $P < .0001$), and spent more time using the e-consent application ($B = 38.62$, $P = .026$). Similarly, when compared with white participants, participants of races other than black or white reported significantly lower subjective understanding ($B = -5.20$, $P = .014$), lower objective knowledge ($B = -0.55$, $P < .0001$), lower perceived voluntariness ($B = -1.85$, $P = .001$), lower trust in medical researchers ($B = -4.22$, $P < .0001$), and more time spent using the e-consent application ($B = 77.20$, $P = .004$). Also, when compared with non-Hispanic participants, Hispanic participants reported lower trust in medical researchers ($B = -2.33$, $P = .013$) and more time spent using the e-consent application ($B = 66.43$, $P = .018$).

Finally, we conducted exploratory bivariate analyses of outcomes between conditions for racial minority (i.e. all races except white) participants only (n = 396). Among minority participants, statistically significant differences were observed between consent conditions for perceived voluntariness (standard = 36.3, interactive only = 35.3, interactive trust-enhanced = 37.4; $P = .019$) and objective knowledge of consent information (3.1, 2.9, and 3.4, respectively; $P = .046$). These differences were marginally significant at 1-week follow-up for perceived voluntariness (standard = 36.1, interactive only = 35.9, interactive trust-enhanced = 37.5; $P = .057$) and not significant for objective knowledge (3.7, 3.6, and 3.8, respectively; $P = .591$).

DISCUSSION

The primary results of our randomized trial of 3 e-consent approaches for health record sharing indicated no effect of interactivity alone or interactivity with trust enhancement on participant satisfaction with or subjective understanding of the consent. Similarly, we found no between-condition differences for our secondary outcomes of objective knowledge of consent information, perceived voluntariness, trust in medical researchers, consent decision, and time spent using the application. Offering interactive features and trust-enhancing messages to standard consent information did not improve participants' consent experiences. At the same time, the addition of interactive features and trust enhancement messages did not appear to detract from the average participant's consent experience, as we also found no negative effects of these features on consent outcomes. Furthermore, given that only 4.1% of participants who were offered interactive features chose to click on 1 or more hyperlinks, these findings suggest that many people, when asked in a primary care setting to share their health records for research, are not motivated to seek additional information.

We also found that a large majority of participants (94.3%) across all 3 e-consent conditions agreed to share their health records for research. This finding echoes previous research indicating high levels of willingness in the general population to share individually identifiable health record information for future research.[32–35] Additionally, participants in this study, regardless of consent condition, demonstrated high rates of satisfaction with the consent process, perceived voluntariness of the process, and trust in medical researchers. Moreover, the median time spent reviewing the application was only 2.71 minutes. Together, these findings suggest that most patients consenting to share their health records for research in the context of their primary care provider's office do not require significant time or information beyond standard consent information to feel satisfied, informed, and in control of their decision to share their health records.

The findings of this study have implications for policies and practices surrounding broad consent to share protected health information for research. On one hand, our results suggest limited benefit to healthcare organizations in developing e-consent systems with additional content and trust-enhancing messages that are interactively delivered. On the other hand, if costs are relatively low for developing such systems (eg, if an organization already has an EHR with e-consent functionality), healthcare systems might consider adding interactive or trust-enhancing elements without harming patient satisfaction or understanding. Furthermore, most patients in our study spent minimal time reviewing and completing the e-consent, suggesting it is relatively easy to incorporate enhanced e-consent features into primary care clinic workflows. If it is relatively low-cost to develop and implement, an enhanced e-consent may also add value by better meeting the needs of patient subgroups who do desire more information when making a consent decision. Indeed, our prior qualitative study on patient perceptions of using an interactive e-consent application reinforced the notion that some patients are higher information seekers than others and, at least when asked hypothetically, desire an interactive e-consent that offers additional information and trust-enhancing messages.[16] Overall, healthcare organizations will need to carefully weigh this and other existing evidence, from both ethical and operational perspectives, of the value of implementing broad consent and different system design options.

Moreover, consistent with previous work,[35–39] the present study clearly indicated differences in the consent experiences of racial and ethnic minority participants and participants with lower education. Participants in these groups, on average, spent significantly more time reviewing the e-consent, yet reported lower scores on several important outcome measures. While offering additional information via interactivity and trust-enhancing messages did not improve these participants' experiences, our findings do suggest the potential value of other novel approaches to consent that ensure vulnerable groups are equally informed when consenting to research. For example, in exploratory analysis on our subgroup of racial minority participants, we found significant differences between consent conditions at immediate follow-up for perceived voluntariness and objective knowledge. Interestingly, these differences indicate lower perceived voluntariness and objective knowledge for racial minority participants allocated to the interactive-only condition relative to the standard consent and the interactive trust-enhanced consent. One potential explanation for these findings is an unfavorable effect of interactive features alone in the absence of trust messaging among some participants. Specifically, among patients such as racial minorities who may already be wary of research motivations and practices,[40–42] the added volume of information presented in the interactive-only consent may have been overwhelming, resulting in reduced knowledge and perceptions of voluntariness. The presence of trust messaging in the interactive trust-enhanced consent may have then served to mitigate any negative effects of the additional information presented. Given the exploratory nature of these ancillary results, they are not definitive but may inform hypotheses for future research on developing improved e-consent processes—especially research that focuses on patient subgroups who report poorer experiences with consent processes and research in general. Previous work has identified ways for researchers to increase satisfaction and comprehension of informed consent among minority patients, including increased direct contact with study investigators, availability of take-home materials related to the study, and the ability for potential participants to talk to

someone currently participating in the study.[43–45] To our knowledge, these strategies have not been tested in the context of broad consent, but academic health centers may consider incorporating these strategies as they design and evaluate broad e-consent tools.

The strengths of this study include its randomized, controlled design and comprehensive set of important consent outcomes. The e-consent intervention functionality and content were developed based on federal requirements for informed consent and an iterative design process with significant patient feedback.[16] Also, this study enrolled a relatively large and diverse sample of patients in the context of a large academic health center's family medicine clinics. Furthermore, the study implemented and compared 3 versions of an actual research consent, rather than involving hypothetical, nonbinding consent scenarios.[46–48]

Perhaps the primary limitation of this study is that nearly 40% of clinic patients approached by a research assistant to participate in our e-consent study declined to do so. Patients typically declined due to a reported lack of time to complete the full study protocol, which included an extensive survey about their consent experience. However, as has been observed in other studies, we expect that many more patients would actively make a consent decision if the process were fully integrated into clinic workflows and systems.[49] In our study, nearly all patients who took the time to participate (94.3%) agreed to share their health record information. Therefore, this limitation should not be viewed as a weakness of potential implementation nor of patients' willingness to provide broad consent. Instead, this, along with the fact that the study was conducted in 4 clinics in a single health center, may limit the generalizability of our results to the broader population of adult patients seeking primary care. Partially mitigating this limitation, our participant sample was demographically similar to the underlying patient population at our institution. Moreover, our participant sample was diverse in terms of gender, race, and education, including a significant number of women, black/African-American patients, and patients with less than a college education. Therefore, given known barriers to appropriate and effective research involving vulnerable patients, these characteristics of our sample composition strengthened our contribution to knowledge about consent among these groups.

Our study is also limited by the exclusion of non–English-speaking participants. Future work should explore broad consent processes among patients from different cultural backgrounds, who may face additional barriers to comprehension, satisfaction, and voluntariness. Also, our study analysis is limited by the large number of hypothesis tests over our primary, secondary, and exploratory analyses. This increases the likelihood that, over our multiple hypothesis tests, we inferred statistically significant results that were simply due to chance. Also, the instruments we used to assess the primary outcomes of decisional satisfaction and subjective understanding have not been validated for use in the specific context of broad consent. Based on our review of the literature, these represented the best existing instruments for assessing our consent outcomes of interest. Future work should seek to advance measurement related to broad consent and consent for EHR research use by developing and validating new instruments.

Finally, our findings may not be applicable to incorporating interactivity or trust enhancements into clinical consents or other types of research consents. Specifically, in light of our findings along with previous evidence that most people are willing to consent to research uses of their identifiable personal health record information,[33–35] patients may have different information needs when considering participation in research perceived as riskier or more complex. Future work could examine whether incorporating interactive information exploration or trust enhancements into riskier or more complex consent scenarios adds more value. Also, future work could focus on the effect of e-consent enhancements on certain subpopulations, such as racial and ethnic minorities, who are historically less willing to agree to participate in research.[40,42]

CONCLUSION

In the context of using an electronic consent application to consider sharing individually identifiable health records for future research, we found that a large majority of patients were willing to share and reported positive consent experiences. However, incorporating optional additional information and messages designed to enhance trust in the research process did not improve consent experiences. To help improve the consent experiences of racial and ethnic minority participants and those with lower educational attainment, it may be valuable for future research to explore other novel consent technologies and processes. As EHRs' content becomes more expansive and includes new types of data, these findings provide new knowledge on patients' current acceptance of consent processes for EHR data sharing. Moreover, these findings provide important insights on the limits of conceptually supported design features in actually enhancing patients' consent experiences.

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AUTHOR CONTRIBUTIONS

CAH was responsible for the study concept and design, overseeing data collection, analysis and interpretation of the data, and initial draft of the manuscript. EHG was responsible for analysis and interpretation of the data and initial drafting of the manuscript. KPR was responsible for design, collection, analysis, and interpretation of the data. JLK, AGMIII, KWG, BB, and REM were responsible for the study concept and design. BB also oversaw data analysis. REM also oversaw data collection. All authors approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

None declared.

REFERENCES

1. Hersh WR. Adding value to the electronic health record through secondary use of data for quality assurance, research, and surveillance. *Am J Manag Care* 2007; 81: 126–8.
2. Ross M, Wei W, Ohno-Machado L. "Big data" and the electronic health record. *Yearb Med Inform* 2014; 9 (1): 97.

3. Luo J, Wu M, Gopukumar D, *et al*. Big data application in biomedical research and health care: a literature review. *Biomed Inform Insights* 2016; 8: S31559.
4. Embi PJ, Payne PR. Evidence generating medicine: redefining the research-practice relationship to complete the evidence cycle. *Med Care* 2013; 51: S87–91.
5. McGlynn EA, Lieu TA, Durham ML, *et al*. Developing a data infrastructure for a learning health system: the PORTAL network. *J Am Med Inform Assoc* 2014; 21 (4): 596–601.
6. Thadani SR, Weng C, Bigger JT, *et al*. Electronic screening improves efficiency in clinical trial recruitment. *J Am Med Inform Assoc* 2009; 16 (6): 869–73.
7. Fleurence RL, Curtis LH, Califf RM, *et al*. Launching PCORnet, a national patient-centered clinical research network. *J Am Med Inform Assoc* 2014; 21 (4): 578–82.
8. Hernandez AF, Fleurence RL, Rothman RL. The ADAPTABLE trial and PCORnet: shining light on a new research paradigm. *Ann Intern Med* 2015; 163 (8): 635–6.
9. Federal Policy for the Protection of Human Subjects, 45 CFR part 46 Office for Human Research Protections (OHRP), ed. 2018; Vol 82, No. 12.
10. Damschroder LJ, Pritts JL, Neblo MA, Kalarickal RJ, Creswell JW, Hayward RA. Patients, privacy and trust: patients' willingness to allow researchers to access their medical records. *Soc Sci Med* 2007; 64 (1): 223–35.
11. Donald JW, Karim K, Kalpana N, Charlie G, Anne MH. Patients' consent preferences for research uses of information in electronic medical records: interview and survey data. *BMJ* 2003; 326 (7385): 373–376.
12. Caine K, Hanania R. Patients want granular privacy control over health information in electronic medical records. *J Am Med Inform Assoc* 2013; 20 (1): 7–15.
13. Whiddett R, Hunter I, Engelbrecht J, Handy J. Patients' attitudes towards sharing their health information. *Int J Med Inform* 2006; 75 (7): 530–41.
14. Marshall EA, Oates JC, Shoaibi A, *et al*. A population-based approach for implementing change from opt-out to opt-in research permissions. *PLoS One* 2017; 12 (4): e0168223.
15. Sanderson IC, Obeid JS, Madathil KC, *et al*. Managing clinical research permissions electronically: a novel approach to enhancing recruitment and managing consents. *Clin Trials* 2013; 10 (4): 604–11.
16. Harle CA, Golembiewski EH, Rahmanian KP, *et al*. Patient preferences toward an interactive e-consent application for research using electronic health records. *J Am Med Inform Assoc* 2018; 25 (3): 360–8.
17. Manson N, O'Neill O. *Rethinking Informed Consent in Bioethics*. Cambridge, UK: Cambridge University Press; 2007.
18. Falagas M, Korbila I, Giannopoulou K, *et al*. Informed consent: how much and what do patients understand? *Am J Surg* 2009; 198 (3): 420–35.
19. Schenker Y, Meisel A. Informed consent in clinical care: practical considerations in the effort to achieve ethical goals. *JAMA* 2011; 305 (11): 1130–1.
20. Rowbotham MC, Astin J, Greene K, *et al*. Interactive informed consent: randomized comparison with paper consents. *PLoS One* 2013; 8 (3): e58603.
21. Jimison HB, Sher PP, Appleyard R, *et al*. The use of multimedia in the informed consent process. *J Am Med Inform Assoc* 1998; 5 (3): 245–56.
22. Synnot A, Ryan R, Prictor M, *et al*. Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database Syst Rev* 2014; 5 (CD003717): 1–141.
23. Zhang Z, Bickmore TW, Paasche-Orlow MK. Perceived organizational affiliation and its effects on patient trust: role modeling with embodied conversational agents. *Patient Educ Couns* 2017; 100 (9): 1730–7.
24. Kneipp SM, Lutz BJ, Means D. Reasons for enrollment, the informed consent process, and trust among low-income women participating in a community-based participatory research study. *Public Health Nurs* 2009; 26 (4): 362–9.
25. Holmes-Rovner M, Kroll J, Schmitt N, *et al*. Patient satisfaction with health care decisions: the satisfaction with decision scale. *Med Decis Making* 1996; 16 (1): 58–64.
26. Fink AS, Prochazka AV, Henderson WG, *et al*. Enhancement of surgical informed consent by addition of repeat back: a multicenter, randomized controlled clinical trial. *Ann Surg* 2010; 252 (1): 27–36.
27. Stryker JE, Wray RJ, Emmons KM, *et al*. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. *Patient Educ Couns* 2006; 63 (1–2): 104–9.
28. Simon CM, Siminoff LA, Kodish ED, *et al*. Comparison of the informed consent process for randomized clinical trials in pediatric and adult oncology. *J Clin Oncol* 2004; 22 (13): 2708–17.
29. Joffe S, Cook EF, Cleary PD, *et al*. Quality of informed consent: a new measure of understanding among research subjects. *J Natl Cancer Inst* 2001; 93 (2): 139–47.
30. Miller VA, Ittenbach RF, Harris D, *et al*. The decision making control instrument to assess voluntary consent. *Med Decis Making* 2011; 31 (5): 730–41.
31. Mainous AG, Smith DW, Geesey ME, *et al*. Development of a measure to assess patient trust in medical researchers. *Ann Fam Med* 2006; 4 (3): 247–52.
32. Weitzman ER, Kaci L, Mandl KD. Sharing medical data for health research: the early personal health record experience. *J Med Internet Res* 2010; 12 (2): e14.
33. Willison DJ, Schwartz L, Abelson J, *et al*. Alternatives to project-specific consent for access to personal information for health research: what is the opinion of the Canadian public? *J Am Med Inform Assoc* 2007; 14 (6): 706–12.
34. Willison DJ, Steeves V, Charles C, *et al*. Consent for use of personal information for health research: do people with potentially stigmatizing health conditions and the general public differ in their opinions? *BMC Med Ethics* 2009; 10 (1): 10.
35. Grande D, Mitra N, Shah A, *et al*. Public preferences about secondary uses of electronic health information. *JAMA Intern Med* 2013; 173 (19): 1798–806.
36. Dimitropoulos L, Patel V, Scheffler S, *et al*. Public attitudes toward health information exchange: perceived benefits and concerns. *Am J Manag Care* 2011; 17 (Spec No 12): SP111–6.
37. Kim KK, Sankar P, Wilson MD, *et al*. Factors affecting willingness to share electronic health data among California consumers. *BMC Med Ethics* 2017; 18 (1): 25.
38. Enama ME, Hu Z, Gordon I, *et al*. Randomization to standard and concise informed consent forms: development of evidence-based consent practices. *Contemp Clin Trials* 2012; 33 (5): 895–902.
39. Stunkel L, Benson M, McLellan L, *et al*. Comprehension and informed consent: assessing the effect of a short consent form. *IRB* 2010; 32 (4): 1–9.
40. Corbie-Smith G, Thomas SB, St. George DMM. Distrust, race, and research. *Arch Intern Med* 2002; 162 (21): 2458–63.
41. Bussey-Jones J, Garrett J, Henderson G, *et al*. The role of race and trust in tissue/blood donation for genetic research. *Genet Med* 2010; 12 (2): 116–21.
42. Corbie-Smith G, Thomas S, Williams M, *et al*. Attitudes and beliefs of African-Americans toward participation in medical research. *J Gen Intern Med* 1999; 14 (9): 537–46.
43. Quinn SC, Garza MA, Butler J, *et al*. Improving informed consent with minority participants: results from researcher and community surveys. *J Empir Res Hum Res Ethics* 2012; 7 (5): 44–55.
44. Cohn E, Larson E. Improving participant comprehension in the informed consent process. *J Nurs Scholarsh* 2007; 39 (3): 273–80.
45. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA* 2004; 292 (13): 1593–601.
46. Agre P, Rapkin B. Improving informed consent: a comparison of 4 consent tools. *IRB* 2003; 25 (6): 1–7.
47. Karunaratne AS, Korenman SG, Thomas SL, *et al*. Improving communication when seeking informed consent: a randomised controlled study of a computer-based method for providing information to prospective clinical trial participants. *Med J Aust* 2010; 192 (7): 388–92.
48. Harmell AL, Palmer BW, Jeste DV. Preliminary study of a web-based tool for enhancing the informed consent process in schizophrenia research. *Schizophr Res* 2012; 141 (2–3): 247–50.
49. Iafrate PI, Lipori GP, Harle CA, *et al*. Consent2Share: an integrated broad consenting process for re-contacting potential study subjects. *J Clin Transl Res* 2016; 2 (4): 1.