Leveraging Technology Solutions to Automate Informed Consent in a Clinical Research Hospital

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Abstract

Problem: Paper informed consent (PIC) forms are associated with incomplete and or inaccurate information such as missing signatures and incorrect patient identification. The Food and Drug Administration's Bioresearch Monitoring Program audit for the 2019 fiscal year lists failure to obtain informed consent (IC) requirements as one of the most common violations (2%) by clinical investigators in clinical trials. In a selected practice site, approximately 440 (2%) out of 25,000 PICs were returned by the medical records department to clinicians in 2019 due to incomplete and or inaccurate information. This resulted in significant delays in the start of clinical trials, incurring additional time and effort for participants and clinicians to correct and or re-consent. *Purpose:* The purpose of this quality improvement project was to implement electronic informed consent (EIC) for research participants in the adult oncology, infectious disease, and digestive diseases outpatient clinics in a clinical research hospital. *Methods:* Pre and post implementation surveys were administered to clinicians (n = 43) to obtain baseline perceptions, and compare preferences and satisfaction with using PIC versus EIC. The clinicians were trained on using EIC for signatures, then EIC was implemented and tracked for eight specific protocol studies. *Results:* The average confirmed IC available in the electronic health record (EHR) within one day of signing by clinicians for all three clinics increased from 52.5% (pre) to 61.3% (post). EIC use increased by 20%, and returned consents decreased from an average of 2.2% to 0.6%. Clinician preference to use EIC over PIC increased from 44.8% to 57.1%, Fisher's Exact Test = 0.5256, 2-sided, $p > .05$. *Conclusions:* Replacing PIC with EIC was preferred by clinicians, improved documentation of consent, and decreased the time for consent availability in the EHR. The implications for practice are that automating informed consent is associated with improved consenting processes and supports remote workflows.

Introduction

Paper informed consent (PIC) forms are associated with incomplete and or inaccurate information such as missing signatures and incorrect patient identification (Chhin et al., 2017). These problems have a negative impact on clinical trials such as delayed enrollment and care of participants (Grady et al., 2017). The Food and Drug Administration's (FDA) Bioresearch Monitoring Program (BIMO) audit for the 2019 fiscal year lists failure to obtain informed consent (IC) requirements as one of the most common (2%) violations by investigators in clinical trials. In addition to the key elements of information, comprehension and voluntariness, documentation of informed consent also requires the signatures of the subject or legally authorized representative and the investigator (FDA, 2019).

The selected clinical research hospital used PICs for decades to consent research participants enrolled in clinical trials. Some problems reported with PICs included missing signatures, incorrect dates and incomplete fields. In 2019, approximately 440 (2%) of 25,000 PICs were returned by the medical records department (MRD) to clinicians due to incomplete and or inaccurate information. This resulted in significant delays in the start of clinical trials, incurring additional time and effort for participants and clinicians to correct and or re-consent. In 2019, it took an average of up to 78 days for a signed PIC to be confirmed in the electronic health record (EHR). Confirmation required the MRD staff to manually validate each PIC for completion, and scan into the EHR, before the participant could start the clinical trial. The purpose of this quality improvement (QI) project was to implement electronic informed consent (EIC) for research participants in the adult oncology (ONC), allergy and infectious disease (ID), and diabetes, digestive and kidney diseases (GI) outpatient clinics in a clinical research hospital.

Evidence Review

A literature review was conducted and seven studies were synthesized for the evidence on implementing EIC in a clinical research setting. The studies appraised based on Melnyk and Fineout-Overholt (2015) evidence ratings are shown in the Evidence Review Table (Appendix A). The Synthesis Table with quality ratings by Newhouse (2006) is shown in Appendix B. Of the two Level II randomized controlled trials (RCT) comparing paper-based with tablet-based consents, Warriner et al. (2016) found participants and staff to have greater comprehension and satisfaction with tablets. This RCT used blinding of the participants, but the sample size was small (n = 33) and homogenous to only older women. Frelich et al. (2015) validated that the REDCap (iPad-based) eConsent was compliant and feasible in a clinical research setting. The participants reported greater preference to use eConsent over paper consent for research studies. Although the sample size was small (n = 51), there was a sufficient number of participants per group (n = at least 18) based on a power analysis of at least 80%. A third Level II expert committee report (Lentz et al., 2016), based on extensive literature review (n = 45), expert reviews (n = 25), and expert multi-stakeholder meetings (n = 60), recommended the use of eConsent to improve the IC process.

In the two Level III mixed-methods studies, Jayasinge et al. (2020) identified similarities in findings for user-friendliness, immediate comprehension and retention after one week when comparing paper with tablet-based consent amongst older adults. Despite the small sample size for the randomized trial (n = 20), the study was well-designed, with 100% retention of research subjects and no adverse or unexpected events. Madathil et al.'s (2013) study added the comparison of existing electronic capture method (Topaz system) and paper-based consent systems with new iPad-based and touchscreen-based electronic consenting systems. Staff and

participants also reported better comprehension and awareness with the eConsents, but the small sample size (n = 50) limits the generalizability.

The two Level VI literature reviews focused on describing eConsent in academic medical centers (Chen et al., 2020) and the recruitment of research study participants (Skelton et al., 2020). Chen et al.'s (2020) review (n = 220) indicated that no standards or guidelines, or leading commercial solution exist for replacing paper consents with electronic consent. Skelton et al.'s (2020) rigorous review of studies (n = 18) with eConsent intervention compared to paper or alternative found eConsent to be well received by participants, with user-friendly interfaces, and improved comprehension of documentation reported by participants and researchers. The majority of the studies reviewed by Skelton et al. (2020) showed low to moderate risk of bias (n = 15), but the review appraisal checklist allowed only for qualitative synthesis of the results.

In summary, the majority of studies (over 80%) compared the use of PICs with EICs and established the evidence that EICs improve comprehension, satisfaction, and overall user experience for participants and staff (Frelich et al., 2015; Jayasinghe et al., 2019; Madathil et al., 2013; Warriner et al., 2016). EICs were also reported to be well received, user-friendly, with a greater preference to use them over PICs (Frelich et al., 2015; Jayasinghe et al., 2019; Skelton et al., 2020). In addition to decreased error rates, EICs allow for real-time communication and tracking, are easily integrated with the EHR, enable remote participation, and improve version control and document storage (Chhin et al., 2017; Reeves et al., 2020; St. John et al., 2017). Even though some of the study findings are non-generalizable due to small sample sizes, and predominance of educated Caucasian females, the majority of studies were well-conducted. These findings warrant the need for future studies with different populations and larger sample sizes to make the outcomes more generalizable to the greater population.

Theoretical Framework

The Unified Theory of Acceptance and Use of Technology (UTAUT) by Venkatesh et al. (2003) serves to predict the reasons why participants and staff may accept or reject the new EIC technology, and provides ideas on how to improve technology acceptance. As such, it has been applied in healthcare information technology projects (Jacob et al., 2020). The core determinants are effort expectancy (ease of use), performance expectancy (extent of how participant or staff perceives the technology as beneficial), social influence (extent of who they perceive influences them to use the technology), and facilitating conditions (perception of organizational and technical support) (Venkatesh et al., 2003). All four determinants are influenced by age, gender, experience and voluntariness. A modified diagram of UTAUT is depicted in Figure 1.

The core determinants were leveraged by promoting participant and clinician acceptance through involvement in the selection, design, development and testing of EIC. User acceptance testing was therefore critical prior to implementation of this project (McBride & Tietze, 2019). End user education and training, including the ability for users to interact in a test or mock environment promoted ease of use (effort expectancy) and improved their experience with the new technology. The change champions (physician, genetic counselor, research nurse and program coordinator) were key players in marketing the usefulness and benefits of the technology, such as the immediate availability of signed EICs in the EHR. They also exerted their social influence in promoting the acceptance of EIC. Facilitating conditions included the availability of educational materials (videos, quick reference guides, frequently asked questions), just-in-time training by the project team and change champions, and IT support for the devices. The overall cultural factors, socio-economic status and educational level influenced individuals' behavioral intentions to use EIC, especially for research participants.

Methods

The project was implemented from September 2020 to December 2020 in three adult outpatient clinics, which provide services in oncology, allergy and infectious disease, and diabetes, digestive and kidney disease in a 200-bed academic clinical research hospital. Baseline assessment data was obtained prior to the Coronavirus Disease 2019 (COVID-19) pandemic.

The QI project was implemented by the MRD in collaboration with the Doctorate of Nursing Practice (DNP) student as the Project Lead (PL). The team included the clinical site representative (MRD director), implementation manager (MRD deputy director), project manager, information technology (IT) team members and clinic change champions (physician, genetic counselor, research nurse and program coordinator). The evidence-based intervention was the implementation of EIC, which has been shown to decrease error rates, improve comprehension, satisfaction, and overall user experience for participants and staff when compared to PIC (Frelich et al., 2015; Jayasinghe et al., 2019; Madathil et al., 2013; Warriner et al., 2016). Pre-implementation surveys were administered to a convenience sample of 43 clinicians to obtain baseline perceptions on using PIC versus EIC. The clinic teams were then trained one-on-one via remote sessions on using EIC for signatures. A commercial EIC software was installed by the vendor and IT team to interface with the EHR. EIC was configured for eight specific protocol studies determined by the three clinic teams, but the use was not mandatory for clinicians. The ID clinic implemented EIC in the eighth week, while the GI and ONC clinics were delayed until the 14th week. Surveys were sent to each clinic three weeks post-implementation to assess clinicians' preference and satisfaction with using EIC.

Structure measures used to track the implementation progress were the number of staff trained on EIC, and installation of the EIC software enabling the electronic capture of signature

using a signature pad, computer or mobile device. The change champions and clinic teams were trained remotely via a commercial communication platform (Appendix C). Clinicians were provided with a URL to navigate and practice signing EIC in a test environment, and a user manual for reference (Appendix D). The PL collaborated with the implementation manager and a data analyst to develop an Automated Protocol Tracker for real-time monitoring and tracking of data. A screen shot of the tracker is shown in Appendix E. The process measures were EIC usage and the percentage of PICs returned to clinicians. Outcome measures were the confirmed signed informed consents (PIC and EIC) available in the EHR within one day of signing by clinicians and their preference to use EIC over PIC. The signature to confirmation timeframe (the time from initial signing of consent by participant and investigator until it is confirmed) was used to determine the number of days for PIC and EIC to be available in the EHR. The clinician pre- and post-implementation surveys (Appendix F and G) were administered to measure the clinicians' self-reported use of EIC and preference to use EIC over PIC. Run charts of measures and survey reminders were sent weekly via email to the clinic change champions to share with clinicians.

Data was collected using online surveys and audit tools (Appendix H and I). Run charts based on structure, process and outcome measures data were plotted and analyzed for trends and shifts by looking at means to show differences of pre and post EIC implementation data. The project was approved as non-human subject research by the University of Maryland Institutional Review Board (IRB) and also met non-human subject research criteria which did not need IRB approval from the project site. All data collection tools were saved as original files and stored in a secure electronic access-controlled folder to protect the confidentiality of patients. The surveys were sent to clinicians by change champions via email link using an organization-approved HIPAA-secure electronic third-party survey tool, and all survey responses were anonymous.

Results

The results for each of the clinics were combined due to the small sizes of the data obtained from the GI and ONC clinics, which did not implement EIC until the last three weeks. All clinicians (n = 43) were trained on using EIC for signatures. This group comprised of 28.0% (n = 12) investigators, 25.6% (n = 11) research nurses, 11.6% (n = 5) protocol/patient care coordinators, 11.6% (n = 5) certified registered nurse practitioners/physician assistants, 9.3% (n = 4) fellows, 9.3% (n = 4) genetic counselors, 2.3% (n = 1) staff clinician, and 2.3% (n = 1) research coordinator. More than half of clinicians (62.8%) were from the ONC clinic (n = 27).

The mean percentage of confirmed informed consents available in the EHR within one day of signing by clinicians was 52.5% (n = 96) pre for PIC and 61.3% (n = 175) post for PIC and EIC combined. The run chart (Figure 2) revealed an increase from an average below 60% in week one, to around the median of 66% when the ID clinic implemented EIC in week eight. There were two sharp increases to above 80% in weeks 13 and 16, which coincided with the highest numbers of EICs signed by clinicians from all three clinics.

The run chart of electronic informed consent usage (Figure 3) showed a shift as evidenced by a run of nine data points in a row that changed the median in a positive direction from zero, starting on week eight when EIC was implemented in the ID clinic (Ogrinc et al., 2018). Usage of EIC increased by 20% (n = 65) overall for all three clinics combined. This ranged from an average of 0% pre-implementation to 14% with the ID clinic implementation (week eight), then increased to 30% with the GI and ONC clinics implementation (week 14), and ended at 32% for all three clinics combined by week 16.

The overall consents returned to clinicians to correct or reconsent decreased from 2.2% (n = 3) to 0.6% (n = 2) after implementation of EIC (Figure 4). The number of participants, and

subsequently the number of PICs, decreased significantly since the start of the COVID-19 pandemic in March 2020. PICs were returned for only four weeks (weeks one, three, nine and ten) out of the total 16 weeks duration of the project, with zero returned over the last six weeks.

There were 67.4% (n = 29 of 43) responders to the pre-implementation survey, and 46.5% (n = 20 of 43) post. The clinician role demographics were similar for both surveys (Table 1). Nearly 40% of pre survey responders and half of the post survey were clinical trial investigators, while research nurses made up one-third of both the pre and post surveys. Seventy percent of responders (n = 14) self-reported use of EIC. The results from the 8-item Likert survey ranging from "Strongly Disagree" to "Strongly Agree" are shown in Table 2. Categorical analysis of survey item # 7 (Figure 5): "I (would) prefer to use electronic consent over paper consent" involved dichotomizing the Likert responses to "Strongly Agree" vs "Other" responses. Due to the small sample sizes, Fisher's Exact Test was used to compare the frequencies of pre and post responses. The results showed that clinicians with stronger preference (Strongly Agree) to use EIC over PIC increased from 44.8% to 57.1% compared to those with "Other" responses, which decreased from 55.2% to 42.9%, Fisher's Exact Test = 0.5256, 2-sided, $p > .05$. (Table 3).

An unintended consequence of allowing the clinics to determine which PIC to convert to EIC for the project resulted in delays in the teams identifying consents to be implemented. It would have been beneficial to establish the exact implementation dates for the project for each of the clinics. Although conducting the entire project remotely removed the physical presence of the project team from the clinical area, it facilitated greater involvement of the change champions. EIC also promoted the use of the patient portal by research participants. Furthermore, one of the greatest unexpected benefits of implementing EIC was in supporting remote consenting workflows which were necessary to maintain social distancing during the COVID-19 pandemic.

Discussion

The findings of this QI project support the evidence that EIC is associated with improved participant and staff documentation, satisfaction and availability in the EHR (Frelich et al., 2015; Jayasinghe et al., 2019; Madathil et al., 2013; Warriner et al., 2016). The average number of consents returned to clinicians to correct or reconsent decreased from 2.2% (n = 3) to 0.6% (n = 2) after implementation of EIC. As opposed to PICs, which were subject to missing signature and date fields, the mandatory fields on EIC prevented the clinicians and participants from making such errors. Chhin et al. (2017) found electronic consents to decrease error rates one year post implementation when compared with paper consents in a radiation medicine outpatient clinic. The decreased errors were associated with improved efficiency and consent documentation. However, it should be noted that the significant decrease in PICs during the COVID-19 pandemic coincided with a decrease in the volume of research participants.

Another outcome improvement was the availability of confirmed consents in the participants' EHR. The mean percentage of confirmed informed consents available in the EHR within one day of signing by clinicians increased from 52.5% (n = 96) pre-implementation for PIC to 61.3% (n = 175) post-implementation for both PIC and EIC. Confirmation of PIC required for MRD staff to manually validate each signed PIC for completion, and then scan into the EHR, before the participant can begin the clinical trial, which could take up to several days. With the implementation of EIC, MRD staff were immediately alerted via automated report to validate and confirm the consent upon completion of the electronic signatures. As such, every EIC became available in EHR within 24 hours. Studies by Madathil et al. (2013), Frelich et al. (2015) and Lentz et al. (2016) support decreased staff and patient workloads with electronic

based consenting systems. Also, EIC allowed for real-time communication and tracking, and was easily integrated and readily available in the EHR (Chhin et al., 2017).

Similar to the findings from current literature comparing paper and electronic consents in the outpatient setting, the clinicians in this project reported that they preferred EIC over PIC with no statistically significant differences in their responses. There was an overall stronger clinician preference to use EIC over PIC, which increased from 44.8% (pre) to 57.1% (post), compared to those with "Other" responses, which decreased from 55.2% to 42.9%. In Warriner et al.'s (2016) study, staff reported greater satisfaction with using a tablet versus paper for consent, but the differences were not statistically significant. However, Frelich et al. (2015) found statistically significant differences in the participants who reported a greater preference to use electronic consent in the future. EICs were also found to be user-friendly and well-received by staff and participants, including older adults (Jayasinghe et al., 2019; Skelton et al., 2020).

The small sample size limits the generalizability of this project's findings to other populations or settings, and the consents and workflows are unique to the organization. There is also potential bias with self-reported use of EIC and preference to use EIC from the post-implementation survey. Additionally, the surveys were not paired pre and post surveys. Other limitations of the project were the optional use of EIC by clinicians, which may have resulted in its low usage (20%), and the delayed implementation in the GI and ONC clinics, resulting in small sizes of the data collected. Even though the project supported remote workflows for social distancing, the lack of physical onsite support by the project team could have also contributed to the low staff participation.

Conclusion

Findings from this QI project suggests that replacing paper with electronic consent was preferred by clinicians, improved documentation of consent, and decreased the time for consent availability in the EHR. These findings are supported by the evidence that EIC is associated with improved participant and staff documentation, satisfaction, and availability in the EHR (Frelich et al., 2015; Jayasinghe et al., 2019; Madathil et al., 2013; Warriner et al., 2016). PICs were associated with incomplete and or inaccurate information in the organization, resulting in significant delays in participant enrollment and or care, and increased time, effort and workload for participants and clinicians. EIC use showed improved outcomes for all the project goals.

A major strength of this project was the collaboration of the PL with the clinic change champions, who helped to facilitate the use of EIC in their respective areas. Another strength was the ability to implement the entire project remotely. The project took place during the COVID-19 pandemic which mandated for social distancing to prevent the spread of the virus. Just-in-time remote support was provided to end-users as needed. The organization plans to utilize this model to spread EIC to other outpatient clinics and inpatient units this year. The implications for practice are that automating informed consent is associated with improved consenting processes and supports remote workflows.

Since the project site did not approve for research participants to be surveyed, future QI projects should engage them to assess their perceptions and satisfaction with using EIC as a consumer/patient-facing technology. There should be an evaluation of the impact of EIC on non-clinical staff workflows such as the medical records department. There is also the need to explore the impact of EIC on participant comprehension, especially for older adults. Finally, this QI project findings will be disseminated within the organization and at a national conference.

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Table 1

*Baseline Demographics of a Sample of Clinicians Surveyed About Their Perception and Use of Electronic Informed Consent Compared with Paper Informed Consent (N = 43): Pre (N = 29) *Post (N = 14) and *14 Post).*

	Pre N (%)	Post N (%)
Clinic Types		
Digestive	9 (31.0)	1 (7.1)
Oncology	16 (55.2)	11 (78.6)
Infectious Disease	4 (13.8)	2 (14.3)
Clinician Roles		
Protocol/Patient Care Coordinator	2 (6.9)	0 (0.0)
Fellow	2 (6.9)	0 (0.0)
Nurse Practitioner/Physician Assistant	2 (6.9)	1 (7.1)
Research Nurse	9 (31.0)	5 (35.7)
Investigator	11 (37.9)	7 (50.0)
Genetic Counselor	0 (0.0)	1 (7.1)
Other (Research Trainee, Quality Assurance, Research Coordinator)	3 (10.3)	0 (0.0)
***Post Implementation (N = 20):**		
Used electronic consent		
Yes	N/A	14 (70.0)
No	N/A	6 (30.0)
Problems with electronic consent (N = 14)		
Yes	N/A	5 (35.7)
No	N/A	9 (64.3)
Satisfied with support received		
Yes	2	2 (40.0)
No	3	3 (60.0)

Note: *N = 20 clinicians completed the post-implementation survey, but N = 6 who reported that they did not use the electronic informed consent did not complete the remainder of the survey.

Table 2

Clinician Pre-Implementation and Post-Implementation Survey Responses (All Clinics)

Paper (Pre)/ Electronic (Post)	Phase	Strongly Agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly Disagree N (%)
1. The **paper/electronic** protocol informed consent is easy for me to use when consenting a patient.	Pre	5 (17.2)	14 (48.3)	6 (20.7)	4 (13.8)	0 (0.0)
	Post	7 (50.0)	6 (42.9)	0 (0.0)	1 (7.1)	0 (0.0)
2. Introducing the patient to the **paper/electronic** informed consent is easy.	Pre	7 (24.1)	14 (48.3)	7 (24.1)	1 (3.4)	0 (0.0)
	Post	6 (42.9)	5 (35.7)	2 (14.3)	1 (7.1)	0 0.0)
3. At the end of the consent process, I felt confident that the patient understood the relevant protocol and clinical trial participation expectations.	Pre	8 (27.6)	15 (51.7)	6 (20.7)	0 (0.0)	0 (0.0)
	Post	6 (42.9)	8 (57.1)	0 (0.0)	0 (0.0)	0 (0.0)
4. The **paper/electronic** consent form helps me to focus the discussion with the patient on areas where he/she has questions.	Pre	6 (20.7)	13 (44.8)	8 (27.6)	2 (6.9)	0 (0.0)
	Post	2 (14.3)	6 (42.9)	5 (35.7)	1 (7.1)	0 (0.0)
5. It is effective to consent the patient using **paper/electronic** informed consent.	Pre	5 (17.2)	13 (44.8)	7 (24.1)	3 (10.3)	1 (3.4)
	Post	7 (50.0)	4 (28.6)	2 (14.3)	1 (7.1)	0 (0.0)
6. It is efficient to consent the patient using **paper/electronic** informed consent.	Pre	2 (6.9)	7 (24.1)	9 (31.0)	8 (27.6)	3 (10.3)
	Post	10 (71.4)	3 (21.4)	1 (7.1)	0 (0.0)	0 (0.0)

Paper (Pre)/ Electronic (Post)	Phase	Strongly Agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly Disagree N (%)
7. I would prefer to use **electronic** consent.	Pre	13 (44.8)	4 (13.8)	10 (34.5)	2 (6.9)	0 (0.0)
	Post	8 (57.1)	5 (35.7)	1 (7.1)	0 (0.0)	0 (0.0)
8. I would prefer to use **paper** consent.	Pre	0 (0.0)	3 (10.3)	14 (48.3)	7 (24.1)	5 (17.2)
	Post	0 (0.0)	0 (0.0)	4 (28.6)	4 (28.6)	6 (42.9)

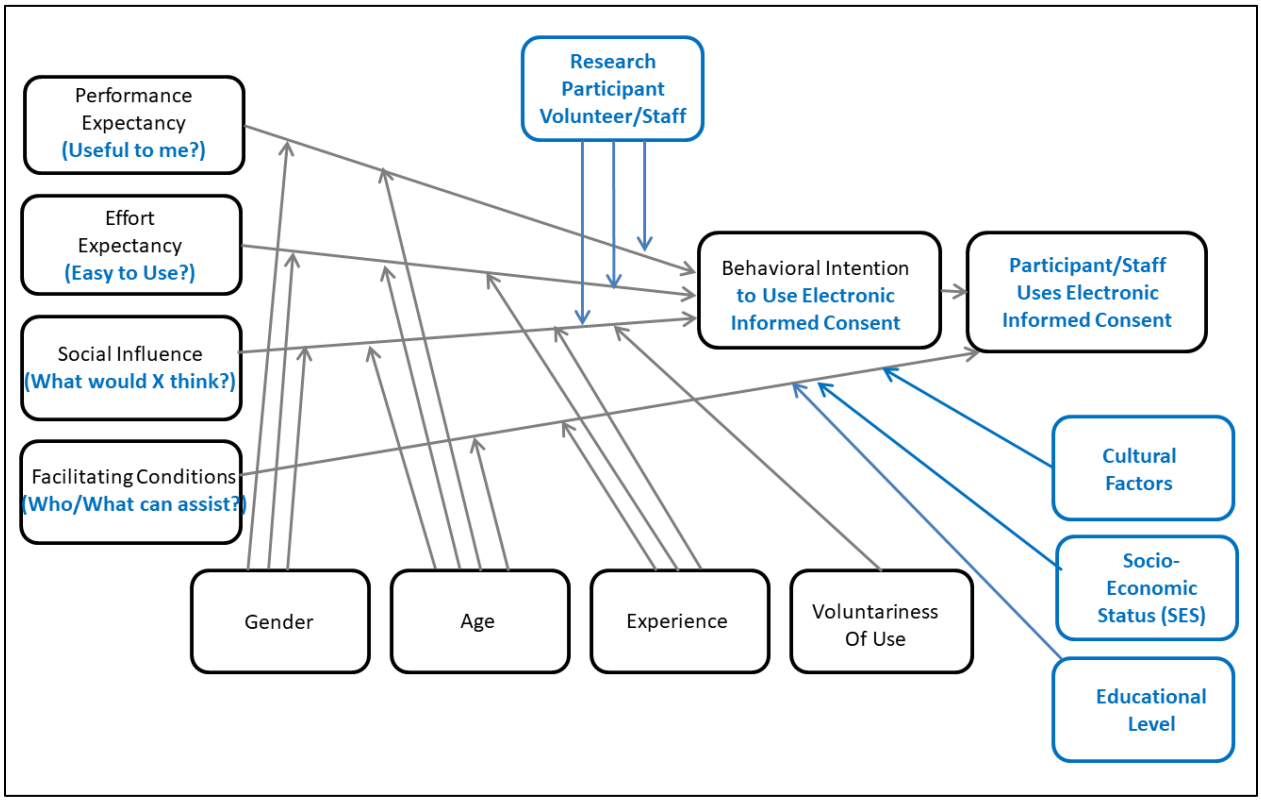
Table 3

Categorical Analysis of Clinician Pre-Implementation and Post-Implementation Survey Responses for Survey Item #7

	Phase	Strongly Agree N (%)	Other N (%)	Fisher's Exact	p-value
7. I would prefer to use **electronic** consent.	Pre	13 (44.8)	16 (55.2)		
	Post	8 (57.1)	6 (42.9)	0.5256	> .05

Figure 1

Modified Unified Theory of Acceptance and Use of Technology (UTAUT)



Note. A modified Unified Theory of Acceptance and Use of Technology (UTAUT) adapted from Venkatesh et al. (2003).

Figure 2

Run Chart of Confirmed Protocol Informed Consents Accessible in the Electronic Health Record Within 1 Day (All Clinics)

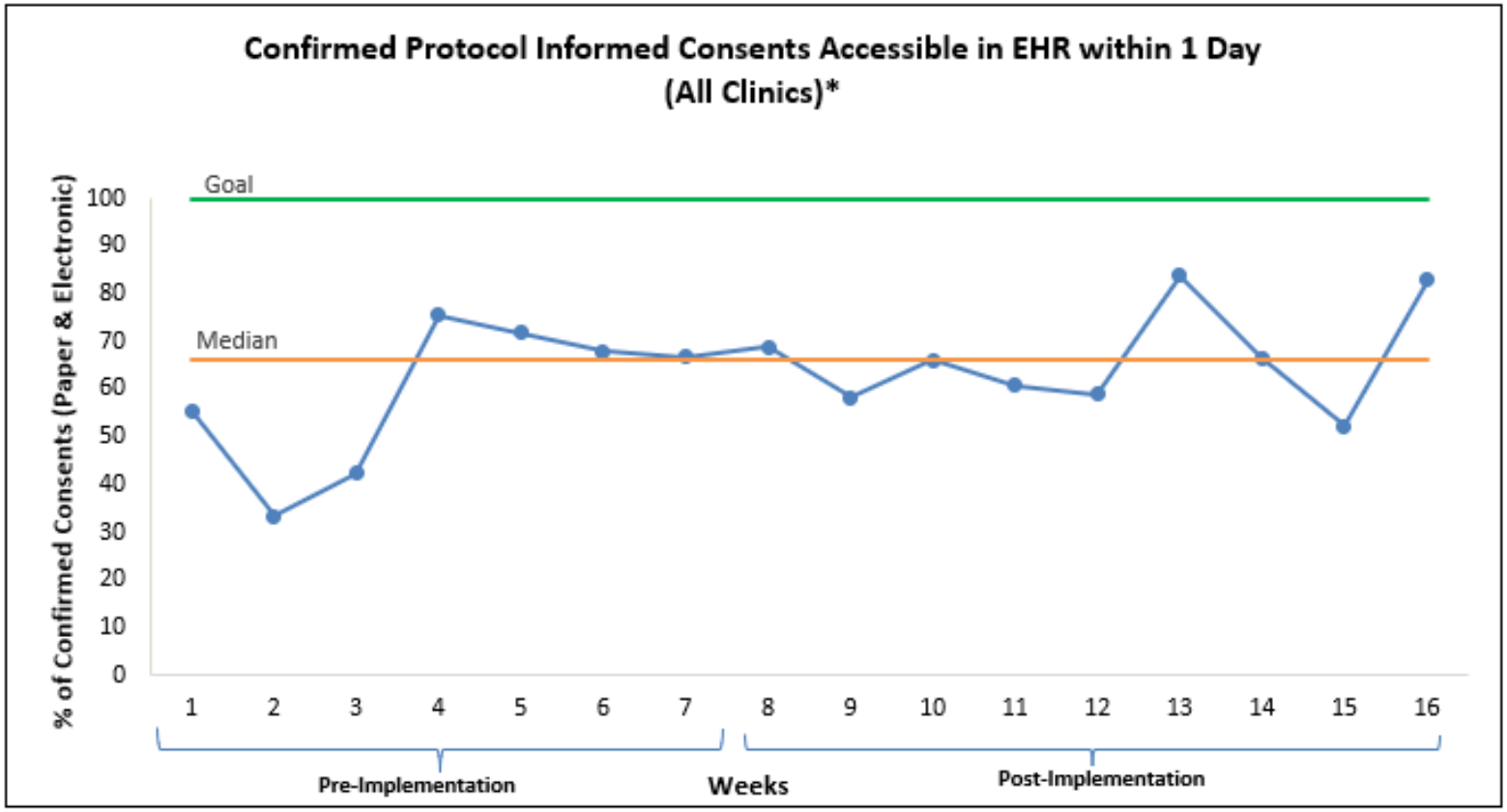


Figure 3

Run Chart of Electronic Informed Consent Usage (All Clinics)

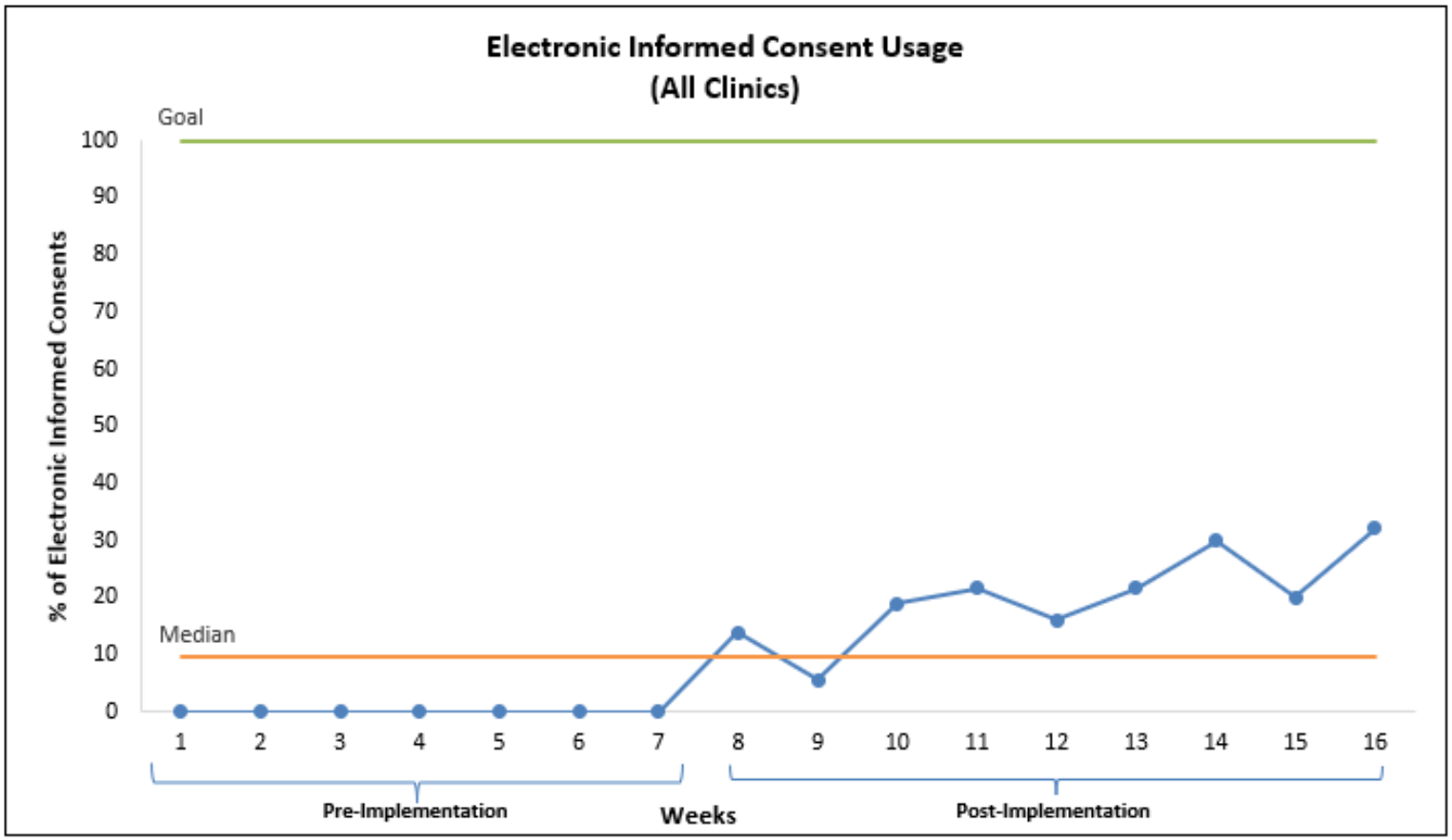


Figure 4

Run Chart of Paper Informed Consents Returned to Clinicians (All Clinics)

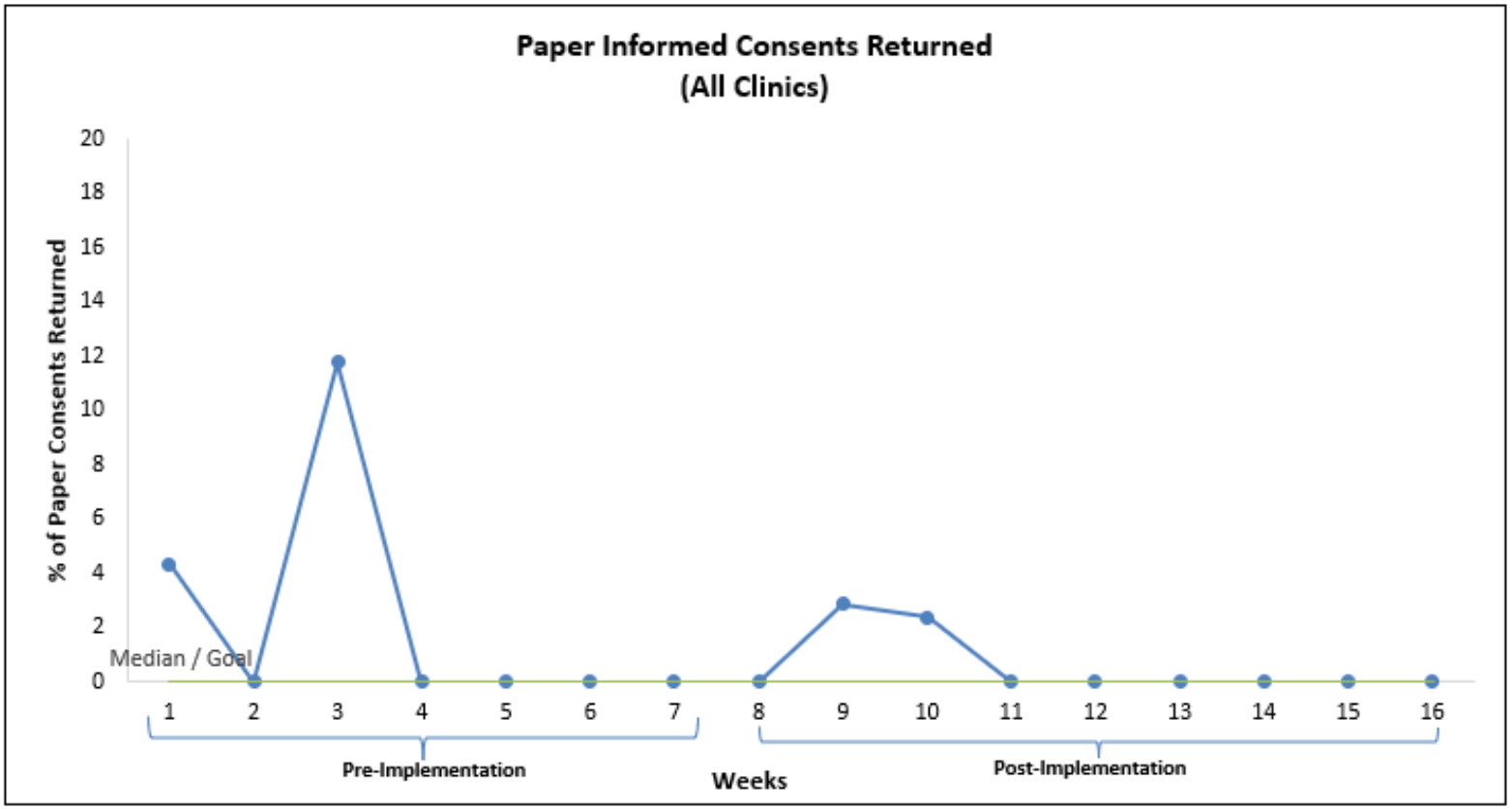
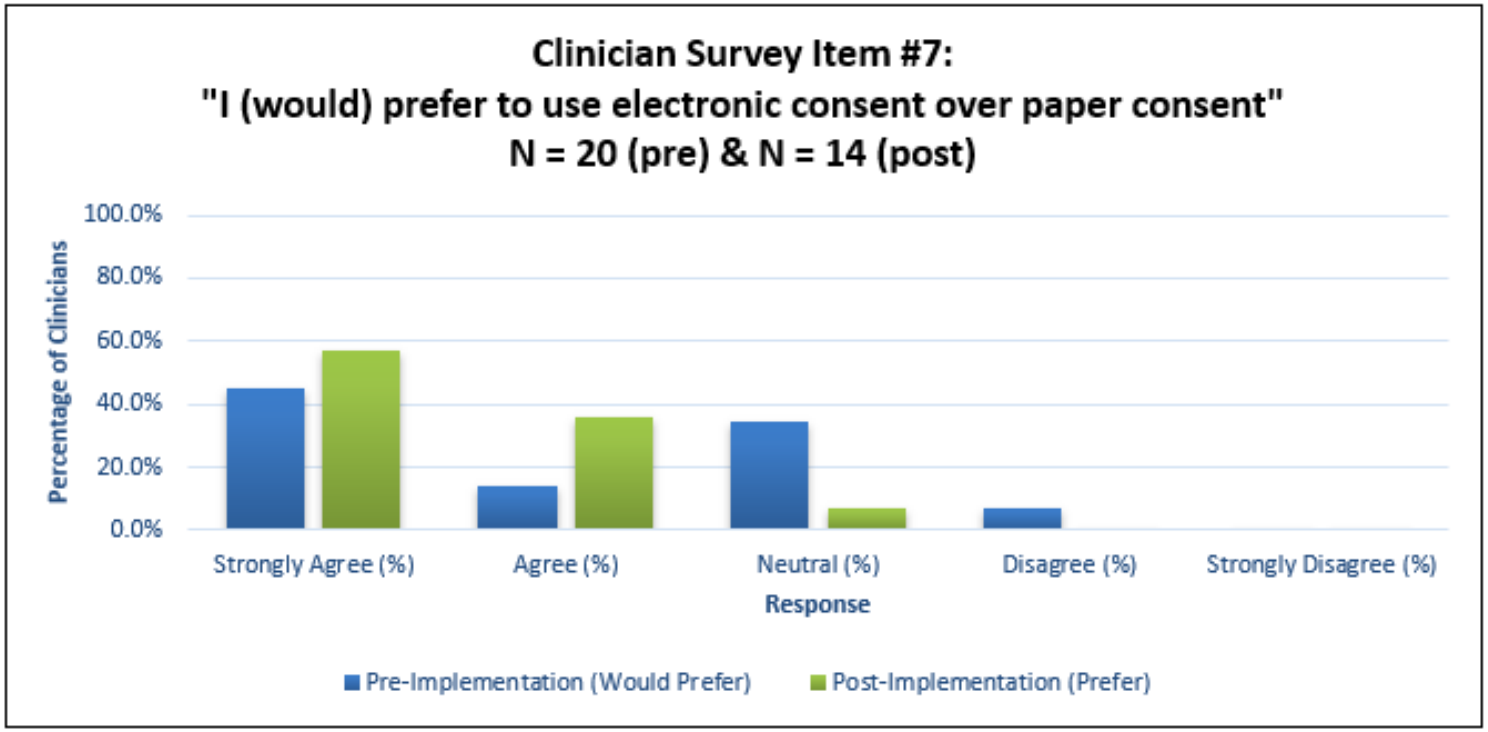


Figure 5

Clinician Pre-Implementation and Post-Implementation Responses for Survey Item #7



Appendix A

Evidence Review Table

Citation: Warriner, A.H., Foster, P.J., Mudano, A., Wright, N.C., Melton, M.E., Sattui, S.E., Calmbach, W., Curtis, J.R., Kilgor, M., Lewis, C.E., Pace, W., & Saag, K.G. (2016). A pragmatic randomized trial comparing tablet computer informed consent to traditional paper-based methods for an osteoporosis study. *Contemporary Clinical Trials Communications, 3,* 32-38. https://dx.doi.org/10.1016%2Fj.conctc.2016.02.003					**Level II (Melnyk)**
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
The purpose of this pilot study was to compare "patient comprehension and satisfaction and provider satisfaction with electronic informed consent process compared to traditional paper informed consent process in community practices" (p.32)	Randomized Controlled Trial (RCT)	**Sampling Technique:** Convenience **# Eligible:** N = 9 community-based practice sites from the American Academy of Family Physicians National Research Network, Alabama Practice Research Network and South Texas Ambulatory Research Network. N = 43 women screened for eligibility to participate in a future osteoporosis trial Inclusion Criteria: Women > = 55 years old and < = 1 year Alendronate use who presented to clinic	**Control:** Paper informed consent process **Intervention:** Electronic informed consent process **Intervention fidelity (describe the protocol):** Randomized to begin with either tablet or paper informed consent process, then switched to the alternate process after completion of 3 participant enrollment for a total of 6 participants for each practice. <u>Electronic informed consent process:</u> 1. Information on tablets described	**DV:** (1) Participant comprehension and satisfaction with electronic informed process compared to traditional paper consent, (2) Provider satisfaction with electronic informed process compare to traditional paper consent **Measurement tool (reliability), time, procedure:** Participant comprehension measured using multiple choice questions based on the validated Health-Information Technology Usability Evaluation Scale and Quality of Informed Consent surveys	**Statistical Procedures(s) and Results**: Descriptive statistics for baseline summary of participants and practices. Compared participant statistics between those who completed paper vs tablet consent Compared mean responses to the 7-point participant and practice survey questions on the Likert-scale Two-sided t-test or Fisher's exact test (small sizes) to determine statistical significance

		# Accepted: N = 33 research participants • iPad Informed Consent: N = 15 • Paper Informed Consent: N = 18 **# Control:** N = 18 **# Intervention:** N = 15 **Power Analysis:** None **Group Homogeneity:** Study population homogenous to only older women, but more women in the tablet IC group had home computers than in the paper IC group	research study using audiovisual – animated video with avatars which describes important study details, e.g., randomization, risks, benefits of the osteoporosis pragmatic clinical trial 2. Completed seven comprehension multiple choice questions. Hints provided for incorrect answers, and option to review. 3. Signed electronic consent on tablets by entering social security number and date of birth and co-signed by clinic staff. 4. Completed comprehension and satisfaction assessment <u>Traditional paper informed consent:</u> 1. One-on-one meeting between clinic staff and participants to describe study and answer questions. 2. Provided additional time to review paper informed consent and ask questions 3. Entered social security number and date of birth and signed	Provider satisfaction was measured using survey of 10 questions using a 7-point Likert response set	**Results:** Patients and office staff reported greater comprehension and satisfaction with the tablet informed consent, but no statistically significant difference in participant comprehension and satisfaction between the paper [mean = 11.4 (SD 1.6)] vs. tablet [mean = 12.2 (SD 1.0). Provider and practice staff preferred the tablet (mean 6.6, SD 0.5) over the paper informed consent (mean 6.0, SD 0.8) (two-sided t-test p = 0.02) for recruitment and enrollment of potential study participants, but not significant. Perceived time spent completing tablet consent process was higher with the tablet process [28.3 min (SD 16.3)] than paper [19.0 min (SD 6.9)], p = 0.08.

			paper consent, and co-signed by clinic staff. 4. Completed comprehension and satisfaction assessment IRB approved informed consent eConsent tool HIPAA and FDA compliant Participants initially "blind" to the actual purpose of the consent study comparing paper vs electronic <u>Physician and practice staff satisfaction survey:</u> Telephone surveys (10 questions using a 7-point Likert scale) 1. After enrolling 3 participants using paper consent process 2. After enrolling 3 participants using electronic consent process 3. After completing both processes at end of study		

Citation: Jayasinghe, N., Moallem, I., Kakoulis, M., Ojie, M., Sar-Graycar, L., Wyka, K., Reid, M.C., & Leonard, J.P., (2019). Establishing the feasibility of a tablet-based consent process with older adults: A mixed-methods study. *The Gerontologist, 59(1),* 124-134. https://doi.org/10.1093/geront/gny045					**Level III (Melnyk)**
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
The purpose of this study was to "examine the feasibility and acceptability of using a tablet-based informed consent process to enroll older individuals in a mock clinical trial." (p. 126)	Mixed methods study with two phases: Phase 1- Focus group trial and discussion (Qualitative) Phase 2 – Randomized trial of paper-based versus tablet-based consent	**Sampling Technique**: Convenience sample recruited via flyer and pamphlet advertisements, with a $30 compensation for participation. **# Eligible:** N = 35 community dwelling women and men aged 65 years and older **# Accepted:** N = 15 (Phase 1) N = 20 (Phase 2) Inclusion Criteria: Age 65 years or older, cognitively intact, and able to speak and read in English. Exclusion Criteria: Legally blind, severe hearing loss not correctable by assistive device, unable to use finger to swipe a touchscreen, and no working telephone at home to permit follow up (based on self-report)	**Control:** N/A **Intervention:** Paper or tablet-based informed consent process (Phase 2 – Randomized Trial) Intervention Group Participants assigned to a tablet-based consent study condition (same consent wording as paper-based consent) Control Group: Participants assigned to a paper-based consent study condition **Intervention fidelity (describe the protocol):** IRB approval was obtained Phase 1 – Focus Group3 dual-moderator focus groups with 4-6 participants in each group (no relationship with each other).	**DV:** Phase 1 – Focus Group (1) Participant feedback about perceptions of tablet-based consent Phase 2 – Randomized Trial: (1) Time spent reviewing consent form was recorded (in minutes) (2) User-friendliness (Likert) (3) Immediate comprehension of study (4) Retention of information at 1 week (Brief Assessment of Capacity to Consent) Measurement tool (reliability), time, procedure: Measurements for both phases: (1) Mental status (Mini-mental State Exam) (2) Attitudes towards technology (Computer	**Statistical Procedures(s) and Results:** Phase 1 – Focus Group: Summative content analysis of focus group transcripts Phase 2 – Randomized Trial: Used independent samples t-tests for continuous variables and chi-square tests for categorical variables to compare participants in the tablet-based consent and paper-consent groups based on sociodemographic and clinical measures. **Results:** Phase 1 – Focus Group: Participants were interested in the tablet-based informed consent, but cautioned that their peers would need to be adequately

		# Control: N/A **# Intervention:** N = 20 (Phase 2 - Randomized Trial) **Power Analysis:** None, but sample sizes for both phases guided by validated studies which were included in the reference **Group Homogeneity:** Homogenous to older adults with a mean age of 77.47 (focus group) and 74.65 (randomized trial). Mostly white females (90% for focus group) and (85% for randomized trial)	Groups divided into 3 age categories: (1) Young-old (65-74) (2) Middle-old (75-84) (3) Old-old (85 and over) Completed brief baseline measure and paper-based informed consent to participate in study. Focus group discussions which lasted up to 60 mins was led by 2 researchers; 2 tablets per focus group. Each participant individually: (1) Oriented to tablet-based consent (2) Interacted with tablet-based consent for 5 minutes (3) Briefly viewed paper consent Then guided group discussion with open-ended questions to regarding their perspectives, comparisons, perceptions, and responses between the paper and tablet-based consents	Anxiety Rating Scale) (3) Attitudes towards clinical trials (Attitudes Towards Cancer Trials Scale) Also collected participants' socio-demographic information Additional measurements for Phase 2 (Randomized Study): (1) Cognitive functioning (Trail-Making Test) (2) Health literacy (Test of Functional Health Literacy) (3) Anxiety (State-Trait Anxiety Scale and Trait subscale) (4) Depression (Patient Health Questionnaire-9) (5) Upper extremity disability (Quick-DASH)	oriented to the technology. <u>Phase 2 – Randomized Trial:</u> There were similarities in the tablet-based consent and paper-based consent with regards to user-friendliness, immediate comprehension and retention after 1 week. However, participants took more time (11 mins or 53% increase) to complete the tablet-based consent.

			<u>Phase 2 – Randomized Trial:</u> Block randomization by computer Participants assigned to a study condition in blocks of 2 – tablet or paper condition. (1) Conducted baseline assessment (2) Oriented to a hypothetical clinical trial involving psychosocial treatment for falls-related anxiety (3) Instructed to assume perspective of a potential research participant (4) Paper-based consent – 2nd researcher read out consent and answered participants' questions OR Tablet-based consent – participant reviewed text on tablet while listening to audio version of text. 2nd researcher read out		

			consent and answered participants' questions (5) Assessed comprehension of consent immediately after completion of consent form using a standardized interview. (6) Reassessment 1 week later via phone interview		

Citation: Madathil, K.C., Koikkara, R., Obeid, J., Greenstein, J.S, Sanderson, I., Fryar, K., Moskowitz, J., & Gramopadhye, A.K. (2013). An investigation of the efficacy of electronic consenting interfaces of research permissions management system in a hospital setting. *International Journal of Medical Informatics, 82*, 854-863. https://dx.doi.org/10.1016%2Fj.ijmedinf.2013.04.008					**Level III (Melnyk)**
Purpose/ Hypothesis	**Design**	**Sample**	**Intervention**	**Outcomes**	**Results**
This study was done to investigate "the efficacy of these interfaces (a stationary touchscreen interface to be used in regular patient registration areas, and a tablet-based system presented on an iPad to be used primarily in mobile situations such as an ER), comparing them with the current paper- and Topaz-based systems in order to explore how the two concepts were perceived and experienced by the patients and the registration staff." (p. 2)	Mixed experimental case-control study	**Sampling Technique:** Convenience **# Eligible:** N = 50 participants in a South Carolina hospital (academic medical and research institution) comprising of: N = 40 patients 18-77 years, and N= 10 hospital registration staff aged 23-74 years, with at least one year experience working in registration **# Accepted:** N = 50 No participant demographics Equally divided into 4 consenting system environments: (1) Paper-based N = 10 patients (2) Topaz-based (electronic capture method) N = 10 patients	**Control:** Existing consent methods 1) Paper-based consenting system (2) Topaz-based (electronic capture method) **Intervention:** N/A **Intervention fidelity (describe the protocol):** Same procedure followed for all 4 consenting test conditions Patients completed the following: (1) Read and signed consent process base on their assigned consenting system (2) Brief pre-test questionnaire of demographic information (3) Retrospective think-aloud session to detail their concerns with	**DV:** Comparison based on objective and subjective measures of the 4 consenting systems: (1) Paper (2) Topaz (3) iPad (4) Touchscreen Objective measures: (1) Task completion time (2) Number of errors made by participants Subjective measures: (1) Staff NASA TLX Assessment scores (2) Participant and staff post-test questionnaire results **Measurement tool (reliability), time, procedure:** (1) IBM Computer Systems Usability Questionnaire (IBM-CSUQ) (2) NASA TLX Assessment – Staff	**Statistical Procedures(s) and Results:** Normality test – for normal distribution One-way ANOVA with 95% confidence interval to determine for significant differences Post hoc LSD test to determine locus of significant differences Friedman test to identify significant effects **Results:** No significant differences noted in the time to complete tasks for all 4 consenting formats $F(3,36) = 0.483$, $p = 0.696$ Staff and patients reported better comprehension and awareness of consents with iPad based and touchscreen-based

		(3) iPad-based N = 10 patients (4) Touchscreen-based N = 10 patients Each registration staff monitored 1 participant for each consenting system (4 sessions) **# Control**: N/A **# Intervention:** N/A **Power Analysis:** None, but sample size determined from validated usability studies **Group Homogeneity:** Unable to determine, except for age (18-77), which is the only demographic reported for participants. The staff population appears to be homogenous to registration staff with at least 1 year experience.	interacting with the interface (4) IBM Computer Systems Usability Questionnaire (IBM-CSUQ) (5) Semantic questionnaire to evaluate their perceived level of understanding of the consent form (6) Debriefing by researcher Staff followed the same steps for each patient assigned to the 4 consenting groups: (1) Same as patient steps 1-4 (2) Debriefing by researcher (3) NASA TLX workload assessment (4) Final post-test questionnaire to rank each system based on their preference	(3) Post-test questionnaire (4) Number of errors – observation of consenting processes by the researcher No mention of reliability or validity of NASA and IBM measurement tools, but article reference included psychometric evaluations	electronic consenting systems Hospital staff experienced the most workload with paper-based system and the least workload with the iPad-based system.

Citation: Frelich, M., Bosler, M.E., & Gould, J.C. (2015). Research Electronic Data Capture (REDCap) electronic Informed Consent Form (eICF) is compliant and feasible in a clinical research setting. *International Journal of Clinical Trials*, *2*(3), 51-55. http://dx.doi.org/10.18203/2349-3259.ijct20150591					**Level II (Melnyk)**
Purpose/Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
"Our objective was to design a 21 CFR Part 11 compliant iPad-based [electronic informed consent form] (eICF) with Research Electronic Data Capture (REDCap). As a secondary aim, we sought to compare subject workload between the eICF and paper consent" (p.52) "A prospective randomized study was conducted to compare the eICF with conventional paper consent for clinical research from June 2013 to September 2014" (p.52)	Prospective RCT	**Sampling Technique:** Convenience **# Eligible:** N = 116 All subjects scheduled for gastric bypass surgery from the period June 2013 to September 2014 **# Accepted:** N = 51 (44%) provided informed consent and completed study **# Control:** N = 26 (51%) paper consents **# Intervention:** N = 25 (49%) eICF **Power Analysis:** Designed to provide at least 80% power to detect a 58% decrease in NASA-TLX Workload in the eICF group compared to the paper consent group at	**Control:** Paper informed consent form **Intervention:** Electronic informed consent form (eICF). **Intervention fidelity (describe the protocol):** Random assignment to eICF or paper informed consent through envelope assignment Six-page paper consent transferred to REDCAP survey platform which was 21 CRF Part 2 compliant. The paper and eICF form content remained identical. The eICF was accessed on an encrypted iPad connected to secure Wi-Fi network. Subjects used scroll bar to navigate the device screen and interacted on	DV: (1) Patient perception of wait times (2) Subject workload between eICF and paper consent Measurement tool (reliability), time, procedure: Subject workload: (1) NASA Task Load Index (NASA-TLX) (2) Subjective patient feedback regarding the consent process immediately after signing consent Validated NASA-TLX scale used for subjective assessment of human-machine task difficulty Uses six weighted subscales to calculate a workload score. Six scales are comprised of 21 gradations (ranging from very low to very high) rating task	Statistical Procedures(s) and Results: Two-tailed tests used for continuous data Two-tailed Fisher's exact test used to compare categorical data statistically significant if p-value <0.05 Results: <u>Subject Workload</u> No significant differences in subject workload between eICF and paper consent groups based on NASA-TLX Weighted Scale or Total-TLX Scores <u>Subjective Feedback</u> eICF group rated a statistically significant ($p<0.01$) higher preference for using the eICF in future research studies (6.4±1.5) versus the paper consent group (5.0±1.9).

		a two-sided 5% significance level Expected SD of 25 NASA-TLX points At least 18 subject per group for 80% power **Group Homogeneity:** There was no significant difference between the groups, except that the subjects were mostly females (N=40 or 78%) and overall mean age 44.4 years	the touchscreen using their fingers. After reading consent, subjects answered questions to confirm all parts of the eICF completed, then signed by performing a double name entry. Paper informed consent Participants read the 6-page printout and signed the form	difficulty for mental demand, physical demand, temporal demand, performance, effort and frustration. .	One error with eICF due to one participant's inadvertent submission of the consent before completing

Citation: Lentz, J., Kennett, M. Perlmutter, J., & Forrest, A. (2016). Paving the way to a more effective informed consent process: Recommendations from the Clinical Trials Transformation Initiative. *Contemporary Clinical Trials, 49*, 65-69. https://doi.org/10.1016/j.cct.2016.06.005					**Level II (Melnyk)**
Purpose/Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
The purpose of this study is stated as "Using evidence gathered through a comprehensive literature review, expert interviews, and a multi-stakeholder meeting, the CTTI Project Team, composed of a diverse group of stakeholders from across the clinical study enterprise, developed recommendations around four key topics: 1) conducting the [Informed Consent Process] ICP, 2) training research staff, 3) improving the ICD, and 4) using electronic consent (e-consent). This manuscript describes the methods employed to delineate the current issues with IC and the solutions proposed via the CTTI Informed Consent Project Recommendations for a successful ICP." (p. 80)	Expert committee consensus recommendation report	**Sampling Technique:** Research Strategy: (1) Literature review (2) Expert reviews (3) Expert meeting Literature Review: • N = 45 articles assessed • 4 parallel systematic reviews of primary literature • Conducted between May and June 2014 • Inclusion Criteria: Publications in English during or after 2000 Expert Interviews: • N = 25 informed consent experts in the US • 1-hour telephone interviews Expert Meeting: • N = 60 stake-holders from different disciplines and industries • 2-day meeting	**Intervention:** N/A **Intervention fidelity (describe the protocol):** N/A Developed consensus on areas of ICP that need improvement and provided general recommendations for best practices	**DV:** N/A Developed consensus on areas of ICP that need improvement and provided general recommendations for best practices **Measurement tool (reliability), time, procedure**: N/A	**Statistical Procedures(s) and Results:** N/A Conclusion: The main foundation topics of the recommendations: (1) Define effective informed consent process (2) Train research staff (3) Improve the informed consent document (4) Explore use of electronic consent: - Use of recommended tiered informed consent document provides critically relevant information to assist participants with decision-making, and leads to participant-centric informed consent - Share best practices and lessons learned

Citation: Chen, C., Lee, P. I., Pain, K. J., Delgado, D., Cole, C. L., & Campion, T. R., Jr. (2020). Replacing paper informed consent with electronic informed consent for research in academic medical centers: A scoping review. *AMIA Joint Summits on Translational Science proceedings. AMIA Joint Summits on Translational Science,* 80–88. https://pubmed.ncbi.nlm.nih.gov/32477626/					**Level VI (Melnyk)**
Purpose/Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
This study stated its purpose as "Although experts have identified benefits to replacing paper with electronic consent (eConsent) for research, a comprehensive understanding of strategies to overcome barriers to adoption is unknown. To address this gap, we performed a scoping review of the literature describing eConsent in academic medical centers" (p. 80)	Literature Review	**Sampling Technique:** Search Strategy: Conducted a scoping review of the literature in Ovid MEDLINE® (In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to Present), Ovid Embase (1974 to present), the Cochrane Library (Wiley), Scopus (Elsevier), and ABI/Inform (ProQuest) Timeframe: December 11-15, 2017 Additional search for records in February, 2019 involved: (1) Reviews of bibliographies of included articles 2) Citation in papers **# Eligible:** N = 220 out of 2872 articles assessed for eligibility. Inclusion Criteria:	**Intervention:** N/A **Intervention fidelity (describe the protocol):** Three reviewers followed the Joanna Briggs Institute recommendations for scoping review. Defined the review in Population, Intervention, Comparison and Outcome (PICO) format: • P = centers conducting clinical research with affiliations to major medical schools • I = electronic informed consent process • C = eConsents compared to paper consents • O = Efficacy of eConsent	**DV:** Conducted a scoping review of the literature to describe eConsent use in academic medical centers **Measurement tool (reliability), time, procedure:** Joanna Briggs Institute recommendations for scoping review	**Statistical Procedures(s) and Results:** The majority of articles involved original research, and on the adult population Conclusion: There were no standards or guidelines, or leading commercial solution for replacing paper consents with electronic consent among academic medical centers. There were varied eConsent implementations addressed issues based on the following: (1) Ethical, legal and social e.g., digital divide, trust (2) User interface/user experience e.g., provider task load and participant comprehension

		Articles describing electronic informed consent processes at clinical research centers, or articles comparing the effectiveness, efficiency, and cost of paper-based versus electronic informed consent process Exclusion Criteria: Articles only describing using electronic content for recruitment / information, but did not obtain consent using electronic format **# Accepted:** N = 69 (mostly conducted in the US = 50) **# Control: N/A** **# Intervention: N/A** **Power Analysis: None** **Group Homogeneity:** Original research articles on adult population	Categorized each study by type based on the Journal of the American Medical Informatics Association, e.g., research, original, perspective review, as well as study population, disease area and purpose. Studies were also grouped under the following issues: (1) Ethical, legal and social (2) User interface/user experience (3) Comparison of electronic and paper methods (4) Enterprise information technology scalability (5) Ability for participants to change consent options Performed comparison of ratings and resolution of disagreements through discussion. Provided specific details of studies and the search strategy in a separate multimedia appendix. Created Preferred Reporting Items for		(3) Comparison of electronic and paper methods (4) Enterprise information technology scalability (5) Ability for participants to change consent options

			Systematic Reviews and Meta-Analyses (PRISMA) workflow diagram of the review process		

Citation: Skelton, E., Drey, N., Rutherford, M., Ayers, S., & Malamateniou. (2020). Electronic consenting for conducting research remotely: A review of current practice and key recommendations for using e-consenting. *International Journal of Medical Informatics, 143* (104271), 1-12. https://doi.org/10.1016/j.ijmedinf.2020.104271					**Level VI (Melnyk)**
Purpose/Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
The purpose of this article is to "to identify the key considerations for a successful implementation of e-consent for recruitment of research study participants. Existing literature was collated, critically appraised, and synthesized to answer the following: 1) What are the advantages and challenges of e-consent for research participants and researchers? 2) What are the key recommendations for researchers implementing econsent processes?" (p. 2-3)	Systematic review	**Search Strategy:** Conducted a comprehensive free text and medical subject heading (MeSH) search of 10 electronic databases (CINAHL, Medline (via EBSCOHost), Embase, DARE, HTA (via OVID Online), PubMed, the Cochrane Library, Scopus, Web of Science, NHS Evidence). Timeframe: April 2020 **# Eligible:** N = 27 out of 665 articles assessed for eligibility. Inclusion Criteria: • Studies published in English language peer-reviewed journals from 2010– 2020 • E-consent intervention for adult (≥ 18 years) research participants	**Intervention:** N/A Intervention fidelity (describe the protocol): Utilized Boolean operations, and truncation features in combination with key search terms identified using a Population, Intervention, Comparison and Outcome (PICO) format: • P = adult research participants; adult researchers • I = electronic consent; e-consent; tele-consent; informed consent • C = paper consent; face-to-face consent; in person; conventional; traditional • O = experience; satisfaction; perception; usability; feasibility; comprehension	**DV:** Conducted a critical appraisal and synthesis of the literature to answer the following: 1) What are the advantages and challenges of e-consent for research participants and researchers? 2) What are the key recommendations for researchers implementing econsent processes? **Measurement tool (reliability), time, procedure:** Used Critical Skills Appraisal Programme (CASP) checklist to assess the methodological quality of included studies (used to determine the risk of bias)	**Statistical Procedures(s) and Results:** Used narrative synthesis for data analysis which generated 5 provisional codes, and domain summaries obtained from extracted data relating to the following primary themes: (1) Accessibility and user-friendliness of e-consenting system (2) User-engagement and comprehension (3) Customizability to participant preferences and demographics (4) Data security (5) Impact on research teams Most of the studies reviewed were determined to have a low to moderate risk of bias (n = 15) based on the Critical Appraisal

		• One of the outcome measures of user-evaluation of the consent intervention • Preference of a control comparison with an alternative consent method (e.g., paper-format), but not mandatory • All primary research study designs (randomized control, cohort, case-control, qualitative). Exclusion Criteria: Grey literature, conference abstracts, editorials and opinion articles **# Accepted:** N = 18 (mostly conducted in the US = 16): 6 Cohort 5 Qualitative 4 Randomized Controlled-Trials 2 Mixed-Methods 1 Case-Control **# Control: N/A** **# Intervention: N/A**	Utilized literature review matrix to enable data extraction of study characteristics Provided specific details of studies and the search strategy in a separate multimedia appendix. Created Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart of the study selection process		Skills Program (CASP) tools

		Power Analysis: None **Group Homogeneity:** Studies mostly representative of the local population, but predominant of mostly educated white females.			

Appendix B

Synthesis Table

Evidence Based Practice Question (PICO): In a clinical research hospital, does automating informed consent (implementing electronic informed consent) improve the documentation and availability of confirmed consents in the electronic health record for outpatient adults?			
Level of Evidence	**# of Studies**	**Summary of Findings**	**Overall Quality**
II	**3**	Warriner et al. (2016) found that participants and staff reported greater comprehension and satisfaction with the tablet informed consent, but there was no statistically significant difference, even though staff preferred the tablet format over paper. Frelich et al. (2015) validated that the REDCap (iPad-based) electronic informed consent platform was compliant and feasible in a clinical research setting, with no statistically significant differences in the participants' workload when compared to paper. Participants in the eConsent group stated greater preference for use in future research studies, which was statistically significant.	Summary: For these two RCTs, the researchers compared paper informed consent processes with electronic consents processes. C -This was a well-conducted and well-controlled RCT, with participants initially blinded to the actual purpose of the study, and limitations described. However, the sample size was small (n = 33) especially for a pragmatic clinical trial, which evaluates the effectiveness of interventions in real-world setting. The study findings are homogenous to women aged 55 years and older and therefore cannot be generalized to the public. Also, more women in the tablet group had home computers (12) than in the paper group (8), which could have influenced their preferences for the tablets. B – Even though the sample size was small in this study (n = 51), there were sufficient participants per group to meet the least amount needed (n = at least 18) based on a power analysis of at least 80% to detect a 58% decrease in workload when the two groups were compared. The study was well-conducted with consistent and definitive results. However, participants may have preferred the eConsent due to the majority of them being young (mean age = 44 +- 11.6). Also, there were more females than males. Thus, the study findings are non-generalizable to the larger U.S. population.

		Lentz et al's (2016) expert committee report recommended addressing four main foundation topics to define effective IC process, train staff, improve the IC document and explore use of eConsent to make it participant-centric and assist with decision-making.	A - This was a well-described review and recommendation by the expert Clinical Trials Transformation Initiative (CTTI) committee. The report outlined the three research strategies of an extensive literature review, expert reviews and expert multi-stakeholder meetings to develop recommendations for a more effective consent process. The sample sizes were sufficient for the three key areas and there were definitive recommendations.
III	**2**	Madathil et al.'s (2013) study found staff and patients reported better comprehension and awareness of consents with iPad-based and touchscreen-based electronic consenting systems when compared with paper-based and electronic capture method (Topaz system). There were also no significant differences in the times spent completing the consents. Jayasinghe et al.'s (2019) study found older adult participants were interested in tablet-based informed consents, but they perceived that their peers would need adequate orientation to the technology. There were similarities in findings for user-friendliness, immediate comprehension and retention after 1 week when the tablet-based consent was compared to paper-based consent, but participants took more time to complete the tablet-based consent.	Summary: The two Level III studies also compared paper-based consents with electronic consents. B - The study was well-conducted with extensive, high level statistical analyses of the results, but the sample size was relatively small (n = 50). The researchers did not address the limitations of the study. However, the study involved multiple steps for the participants, including several assessment tools. The staff participants each spent approximately 80 minutes for the four conditions session assigned to them. Another limitation is that there was no information on patient demographics, which could have influenced the results. B – This was a well-designed mixed methods study which comprised of a qualitative focus group (n = 15) and randomized pilot trial (n = 20). There was 100% retention of research subjects and no adverse or unexpected events. The small sample size is adequate for the qualitative study, but not for the pilot study. However, the small sample sizes were guided by validated studies and trialed on five subjects prior to being finalized. The hypothetical nature of the mock study may have the resulted in less effort and motivation of participants to process the information. Even though findings of the study can only be generalized to college-educated Caucasians in large academic medical center, it addressed different age ranges within the older adult population. Nevertheless, categorizing the participants based on gender may have had a different effect on the study's outcome.

VI	**2**		Summary: For these two Level VI literature reviews Chen et al. (2020) explored eConsent use in research done in large academic medical centers, while Skelton et al. (2020) looked at eConsent specifically done in the recruitment of research study participants.
		Chen et al's (2020) review of the literature describing eConsent in academic medical centers established that no standards or guidelines, or leading commercial solution exist for replacing paper consents with electronic consent. The institutions described varied implementations based on five critical categories of ethical, legal and social (most frequently addressed = 81%), user interface/user experience, comparison to paper, enterprise scalability and changes to the consent (least addressed = 25%). There are opportunities for researchers and software vendors to develop eConsent solutions in these areas, but human interaction cannot be replaced by eConsent.	B – This scoping review was done to comprehensively describe the eConsent process. The sample size (n = 220 articles) was adequate for a review. The researchers describe an extensive search strategy and specific study details referenced to a hyperlink. However, the hyperlink could not be accessed for verification. Also, there was no evaluation of strengths and weakness of the studies. Therefore, the details of the search strategy and synthesis of the studies could not be validated.
		Skelton et al's (2020) critical appraisal and synthesis of the literature of studies using e-consents in the recruitment of research study participants (n = 18) found most of the studies to have a low to moderate risk of bias (n = 15) based on the Critical Appraisal Skills Program (CASP) tools. E-consenting formats were reported to be well received by participants, the interfaces were found to be user-friendly for participants and researchers, and participant comprehension of consenting documentation was adequate.	B –The researchers described an extensive search strategy consisting of comprehensive free text and medical subject heading (MeSH) search of 10 electronic databases guided by a PICO, and including a PRISMA flowchart for study selection. The sample size (n = 15 articles) was adequate for the review, based on the rigorous screening process to assess the articles for eligibility. A limitation was that the Critical Skills Appraisal Programme (CASP) checklist used to guide the appraisal of the studies did not use a quantitative scoring system, resulting in only qualitative synthesis of the results due to high variability in their methods. Also, only one-third of the studies compared e-consent with the control (paper-based consent), thereby limiting the generalizability of the findings, which is further limited due to predominance of mostly educated white females in the overall studies.

Appendix C

Lesson Plan - Electronic Informed Consent Training for Clinicians

Learning Objectives	Content Outline	Method of Instruction	Time Spent	Method of Evaluation
Describe overview of E-consent for signatures	• Introduction • What is E-Consent? • Why E-Consent?	• Remote presentation / Computer-based tutorial or video	2 minutes	Verbalize understanding
Describe the benefits of E-consent	• Reduce risk • Enhance patient safety • Increase patient satisfaction • Ensure accreditation and regulatory compliance	• Remote presentation / Computer-based tutorial or video	3 minutes	Verbalize understanding
Demonstrate how to access E-Consent	• Login Access through the electronic health record (EHR) • Access through URL	• On-screen demonstration / Computer-based tutorial or video	2 minutes	Navigate in test environment (Hands-on practice)
Review E-Consent screen layout and general navigation	• Tabs • Menu	• On-screen demonstration / Computer-based tutorial or video	5 minutes	Verbalize understanding
Review E-Consent features and functionality	• Browse • Search • Favorites • Patient • Pending Signatures	• On-screen demonstration / Computer-based tutorial or video	5 minutes	Verbalize understanding
Demonstrate /Instruct patient how to complete signatures	• Patient signature on signature tablets • Patient signature on smart phone or tablet (mobile signature capture)	• On-screen demonstration / Computer-based tutorial or video	3 minutes	Navigate in test environment (Hands-on practice)

Learning Objectives	Content Outline	Method of Instruction	Time Spent	Method of Evaluation
Review completed E-Consent documentation in EHR	• Documents Tab • Consents Tab • Protocol Tab	• On-screen demonstration / Computer-based tutorial or video	3 minutes	Verbalized understanding
Demonstrate how to print consent for patient	• Patient copy	• On-screen demonstration / Computer-based tutorial or video	2 minutes	Navigate in test environment (Hands-on practice)
Describe how to troubleshoot electronic consent	• Login issues • Signature captures • Remote signatures • Device issues	• Remote presentation / Computer-based tutorial or video	5 minutes	Verbalize understanding / Respond correctly to troubleshooting FAQs

Note: Electronic Informed Consent training to be done remotely via a screen-sharing presentation platform. Future training will be done via computer-based tutorial/video.

Appendix D

Electronic Informed Consent User Manual

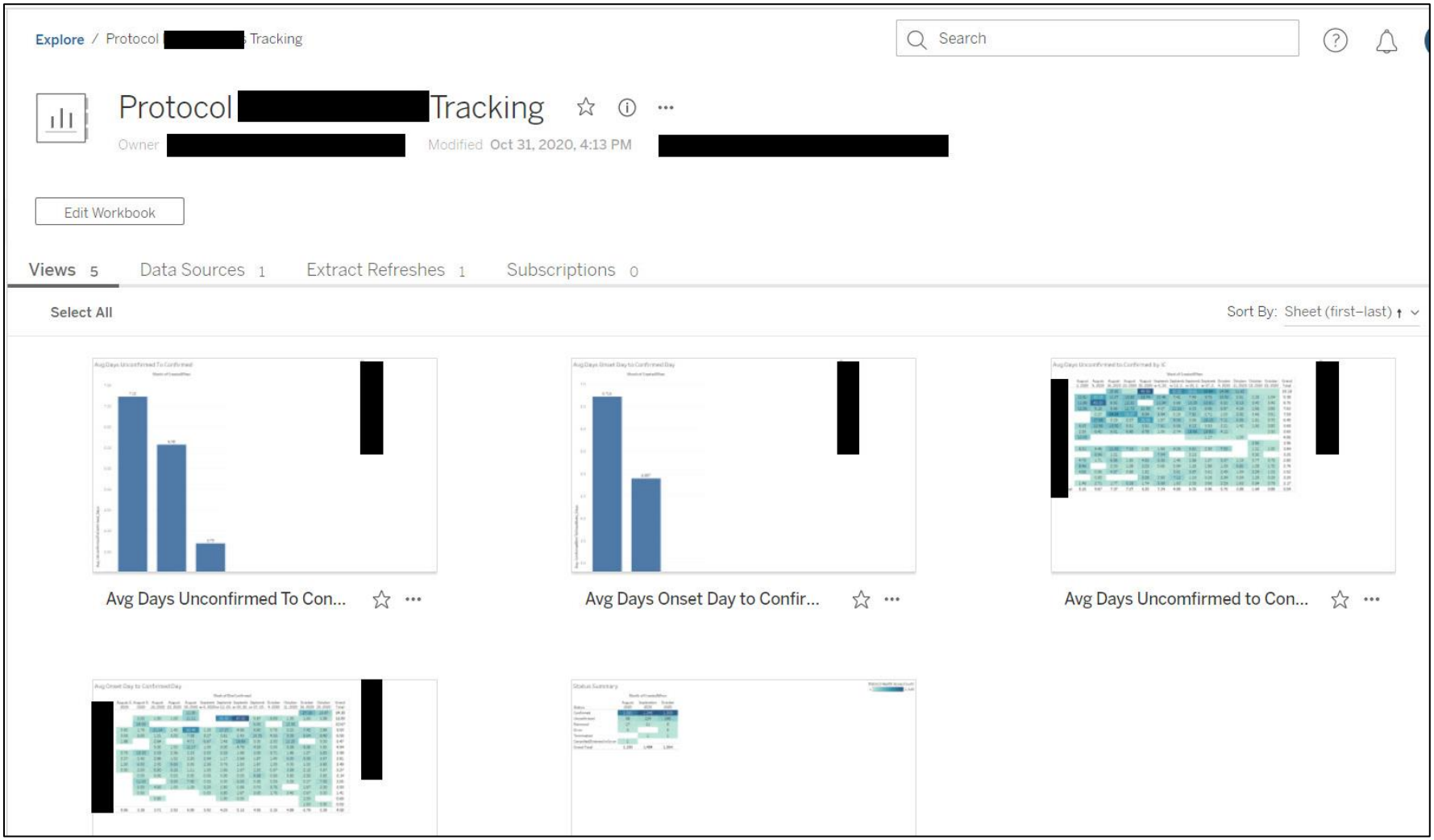
[redacted] Consent Early Adopters

User Manual

1

Appendix E

Automated Protocol Tracker



Appendix F

Clinician Pre-Implementation Survey

Clinician Pre-Implementation Survey

Dear Investigator and Study Coordinator, we would like your feedback on the use of the current paper protocol informed consent forms. Your responses will help us decide whether or not to explore the use of electronic consents in the future. Please note that your answers are confidential.

1. Please mark the box that best represents how you feel about your use of the current paper informed consent for each of the statements below:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The paper protocol informed consent is easy for me to use when consenting a patient.	○	○	○	○	○
Introducing the patient to the paper informed consent is easy.	○	○	○	○	○
At the end of the consent process, I feel confident that the patient understood the relevant protocol and clinical trial participation expectations.	○	○	○	○	○
The paper consent form helps me to focus the discussion with the patient on areas where he/she has questions.	○	○	○	○	○
It is effective to consent the patient using paper informed consent.	○	○	○	○	○
It is efficient to consent the patient using paper informed consent.	○	○	○	○	○
I would prefer to use electronic consent.	○	○	○	○	○
I would prefer to use paper consent.	○	○	○	○	○

2. What is your role?

○ Investigator

○ Research Nurse

○ Protocol Coordinator

Other

3. Choose the appropriate clinic:

Oncology

Infectious Diseases

Diabetes, Digestive and Kidney Diseases

4. In the space below, please provide any comments about your experience or concerns (issues, etc.) regarding paper consents.

Submit

Survey adapted from:

Transcelerate eConsent Survey Template for Sites.

http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/eConsent-Site-Survey-Template.docx

TransCelerate eConsent Survey Template for Patients.

http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/eConsent-Patient-Survey-Template.docx

Appendix G

Clinician Post-Implementation Survey

Clinician Post-Implementation Survey

Dear Investigator and Study Coordinator, we would like your feedback on the use of the new tablet/electronic consent tool to sign protocol informed consent. Your responses will help us decide on how we could make the experience better. Please note that your answers are confidential.

1. Have you used the electronic protocol informed consent to obtain patient consent?

- ○ No (If 'No', Go to #2)
- ○ Yes (If 'Yes', Go to #3)

2. In the space below, please enter the reason(s) why you have not used the electronic consent to obtain patient consent:

Go to End of Form (Submit)

3. Please mark the box that best represents how you feel about your recent use of the electronic informed consent tool for each of the statements below:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The electronic protocol informed consent (e-consent) tool was easy for me to use when consenting a patient.	○	○	○	○	○
Introducing the patient to the e-consent was easy.	○	○	○	○	○
At the end of the consent process, I felt confident that the patient understood the relevant protocol and clinical trial participation expectations.	○	○	○	○	○
The e-consent helped me to focus the discussion with the patient on areas where he/she has questions.	○	○	○	○	○
It was more effective to consent the patient using e-consent.	○	○	○	○	○
It was more efficient to consent the patient using e-consent.	○	○	○	○	○
I prefer to use electronic consent over paper consent.	○	○	○	○	○
I prefer to use paper consent over electronic consent.	○	○	○	○	○

4. Did you encounter problems with using e-consent?

○ Yes (If 'Yes', Go to #5)

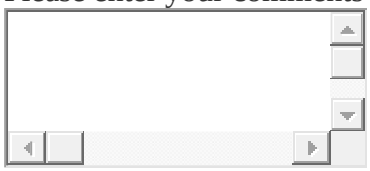
○ No (If 'No', Go to #7)

5. Were you satisfied with the support you received?

○ Yes (If 'Yes', Go to #7)

○ No (If 'No', Go to #6)

6. Please enter your comments about the support you received in the text box below:



7. What is your role?

- Investigator
- Research Nurse
- Protocol Coordinator
- Other

8. Choose the appropriate clinic:

- Oncology
- Infectious Diseases
- Diabetes, Digestive and Kidney Diseases

9. In the space below, please provide any comments about your experience or concerns (issues, etc.) regarding e-consents.

Submit

Survey adapted from:

Transcelerate eConsent Survey Template for Sites.

http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/eConsent-Site-Survey-Template.docx

TransCelerate eConsent Survey Template for Patients.

http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/eConsent-Patient-Survey-Template.docx

Appendix H

Electronic Reports Data Collection Tool: To compare the Signature-to-Confirmation Timeframe for protocol informed consent accessibility in the electronic health record (EHR)

Week # _____

Protocol #	**Informed Protocol Consent Type***	**Initial Date Signed**	**Date Scanned in Electronic Health Record (EHR)**	**Initial Status in Electronic Health Record (EHR)****	**Date Confirmed in Electronic Health Record (EHR)**	**Signature to Confirmation Timeframe*****
Total # of Protocols =						

Key

***Informed Protocol Consent Type:** (1) Paper, (2) Electronic (e-consent)

****Status in EHR:** (1) Confirmed, (2) Unconfirmed, (3) Protocol Change, (4) Active, (5) Inactive

*****Signature-to-Confirmation Timeframe** = Confirmed Date minus Initial Signed Date

Appendix I

Returned Paper Informed Consents (IC) Audit Tool

Week # _____

Protocol #	Initial Date Signed	Date Received by MRD	Date Sent Back to Clinician	Reason Sent Back to Clinician *	Method of Notification**	Date Scanned in EHR	Initial Status in EHR ***	Date Confirmed in EHR	Signature to Confirmation Timeframe****
Total # of Protocols =									

Key
EHR = Electronic Health Record, **MRD** = Medical Records Department

***Reason Sent Back to Clinician:** (1) Investigator signature and or date missing/incorrect, (2) Patient signature and or date missing/incorrect, (3) Witness/Guardian signature and or date missing/incorrect (4) Not original Copy, (5) MRN incorrect/missing, (6) Missing/Incomplete Page(s), (6) Expired Consent

****Method of Notification:** (1) Email, (2) Hand-Delivered, (3) Inter-Department Mail, (4) Postal Mail, (5) Other

*****Status in EHR:** (1) Confirmed, (2) Unconfirmed, (3) Protocol Change, (4) Active

******Signature-to-Confirmation Timeframe** = Confirmed Date minus Initial Signed Date