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Research Article

Research Electronic Data Capture (REDCap) electronic Informed Consent Form (eICF) is compliant and feasible in a clinical research setting

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ABSTRACT

Background: Electronic consent for research has shown success in clinical trial models, but has not been rigorously evaluated as an alternative to conventional paper consent. We sought 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 eICF and paper consent groups.
Methods: This is a prospective, randomized study of subjects who completed an iPad-based eICF versus paper consent for research. The eICF was designed with REDCap and presented on an iPad. Subject workload was measured with the NASA Task Load Index (NASA-TLX) and subjective feedback in regards to consent process was collected.
Results: A total of 116 subjects were screened for consent. Of which, 51 (44%) subjects provided informed consent and completed all study related procedures. Twenty-five (49%) eICF and 26 (51%) paper consents were completed. The eICF group rated a significantly greater preference to use the eICF for future research studies (6.4±1.5) compared to the paper consent group (5.0±1.9), $p<0.01$. There were no significant differences in NASA-TLX Weighted Scale or Total-TLX Scores between groups. One error resulted in the eICF group due to an inadvertent submission by a single subject.
Conclusion: In summary, we have demonstrated that an iPad-based eICF designed with REDCap is both 21 CFR Part 11 compliant and feasible in the clinical research setting. The eICF does not appear to be more technically difficult or demanding than conventional paper consent.

Keywords: REDCap, iPad, eICF, Paper consent

INTRODUCTION

Hospital management systems face substantial challenges capturing and maintaining biomedical research information. Source documents such as paper consent forms for research are becoming monotonous and more voluminous as the requirements for describing every detail continue to grow[1]. In a growing digital era, large pharmaceutical trials that use multimedia consents report increased accessibility, effectiveness, and patient comprehension compared to paper consents[2]. Such electronic interfaces are often described to be as effective as conventional methods. These methods also provide increased privacy and satisfaction during the consent process.[3,4]

There is a growing interest in the application of electronic Informed Consent Forms (eICF) that meet the United States Food and Drug Administration (FDA) regulations for electronic records and electronic signatures (ERES). Specifically, Title 21 of the Code of Federal Regulations Part 11 (21 CFR Part 11) which outlines criteria under which ERES are considered trustworthy, reliable, and

equivalent to paper records.[5] Electronic consent has shown success in clinical trial models, and although limited data has been reported, it has not been fully evaluated as an alternative to standard paper consent. Our objective was to design a 21 CFR Part 11 compliant iPad-based eICF with Research Electronic Data Capture (REDCap). As a secondary aim, we sought to compare subject workload between the eICF and paper consent.

METHODS

After Institutional Review Board (IRB) approval, a prospective randomized study was conducted to compare the eICF with conventional paper consent for clinical research from June 2013 to September 2014. The informed consent process was conducted by two certified clinical research professionals in a similar fashion. All subjects who were scheduled for gastric bypass surgery were approached for informed consent. Subjects who met inclusion criteria were randomly assigned to eICF or paper consent by envelope assignment.

The Clinical and Translational Science Institute (CTSI) of Southeast Wisconsin Informatics Core was used as a central location for data processing and management of the eICF. Vanderbilt University, with collaboration from a consortium of institutional partners, including the Medical College of Wisconsin (MCW), has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. All REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-document. The REDCap server was housed in a local data center at MCW and all web-based information transmission was encrypted. Data backups were performed nightly and stored in a separate location. REDCap was developed specifically around HIPAA-Security guidelines and currently supports more than 1,483 active institutional partners in 91 countries and 173,000 projects with over 236,000 research end-users.[6,7]

The source document for this study was our IRB approved paper consent. This consent was designed by our IRB and administered as a six-page paper printout. The content of the paper consent was transferred to the REDCap survey platform by a trained REDCap programmer. The REDCap survey platform functioned as our 21 CFR Part 11 compliant consent. The eICF was identical to the paper consent and was accessed on an encrypted iPad (diagonal 9.7 inches) linked to the secure main campus Wi-Fi network. Subjects interacted with the device on a touchscreen display using their finger(s).

A scroll-bar enabled subjects to read the single-page eICF. After reading the consent a series of questions in the form of radio-buttons followed to confirm that all elements of the consent were completed as outlined in 21 CFR Part 50.25 and 45 CFR Part 46.116. A double name entry by the patient or legally authorized representative constituted a signature. Completed eICFs were automatically filed on the REDCap server (Figure 1). Audit friendly reports were generated using REDCap's Data Export Tool. Subject workload was measured with the NASA Task Load Index (NASA-TLX) and with subjective patient feedback in regards to the consent process was collected. The NASA-TLX is a validated scale for subjective assessment of human-machine task difficulty. The NASA-TLX uses six weighted subscales to calculate a workload score. The six scales are composed of 21 gradations (range, very low to very high) that rate task difficulty for mental demand, physical demand, temporal demand, performance, effort and frustration. For our study, consenting subjects completed the NASA-TLX and provided consent process feedback immediately after the research consent was signed.

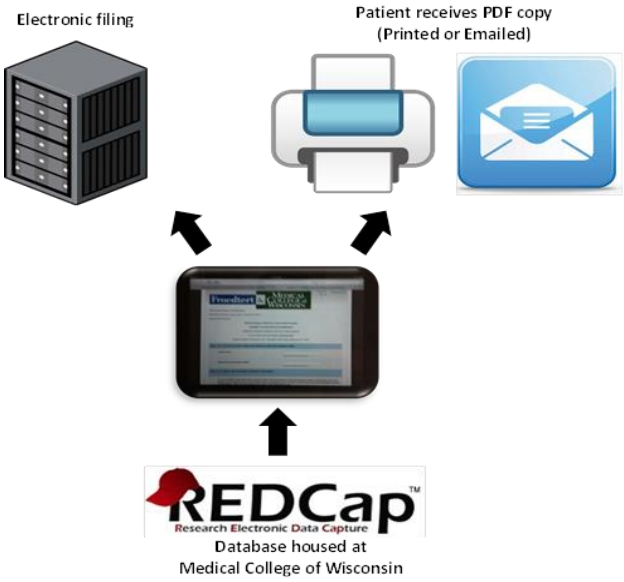

Figure 1: A schematic diagram of the eICF system.
(REDCap was used to design the iPad-based eICF. Completed consents were automatically filed on the REDCap server. Patients who completed the eICF received an Emailed or printed PDF copy of the original signed consent.)

The study was 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 a two-sided 5% significance level. Based on data from studies of the electronic consent in other contexts, a standard deviation of 25 NASA-TLX points was expected. A total of at least 18 subjects per group were needed to provide the desired power. Statistical analyses of our data were conducted using VassarStats (Vassar College, Poughkeepsie, NY). Two-tailed T-tests were used for continuous data and two-tailed Fisher's exact test was used to compare categorical data. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 116 subjects were screened for consent. Of which, 51 (44%) subjects provided informed consent and

completed all study related procedures. Twenty-five (49%) eICF and 26 (51%) paper consents were completed. The majority of subjects were female (40, 78%) and the overall mean age was 44.4 (±11.6, range; 19-63) years. Demographics did not significantly differ between study groups. The eICF group rated a significantly greater preference to use the eICF in future research studies (6.4±1.5) compared to the paper consent group (5.0±1.9), p<0.01 (Table 1). No additional differences in subject feedback were detected.

There were no significant differences in subject workload defined with the NASA-TLX Weighted Scale or Total-TLX Scores between eICF and paper consent groups (Table 2). One error occurred when using the eICF. This error resulted when a single patient inadvertently submitted the consent prior to completion.

Table 1: Subject feedback.

Question	eICF (n=25)	Paper (n=26)	*p* value
How would you rate your level of comfort with this consent?	6.5 (1.1)	6.7 (0.7)	0.42
How would you rate your level of satisfaction with this consent?	6.5 (1.1)	6.4 (1.1)	0.86
This consent is very user friendly.	6.5 (1.1)	6.5 (1.3)	0.91
This consent is simple to use.	6.4 (1.4)	6.4 (1.4)	0.97
I would prefer using an eICF versus paper consent for future research participation.	6.4 (1.5)	5.0 (1.9)	<0.01

Reported as Mean (±SD). The greater the score the more positive the patient rated experience (scale; 1-strongly disagree to 7-strongly agree).

DISCUSSION

We have demonstrated that an iPad-based eICF designed with REDCap is both 21 CFR Part 11 compliant and feasible in the clinical research setting. Furthermore, we have provided evidence that the eICF does not appear to be more technically difficult or demanding than paper consent. Subjects who completed an eICF reported a greater preference to use the eICF in future research compared to the paper consent group. This has important implications ultimately for the design and implementation of eICFs and for the management of future eICF.

Clinical study management details of the eICF were not reproducible with paper consent. The eICF automatic data management and electronic filing system eliminated the need to manually file paper consents.

Table 2: Subject workload defined with NASA-TLX.

Scale Consent	Mean (SD)	*p* value
Mental		0.71
Paper	1.4 (2.0)	
eICF	1.6 (3.2)	
Physical		0.18
Paper	1.6 (3.0)	
eICF	0.7 (0.9)	
Temporal		0.94
Paper	1.4 (2.2)	
eICF	1.4 (2.2)	
Performance		0.13
Paper	1.8 (2.8)	
eICF	0.9	
Effort		0.56
Paper	1.7 (2.9)	
eICF	1.3 (1.8)	
Frustration		0.18
Paper	0.8 (1.0)	
eICF	1.3 (2.0)	
Total Workload		0.66
Paper	8.7 (12.5)	
eICF	7.3 (9.0)	

Reported as Mean (±SD) using two-tailed T-test. Scales Reported as weighted NASA-TLX workload. The eICF refers to electronic Informed Consent Form.

Many institutions still use paper consents, which are manually filed or scanned and stored in a document handling system with no mechanism for conducting systematic queries.[11] The REDCap program offered the benefit of efficient retrieval of eICF information and data for regulatory purposes. Critics of eICF often highlight device and connection problems. In our study, we did not experience device or connection problems. However, backup systems were in place that would allow researcher's to access REDCap and the eICF from desktop computers located in the consent or exam rooms. The added ability to provide subjects with either a paper

copy of the completed consent or an e-mail containing an electronic pdf copy offered flexibility and minimized the use of clinical resources.

The overall eICF error rate in our study was consistent with reports in literature.[3] The inadvertent submission of an eICF by a single subject in our study population could have been avoided if a 'confirm' pop-up notification was programmed into our eICF as a stop mechanism prior to consent submission. However, this function was not available to REDCap programmers. In a study of 1,000 subjects, a 4% error rate would result in 40 erroneously submitted consents. This rate would be unacceptable in today's clinical research setting. Our study team would highly recommend the implementation of a 'confirm' pop-up notification or a similar stop mechanism to prevent inadvertent eICF submission in the future.

Electronic consent error rate may reflect individual user computer skills. In a study to compare iPad to standard paper briefings for radiological examinations, Schlechtweg et al. (2014) noted a positive correlation between the duration of electronic briefing and patient age and a negative correlation between computer skills and patient age[12]. In our study, no significant differences in patient demographics were detected among study groups, including age. One study patient was certified in adult education and expressed concern in regard to using the electronic consent in the geriatric population and stated, "my adult learners have trouble with technology and the eICF may not be a good choice." A number of patients in our study may have had limited previous interaction or no interaction at all with electronic devices. These subjects would possibly benefit from a brief iPad training session prior to using the eICF.

No significant differences in NASA-TLX Total workload among groups were identified. Further analysis of the NASA-TLX subscales suggested no differences in mental, physical demand, temporal, performance, effort, or frustration between eICF and paper consent groups. Our results contradict those of previously published studies. Madathial et al. (2013) compared four consenting methods: paper, electronic signatures using Topaz Systems Inc., a touchscreen system, and an iPad system.[3] The NASA-TLX workload, physical demand, temporal demand, and frustration were significantly lower in the iPad consent group compared to all other groups. These differences were likely associated with individual user ability and experience. In our study, subjects were relatively homogenous in regard to demographics. A system to measure subject technological ability and experience could provide additional explanation related to consent workload.

In our study, no significant difference in terms of overall subject satisfaction was reported between study groups. However, eICF subjects indicated a significantly greater preference to use the eICF for future research studies compared to the paper group. In contrast to our results, patient satisfaction, interface quality, and information quality have been reported to favor iPad consents.[3,4] Consent documents that are dense in pictures or videos rather than text my account for this discrepancy. When eICFs are dense in text, poor readers often go back and re-read information. When using an eICF poor readers have to scroll through several pages of information rather than turn pages. Therefore, the very nature of the iPad (single screen display of all information) magnifies reading and comprehension problems for particular subjects.

Limitations of our study include a small sample size. We did not collect data during the consent process such as total time to complete the consent, and cannot accurately speak as to how much time was necessary to complete each consent process without sacrificing knowledge and comprehension. Baseline performance on an iPad, subject technical ability and experience was not recorded. This prevented our team from being able to speak to the level of previous user experience and how it related to eICF satisfaction and error rate. The majority of our study population tended to be younger, likely computer-savvy (mean age 44±11.6, range 16-63). It is widely recognized that the elderly, on average, are significantly less facile with electronic devices than those who are younger. No patient in our study was eligible (by age) for Medicare or Social Security, much less truly elderly. It is also recognized that younger populations are increasingly developing a distinct disdain for completing paper forms. Future studies will be conducted to evaluate the context of the eICF in a large prospective clinical trial with a well-balanced population of young and elderly subjects. Future studies will also explore the challenges faced by potential participants in giving eICF and how those challenges can be addressed.

CONCLUSION

In summary, we have demonstrated that an eICF designed with REDCap for an iPad was 21 CFR Part 11 compliant and feasible in the clinical research setting. The electronic filing system allowed for efficient storage and retrieval of documents. The eICF does not appear to be more technically difficult or demanding than conventional paper consent. These results will help guide clinical researchers and institutional review boards when considering the design and implementation of future eICFs.

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Conflict of interest: Matthew J. Frelich and Matthew E. Bosler declare no conflicts of interests. Dr. Jon C. Gould serves on the Medical Advisory Board for Torax Medical, Inc.
Ethical approval: Required

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