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Comparison Of Interactive Electronic Versus Standard Document Method For Obtaining Patient Informed Consent

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COMPARISON OF INTERACTIVE ELECTRONIC VERSUS STANDARD DOCUMENT METHOD
FOR OBTAINING PATIENT INFORMED CONSENT

by

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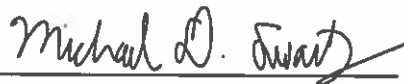
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2020

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OBTAINING PATIENT INFORMED CONSENT

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The primary objective of this study was to determine whether participants who received an interactive electronic consent (EC) had a better understanding of a medical procedure (apheresis) compared to those who received the standard document (SD) consent. The study was conducted with apheresis donors whose responses were used to determine if the EC facilitated better comprehension and retention of consent information by the study participants than by SD consenting methods. By comprehension, the goal was to have participants who can understand, summarize, or make judgments based on the content presented in the informed consent. By retention, the goal was to see if participants could recognize and select information presented in the informed consent.

The two primary endpoints were measured using the Quality of Informed Consent (QuIC) index: knowledge of the various facets of the procedure, including the purpose of treatment and rights (Part A), and understanding of the informed consent items (Part B). Secondary endpoints included the effect of EC vs. SD on decisional conflict, patient satisfaction, and anxiety, as well as preferences between the SD and electronic and whether participants who completed the EC consent were more likely to consent to the procedure.

The specific aims of the study were:

- 1) Obtain post-consent comprehension and understanding, anxiety, and decisional uncertainty in participants who completed SD and EC consent.
- 2) Compare post-consent comprehension, retention, anxiety, and decisional uncertainty in participants who completed the SD and EC consents.
 - a. Also, EC satisfaction with the delivery method was surveyed.

The primary hypothesis was that participants who used the EC would perform better than those who used the SD informed consent across the following domains: 1) comprehension and retention; 2) decisional uncertainty; 3) anxiety, and 4) satisfaction.

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BACKGROUND

Over the last few decades, improving patient understanding of medical procedures has been a public health research priority and is a central component of improving care delivery. The current process for obtaining informed consent from patients has become increasingly recognized as obsolete, only marginally effective, and inefficient. In response, this study evaluated a newly developed electronic consent that automates the user interface as well as the content to improve the educational experience for patients and streamline the process. The electronic application is browser-based and consists of interactive text, illustrations, animations, schematics, and embedded videos to more fully educate patients so they make better-informed decisions. This process can be used to better inform patients regarding procedures, clinical trial participation and sample donation for biobanks.

This project was designed to provide preliminary pilot data that will inform the design and conduct of larger initiatives to identify and develop more effective methods of delivering informed consent.

The idea of optimizing the informed consent process was originally conceived by Dr. Sunil Patel when planning to engage in a breast cancer study (SWOG 212007) to determine the effectiveness of genetic testing certain types of lymph nodes. In answering this question, the study would also answer the question of when or whether to use chemotherapy. Given that this was an experimental approach, designing and explaining the study mechanics, risk, desired outcomes, and potential risks were particularly important. The importance of conveying this information was matched only by the complexity of the science and its implications for breast cancer research and treatment.

There was a need to develop a way to better educate clinicians and study participants on the nuances of the science. The standard document form was too complex and required a lot of time to explain when training clinicians as well as when educating patients. Despite the time investment, there was still a fair amount of anxiety and confusion from patients. The challenge was to relate very complex information to patients and potential study participants in a different way while remaining compliant with informed consent regulations. The goal and benefit were to inform and empower potential study participants to make an informed and comfortable decision to participate in the research. Ultimately, the hope was to improve study accruals, comprehension, and the overall informed consent process.

Compliance with current regulations doesn't require validation of comprehension, measures of knowledge retention, or demonstration of low decisional anxiety. From a

public health perspective, these are critical determinants of truly being certain that a patient or study participant is giving informed consent because they understand that to which they are consenting.

Although the use of the informed consent process has been well described, the use of remote and mobile technologies in apheresis has been the subject of few inquiries to date. Most of the current research involves limited use of audio tools or static forms delivered on tablets. To our knowledge, no previous studies have investigated the role of a fully automated informed consent that utilized multiple forms of media and assessment instruments to measure comprehension and satisfaction.

Informed Consent Process

There are several key elements of the consent process that require information to be shared by the research team with the potential participant in a manner that can be adequately grasped and acted upon. The following steps illustrate the process for informed consent as it applies in clinical and research settings:

- Development and delivery of research study or medical procedure information
- Validation of comprehension of study or procedure information through discussion
- The decision to or not to follow through with procedure or participate in the research study
- Follow-up or commencement

During the first step, the research team provides complete information about the procedure or research as well as participants' rights in a manner that can be understood by the patients and potential participants. Other aspects of the procedure or research study like the benefits of participation as well as the responsibility for care and complications must be carefully explained to patients and participants. In particular, they must be allowed to question the clinical or research team to clear up ambiguities and obtain additional information.

The second step is critically important. The patient or participant must understand what is being asked. This can only happen if the information is presented in a manner that is simple yet conveys the key elements of the proposed research or medical treatment. Although this can be a difficult step, this interaction must occur when the potential patient or participant is calm. Participants may misunderstand the treatment or research if insufficient time is spent explaining it, too little time interacting with the research/clinical team, or their literacy levels have not been considered.

The next step in the process is when the patient or potential participant feels free to agree or not agree to take part in the procedure or research. Therefore, not only must the participant understand the project or medical treatment, but they must also be competent to give his or her consent. This is in part the motivation for reconsidering the most effective ways to deliver informed consent.

The electronic informed consent (EC) includes several different ways of obtaining informed consent. Although the EC allows for a more contemporary and flexible method of delivery, the absence of paper or reduction of face-to-face contact has added to concerns of complications in the consent process. The most common concerns are:

- Ensuring comprehension
- Ensuring all of the necessary content
- Securing and protecting personal information

This study aimed to test the enhanced version of the electronic consent prototype incorporating new decision-support features including multimedia components, to create a novel, electronic consent (EC). This study was conducted with donors who were candidates for apheresis to determine if the prototype facilitates better comprehension and retention of consent information by the study participants than by standard consenting methods. By comprehension, the goal was to have participants who could understand, summarize, or make judgments based on the content present in the informed consent. By retention, the goal was to see if participants could recognize and select information presented in the informed consent. There are other potential benefits of EC such as efficiency, positive accrual impact, and better participant experience that are also important, but not the focus of this study. The information obtained from the study also addresses regulatory obstacles to implementing innovative consent processes and identify questions for subsequent studies comparing EC to traditional paper or consent.

Overview

The informed consent (IC) process for apheresis is of critical importance for two reasons: 1) the recognition of patient protections as an individual right and societal duty, and 2) the dependence of medical progress on patient participation in living saving procedures. Strategies to improve the IC process must, at a minimum, preserve or enhance human subject protections while, ideally, addressing barriers to making medical decisions about procedures.

Guidance from the FDA states "When obtaining informed consent, informed consent must be documented by a signed and dated written consent form except under two specific circumstances, as described in FDA's regulations at 21 CFR 56.109(c) (FDA, 201628) (21 CFR 50.27.) When written informed consent is required, the use of electronic, including digital,

signatures is permitted under FDA's regulations, provided it complies with applicable regulations" (FDA, 201629).

Within the bioethics literature, authors have defined the following elements as essential for IC: 1) competence, 2) disclosure, 3) understanding, 4) voluntariness, and 5) consent. In terms of regulatory requirements (45 CFR 46.116) 12, there are 8 required elements of IC and 6 provisional elements. Thirteen of 14 federally mandated elements are most accurately mapped to the ethical concept of disclosure, with the remaining element mapping to voluntariness. Assessment of competence and documentation of consent is also well-established elements of the existing IC process. Aside from requirements regarding the use of simplified language, federal regulations do not require specific mechanisms to facilitate or ensure patient understanding of clinical procedures.

FDA guidance stipulates that electronic consents be "trustworthy, reliable, and generally equivalent to handwritten signatures executed on paper when they capture the signature of the subject or the subject's LAR (e.g., an encrypted digital signature, electronic signature pad, voice print, and digital fingerprint). However, the FDA does not mandate a specific method of electronic signature. IRBs should consider applicable issues such as how the electronic signature is created if the signature can be shown to be legitimate and if the consent or permission document can be produced in hard copy for review by the subject upon request." (FDA, 2015).

Though the intent and format of the traditional consent process meet regulatory requirements, there remain important concerns about the quality of the IC process (Jefford & Moore, 2008). The current informed consent process involves two major elements: 1) the patient's review of the informed consent document, and 2) extensive discussion between the patient and the health care team (shared decision-making). To date, studies aimed at improving the informed consent process have focused primarily on the first element by enhancing the content, format, or delivery of the consent document. Examples include attempts to shorten consent forms (Davis et al., 1998), simplify language (Jefford & Moore, 2008), and incorporate audiovisual elements (Ryan, McLaughlin, & Hill, 2008), none of which have been shown to reliably improve the quality of informed consent. These findings have led some authors to suggest that the crux of the consent process lies in the second element – the conversation between patient and consent specialist. How this conversation unfolds, however, is highly variable and depends on consent specialist/patient attitudes, provider skill level, and time constraints, among others. In other healthcare settings, decision aids (paper-based or multimedia) have proved highly useful in facilitating these complex discussions by prompting patients to articulate and clarify their decision-related values, and by providing a framework to weigh the pros and cons of each option within the context of these clarified values (Stacey et al., 2011).

Electronic consent (EC) has taken a front seat in the world of e-health technology as it pertains to research and care and will possibly become standard practice in consenting study participants as well as patients. There are several theoretical advantages of EC over standard consenting methods, including the following:

- Improved education to study participants and patients
- Improved decision-making by participants and patients
- Better accrual rates
- Greater efficiency in consent delivery by clinical staff
- Waste reduction/cost savings
- Participation/patients staying in the study to a conclusion

Informing patients about oncology procedures, biobanks, and trials in a comprehensive but understandable fashion is both a challenge and an opportunity. A fundamental re-design of the informed consent process is needed, focused around three primary design principles:

- Patient-centeredness,
- Clinical practicality, and
- Regulatory compliance.

Based on these principles, I have identified an innovative EC platform that has the potential to become a treatment and research resource. If successful, transitioning to EC has the potential to reduce disparities in cancer patient decisions about medical procedures, improve understanding among patients, and increase the willingness of patients to consent to procedures.

Literature Review

Previous attempts to enrich the IC process through the use of audio-visual content have yielded mixed results. Only four studies met inclusion criteria for a recent Cochrane review on this subject, highlighting the relative paucity of data in this arena and underscoring the authors' call for further study. Similarly, incorporation of decision aids into the IC process for medical procedures has not been extensively studied.

Several comprehensive recent reviews suggest that electronic or interactive multimedia approaches generally lead to measurably better patient understanding and improved knowledge, as well as a statistically significant improvement in patient comprehension of impending treatment(s) relative to standard paper-based or consultation-only methods. Studies cited in this review validate that patient comprehension and willingness to undergo treatments are greatly enhanced through interactive audio-video based methodologies. Other recent studies have suggested that videos used during the consent process may

improve understanding of study procedures and that audio-visual interventions improve patient recall about healthcare procedures.

Mahnke et al. set out to determine the best way to improve the consent process by collecting data from a community perspective on computer-based consenting approaches. This study also evaluated whether or not participants were empowered to make informed decisions about participating in research. Regarding informed consent functionality, this study explored various aspects of design and format including readability levels, computer-based delivery, and comprehension (Mahnke et al, 2014).

The tool was consistently delivered, self-paced, and interactive for more detailed queries about the content. Research staff would answer participant questions at any point during the consent, supplemented the computer-based consent, or any technical support needs that might have occurred. The computer-based consent proved to be simple and understandable at low levels of literacy.

Although one of the primary aims of this study was to establish benefits of community involvement in designing informed consents, it also demonstrated support for movement away from paper-based consenting and toward computer-based methods by improved comprehension and retention.

In 2009, Bickmore, Pfeifer, and Paasche-Orlow conducted a study on a computerized consent method on low literacy subjects. Participants received the research consent form by the computer agent, which was then compared to a human and a self-study condition in a randomized trial. The subjects' responses to the consent tool were evaluated based on their level of health literacy (Bickmore and Paashe-Orlow, 2009).

The study found that subjects with higher health literacy scored higher on comprehension than other groups. Additionally, participants were most satisfied and most likely to sign the consent form when delivered by computer regardless of their literacy level. Participants stated that they preferred the computerized consent because it was self-paced, they felt more at ease about re-asking questions, and they didn't feel as insecure about their level of health literacy. The subtext here is that they didn't feel the sense of judgment that they would normally feel with the human-based consent process.

While the majority of the existing research favors a shift toward electronic consents, a few studies reveal mixed conclusions about the difference between standard consent and electronic consents on patient comprehension and decision-making. For example, Valenza et al. tested the efficacy of personalized informed consent generated through an electronic health record (EHR) and its impact on patient decision-making. The study evaluated 50 fifty

patients that were split into 2 groups. One (control) received the standard consent and the second received a "SmartConsent". The participants were evaluated after treatment based on demographics, decisional conflict, satisfaction, health literacy, and knowledge. The researchers concluded that, overall, there were no significant differences between the two methods of consent on decision-making and satisfaction. However, researchers also concluded that there was clear potential for electronic consents to enhance communication between the provider and patients (Valenza, 2014).

A 2014 study on an informed consent tool that was developed to address low literacy and ease of use in an area where a malaria treatment trial was being planned in Gambia. Olanrewaju et al. developed a multimedia informed consent tool that integrated video, animations, and audio narrations. Attempting to demonstrate increased comprehension, this study captured participant understanding by using a validated digitized audio questionnaire. Researchers found that 70% of their sample felt that the consent tool as "clear and easy to understand" as compared to the standard consent. Their high scores on comprehension of adverse events, voluntary participation, and study procedures supported the subjective responses of the participants. Furthermore, "participants expressed satisfaction with the tools and wanted future studies to adopt them" (Olanrewaju, 2014).

Researchers concluded that their newly developed consent tool was acceptable and easy to administer. Additionally, as compared to standard consent, the new tool proved effective in delivering and sustaining comprehension of study information. The results of this study showed a significant increase in recall and comprehension scores. The potential for practice effect was mitigated by the use of digitized close-ended questionnaires, multiple-choice and open-ended items that would prompt the truest measure of participant comprehension.

The major findings of this study, and arguably the most meaningful, were that the tool reliably delivered the same information to participants without variation in content or method. This is critical when considering staff changes, varying skill levels, language and other related barriers that might impede comprehension.

"However, the ultimate benefits of ensuring well-informed research participants through the use of multimedia intervention could, in addition to improving participants' comprehension, protect their freedom to decide, and also potentially improve the quality of data and outcome of the research" (Afolabi et al., 2014). The authors conclude that nothing can replace person-to-person interaction. Therefore, the overall effectiveness of the tool and satisfaction of the participant depends on a combination of technology and human interaction.

Public Health Significance

Each of the aforementioned studies evaluated a different technology or aspect that would impact the comprehension and retention of informed consent information. However, there is no current literature that explicitly explores the impact of a fully electronic consent application delivered via mobile technology for apheresis. Furthermore, there has been no study that addresses the utility of mobile devices in improving comprehension, retention, and decision-making as it pertains to cancer patients receiving apheresis. As some research has indicated, electronic consents can enhance communication between the provider and patients. However, the type of EC and platform upon which it is delivered is critical. The seamless integration of multiple communication aids into one device and proper organization of the content is where previous studies have fallen short in identifying a suitable replacement for SD.

In considering whether or not to pursue the development or implementation of an EC solution into a research or medical treatment setting, one has to establish a real need and clear expected outcomes. Informed consent is not just a signature line or arbitrary concept, it is a process of organizing and delivering complex information that can have severe impacts on a person's health. As such, informed consent information contains medical content, operative procedure descriptions, recovery explanations, risk warnings, treatment protocols, verbal discussions, and question/answer exchanges to verify understanding. This is a process, not just a signature or a box to be checked. This process is critical to the safety of patients and study participants as well as to the integrity of research and medical institutions.

While function and benefits were discussed in the previous sections, the aim here is to establish and distinguish the unique value of EC when comparing it to the standard documents or static digital forms. EC goes a step further than the standard document or static digital form by providing a browser-based algorithm that captures consent requirements, limitations, levels of comprehension, and retention thereby bridging the gap between a standard/static document and EC/dynamic interface.

The use of the term dynamic is intended to establish the feature advantages of EC, which is to empower patients and study participants to actively engage in an informed, comfortable and confident way. The central idea is to give patients and study participants a sense of control throughout the decision-making process as it relates to the course of their healthcare or study participation. EC is conceptually distinct as it addresses the modalities through which a participant's choice is enabled rather than just the use of mobile technology to capture a signature.

It is important to note that the EC process is not intended to replace patient-provider or participant-researcher interaction. Quite the opposite, the personal interaction is necessary to facilitate better healthcare delivery and improved public health outcomes. Furthermore, one of the goals of EC is to enhance patient confidence and participation in healthcare and research settings, which cannot be achieved independently from interaction with medical and research staff.

EC, in concept and utility, is intended to ensure that patients understand the full context of their healthcare or research participation decisions. As such, the methods used to capture informed consent can influence decision-making. For example, if consent is obtained at a hospital, patients may be biased by the sense of urgency of a scheduled procedure. Consequently, they could begin to simply check boxes or opt-out altogether to avoid the decisional anxiety. Another example can be found in how the inherent complexity of medical or technical information is conveyed may influence a patient's or study participant's ability to make an informed decision. These examples set the stage for situations where some individuals may defer the decision-making to those who appear to be in authority or opt-out entirely.

The use of EC has typically been met with a measure of resistance in medical procedures and clinical trial settings. The concern in these settings is establishing certainty around comprehension and retention of complex information. As such, conventional categories for EC have been primarily for browser-based studies and when sending bio-specimens via mail. However, as noted previously, there are advantages to using EC:

- Freedom to complete in any setting
- Reduced literacy and decisional anxiety
- Multimedia options lead to more engagement

Cost of Design and Implementation of EC Technology

In a medical or academic setting, the costs related to any project are often very limited in resources and time. As it pertains to software or application development, this can be particularly challenging, as most people aren't familiar with the process, costs, or in possession of the necessary technical expertise. Medical and academic institutions generally assign technical teams and dollars to specific projects based on daily operational needs. Exploratory or experimental technical project is generally not considered a high priority or likely to yield a high return on investment. This means resources for building a software application may need to be secured through some form of private investment, grant, or research funding.

The EC development project began as collaboration between physicians, project managers, and researchers at MD Anderson Cancer who recognized an opportunity to improve the

effectiveness and efficiency of the consent process in clinical trials as well as broader application to medical procedures.

The initial project was funded by a grant for approximately \$12,000.00. With this funding, the team was able to pay for the physicians' and researchers' time. Of course, this funding was quickly consumed by the effort to design content and technical requirements. However, this prepared the team to identify external partners to begin development discussions based on clear requirements. Requirements are critical for two reasons: 1) they ensure that you develop a product that meets the needs of your project and 2) ensures that the development team more accurately and efficiently produces the desired application.

The cost of software development will depend on how sophisticated the features are and the intended use of the application. This is an important consideration when defining what an application should and how the interface should function. Arguably, a static electronic form is cheaper and is commonly used. Essentially, it is a form that allows you to check boxes and sign it on a mobile device. A static electronic form replaces paper, reduces time and waste. However, it does nothing to enhance a patient or study participant's experience. In essence, a static form on an electronic device is the same as paper. That notion forms the underpinning for why developing a dynamic and interactive application would be more beneficial in a clinical setting. A dynamic form allows users to interact with the content. The task for the project team evolved into developing an application that achieved a few specific aims (enhancing comprehension, retention, lower anxiety) and ensuring that it possessed the necessary features to accomplish them.

As noted, the project team developed content around a clinical trial using validated scales and defined aims that were to be achieved by the application. While the project team had ample clinical and scientific experience, they were in deficit of software development experience. The other concern was that the original study that funded the project had closed and the funds were depleted. The project would not be able to proceed without additional funding.

The team began a search for companies and startups with expertise and willingness to engage with the team at no cost. This meant there needed to be the promise of a different acceptable currency. In this case, the alternative currency was the potential commercial expansion of a highly customized medical software application and/or publication credits. The project was fortunate to find [DrugDev](#). DrugDev provides sponsors, CROs, and sites with solutions that transform clinical research through collaboration, standardization and beautiful technology experience. DrugDev agreed to provide a customized prototype for use in clinical trials or medical procedures if the team would share the performance data and

credits for publication of research findings. During the engagement with DrugDev, the team learned that the following steps are critical to engagement with software developers:

1) *Defining Requirements*

The project team must have a defined list of requirements that establish what the final project should do for the intended users. This step is where the project team and developers engage in detailed discussions about the intended audience, intended use, appearance, outcomes, and desired features of the application. If there is no shell or prototype, information gathered during this step is when they are created.

2) *Design*

If there is no prototype, one is designed based on the requirements. If there is a prototype or shell, then the requirement is used to customize the functionality of the existing tool or application. This usually means a deeper focus on what the user interface and experience should be. That is, how will the application look and feel, how easy is it to use, and what will distinguish it from similar applications.

3) *Development and Testing*

Once the prototype has been created or refined, it must be programmed to function as intended. Once programmed, it must be tested to ensure that the coding follows the necessary protocols to deliver a seamless experience for the user. Testing happens by the programmers (alpha) then by a second external group (beta). Lastly, the project gets to test the application and validate that all of the requirements have been met and that the application functions as intended.

4) *Go-live/Launch*

If any issues are detected, the technical team will fix any coding issues and retest. Once all issues have been addressed and final tests have been completed, the application is loaded to encrypted servers and may available for use.

Generally, software development can be expensive depending on requirements and potential maintenance. On average one can expect to conservatively pay \$40,000 (see below cost table). A \$40,000 project is generally considered to be a small team (developer, designer, programmer) working for about 2 months. Keep in mind that this does not include the salary of the project team or account for sweat equity.

Table 1 Market Costs of EC Design

2018 Global Software Outsourcing Rates

Title of Full Time Employee (FTE)	United States	Latin America	Eastern Europe	Asia
Business Analyst	\$110-\$205	\$45-\$55	\$40-\$63	\$30-\$42
Architect	\$198-\$292	\$60-\$72	\$50-\$77	\$35-\$48
Project Manager	\$133-\$233	\$55-\$66	\$45-\$70	\$35-\$48
Jr. Developer	\$105-\$111	\$35-\$44	\$25-\$42	\$18-\$24
Mid-level Developer	\$132-\$140	\$30-\$52	\$35-\$56	\$24-\$35
Lead Developer	\$176-\$187	\$50-\$61	\$45-\$70	\$30-\$42
Sr. Developer	\$154-\$163	\$45-\$55	\$45-\$70	\$30-\$42
Junior QA	\$77-\$81	\$30-\$39	\$25-\$42	\$15-\$24
Mid-level QA	\$99-\$105	\$35-\$44	\$30-\$49	\$20-\$30
Senior QA	\$143-\$169	\$40-\$50	\$40-\$63	\$25-\$36
Graphic Designer	\$79-\$163	\$40-\$50	\$35-\$56	\$25-\$36

Source: (Diceus, 2019)

From a commercial industry standpoint, the challenge is convincing sponsor or grant lending entities that the return on investment (ROI) outweighs the initial burden and expense of implementing the new technology. This skepticism is shared by healthcare organizations that are reluctant about deploying IT resources to build their own EC tools. The same hesitation plagued many hospitals when they considered incorporating electronic health records into their operations. It is a challenge to justify the high upfront costs, additional training, maintenance, and extended start-up timelines required when the demonstrated benefits have not been substantially documented. The 2017 CRF Health study found that the clinical research professionals' perceptions about the high cost and

uncertain ROI have prevented many companies from becoming early adopters of EC, telehealth, and previously EMR solutions. (Sather, 2018)

Developers, clinicians, and researchers recognize that EC enables better engagement with study participants and patients through personalized portals where information may be individually tailored. Despite the known benefits of multimedia tools to enhance delivery of informed consent information, demonstrating the ROI of EC has been stymied by the limited available data. “While EC could save monitoring time, since documents are managed electronically, and there are potential savings if the tool can reduce protocol deviations, those types of benefits are difficult to quantify. Similarly, better patient comprehension of study requirements could help reduce participant drop-out rates, which could have a significant impact on study cost and data quality, but the cost associated with that outcome would be difficult to measure.” (Sather, 2018)

Investors remain recalcitrant because there is a lack of clear, standardized and comprehensive policies surrounding EC. Patients and clinicians use portals to access electronic health records, which establish a digital environment that integrates patient-related information and clinical study data. Simultaneously, this creates a natural space for EC to enable information to be conveyed in a digital environment with which the patient or study participant is already familiar.

Basic clinical appointments now involve preregistration. Future research studies could involve online registration or prescreening. Online EC enables study enrollment criteria to be compared with prospective study participant medical history based on the information they choose to provide. This suggests that prospective study subjects will be enabled to identify studies that are best suited to their interests or medical needs. Big data organizations, like IBM, have already begun to partner with large healthcare facilities to integrate medical records with EC to assist clinicians with determining which studies may best serve their patients and automatically allow them to consent remotely. This puts the power of the decision-making at the patient’s fingers as well as providing ample time to form questions or conduct online research. This level of early patient or study participant engagement promotes lower decisional anxiety, better comprehension, and comfort with the study or operative procedure.

From a research industry standpoint, EC has gained a lot of attention for use in clinical trials. It offers the potential to address patient recruitment and retention challenges that paper forms cannot. Keeping pace with the cultural evolution that moves in lockstep with technology means developing the necessary tools to securely capture the patient or study participant consent. Obtaining proper consent is critical regulatory compliance requirements, data integrity, human subject protection, and expenses. EC offers a way in

which the process can be presented so it decreases the risk of insufficient or unreliable consent.

While the movement has been slow among research groups as there remains a great deal of policy guidance and research community acceptance, there are several benefits as it relates to clinical and medical procedures as outlined below:

Table 2 Research Benefits of EC

Benefits	Description
Convenience	Complete the consent in a comfortable setting or in advance to arriving on site.
Access to more information	Multi-media/dynamic interfaces offer links to additional resources for informed decision-making.
Engagement	EC capture user questions that aid clinicians, researchers, and participants with getting questions answered.
Retention	Intuitive/interactive EC promotes participant compliance and retention through better comprehension.
Accrual	Enhanced convenience and understanding of what they're signing impacts enrollment rates.
Comprehension	By verifying that participants comprehend consent information through built-in knowledge tests, EC supports better information understanding.
Collaboration	EC makes it easy for sponsors, sites, and IRBs/IECs to work together efficiently.
Reach	The ability to consent participants remotely enables a wider participant base to be reached.
Costs	EC improves recruitment, reducing site consent time, and lowers the risk of litigation and related expenses,

While these benefits highlight some clear advantages, there are also some real precautions to be considered as both clinical trials and research are complex. Moreover, the nature, risks, and severity of different studies present unique challenges. The following are a few key considerations that, while EC may inherently address, must be anticipated and planned for:

- Data security -Verify that the EC system protects patients' private health information and be clear about whom ultimately is liable for security.

- Processes - Be clear and standardized about the protocol around how the EC will be administered as well as how training will be provided to research or medical staff.
- Inspection readiness - Have a clear process that allows access to the EC system if requested by the regulatory authorities during an inspection.

Ethical Consideration

“Informed consent (IC) is essential for the ethical conduct of research and medical treatment. The overarching goal of the IC process is to guarantee that the patient acquires a sound understanding of the purpose, risks, and methodology of a clinical trial and/or medical procedure.” (Abujarad et al., 2018) EC is seeking to facilitate this essential element of research through its adherence to Federal guidelines while simultaneously enhancing patient comprehension, retention, and decisional satisfaction. By extension, the desired outcomes include lower costs and reduced risks to patients and study participants. In regards to the expert consensus on EC, “the Joint Commission reported that, “among patients who sign an IC form, 44% do not understand the nature of the procedure to be performed, and 60-70% did not read or understand the information contained in the form. Thus, the Joint Commission urges reform given the poor potential of the IC process in achieving patient understanding.” (Abujarad et al., 2018)

Objectives

The primary objective of this study is to determine whether patients who receive the interactive electronic consent (IEC) have a better understanding of apheresis compared to those who receive the usual standard document (SD). There are two primary endpoints, each measured using the Quality of Informed Consent (QuIC) index at the time of their first randomization: their knowledge of the various facets of the procedure, including the purpose of treatment and their rights (Part A), and their understanding of the IC form (Part B). Secondary endpoints include the effect of EC vs. SD on decisional conflict, patient satisfaction, and anxiety, as well as preferences between the SD and electronic IC and whether participants who have the EC are more likely to have the procedure.

To achieve this objective, the specific aims of the study are:

- Aim 1) Obtain post-SD and post-EC comprehension, satisfaction, anxiety, and decisional uncertainty in patients who received SD and EC information.
- Aim 2) Compare post-survey and post-EC comprehension, satisfaction, anxiety, and decisional uncertainty in patients who received SD and EC information.

The primary hypotheses was that compared to the SD, the EC would: 1) improve treatment comprehension among participants currently or recently scheduled for apheresis; 2) reduce

decisional uncertainty among participants currently or recently scheduled for apheresis; 3) reduce anxiety, and 4) increase satisfaction.

METHODS

Walk-in apheresis donors were approached as they entered the apheresis clinic. Interested subjects then had a consent interview with the Research Nurse or Research Data Coordinator in a private area (i.e., patient education/consultation room). During this interview, those study subjects learned about the parameters of this study and were consented to participate. Subjects who agreed to participate signed a protocol-specific informed consent that did not include any consent information about the procedure and were randomized to Group A (SD) or Group B (EC).

For subjects who were randomized to the EC group, the visit began with the Research Nurse or Research Data and the subject reviewing how to navigate the EC modules using the iPad. Then, the subjects were left to review the apheresis informed consent material and complete the assessments on the iPad. After the assessments were completed, the EC subjects had the option of meeting with the clinician to discuss any questions or ambiguities they identified in the consent content. Subjects randomized to the SD arm met with the clinician to briefly discuss the apheresis process and were given the SD consent form. After reviewing the SD form, the subjects completed the assessment and engaged in standard discussions with the research nurse and clinician. The two groups received the same informed consent content, however group A received the SD only and Group B received an iPad with consent information.

Study Subjects

Those who chose to participate underwent simple randomization (Kim & Shin, 2014), given the small sample size. Group A was given the SD informed consent and Group B was provided with an iPad that was preloaded with informed consent modules. Demographic data was captured from surveys that included signatures, age, ethnicity, education level, and gender. All measured covariates were balanced by randomization. The following five standardized measures were assessed per participant (Quality of Informed Consent scale, Decisional Conflict scale, Decision Making Process Scale, and State-Trait Anxiety Inventory).

Eligibility criteria include:

- 1) Age \geq 18 years
- 2) Ability to speak, read and understand English
- 3) Apheresis donor at MD Anderson Cancer

MD Anderson Granted IRB Approval for this study per collection of survey responses from actual and potential apheresis donors. This study was considered low risk in that it did not expose patients to health risks. Furthermore, approval was granted because the risk to patient privacy was also very low. IRB included permission to collect patient demographics (age, race, gender, and education). All survey responses were captured and stored on secure servers. No participant identifiers were used or retained for this study.

STUDY DESIGN

Subjects were alternatively assigned to either the EC or SD arms. Demographic data was captured during the interview that included age, ethnicity, education level, and gender. Data on whether or not apheresis was collected was not collected because it is not needed for the evaluation.

The iPad was configured in presentation mode with the appropriate EC module. Group B subjects viewed the EC module in the clinic using the iPad. The EC modules contained no patient identifiers and no personal health information was stored on the iPad. After reviewing the EC module, the subjects engaged in standard discussions with the research nurse and treating physician.

Of note, the study did not include any explicit changes to the format, content, or structure of patient-clinician discussions. As discussed above, the patient-clinician discussion is of critical importance to the overall IC process. While this is an area to examine in future studies of EC, it was not an area of inquiry for the current study. Subject surveys were administered at the end of the consent process via the iPad. The device did not store any patient data to ensure privacy protection and HIPAA compliance. The data collected transferred automatically to encrypted servers.

EC

There was a short video on time required and how to navigate the EC, which was delivered by the clinical staff to EC arm.

Within the EC software, the patient/user intuitively controls the interface with functions including swipe-to-turn pages, interactive illustrations, and a clickable in-line glossary. Embedded videos allow for participants to hear about key features of the procedure directly from the physician. A notepad feature allows participants to save, print, or email questions to the research team. A unique “tell me more” feature allows participants to individually titrate the information stream by clicking on specific areas (e.g. “Tell me more about side effects” or “Tell me more about how the treatment works”). A productive collaboration

with the MD Anderson Office of Patient Education and feedback from our community oncology colleagues led to significant language and interface improvements.

MEASURES AND INSTRUMENTS

The following scales selected for this study have been standardized for use in the clinical trial and medical procedure settings. Although other scales, like the Deaconess Informed Consent Comprehension Test (DICCT), Brief Informed Consent Protocol (BICEP) Basic Investigator Questionnaire (BIQ), and the Modular Informed Consent Comprehension Assessment (MICCA), they weren't used as frequently in research which was considered as less trusted in studies pursuing similar aims. However, the scales selected for this study have shown good internal reliability and test-retest reliability (Stalmeier, et al., 2004). Surveys were administered to study participants as described above employing the following five standardized measures, each lasted approximately 20 minutes:

- Quality of Informed Consent scale (QuIC)
Comprehension was assessed using the validated Quality of Informed Consent (QuIC) scale. The QuIC is a valid and reliable questionnaire that is easy to use and designed to reduce researcher and subject biases. It's designed to measure actual (objective) and perceived (subjective) understanding of consent information (Joffe et al., 2001). It can also be used in the initial training of clinicians and study participants.

The QuIC scale consists of two parts: Part A assesses objective (or actual) understanding of the procedure and Part B assesses perceived (or subjective) understanding of the procedure. We developed a procedure-specific QuIC part A and use a standard QuIC part B. The QuIC scale has 10 items and yields two continuous scores, one for objective understanding and one for perceived understanding. (Appendix A.)

- Decisional Conflict Scale (DCS)
The DCS measures the degree of uncertainty of patient or research subject decision-making. The DCS measures 5 dimensions of decision-making across personal perceptions of:
 - a. Uncertainty in choosing options;
 - b. Modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; and
 - c. Effective decision making (in full version) such as feeling the choice is informed, values-based, likely to be implemented and expressing satisfaction with the choice.

This instrument was selected because studies validating it revealed that decisional conflict could be lowered with decision-supporting interventions (Kim & Shin, 2014). Information about options, benefits, risks, and side effects empowers patients and study subjects to make an informed decision.

This is a commonly used outcome measure in studies of patient decision aids, the 16-item DCS was adapted for the decision about participating (Garvelink, et al., 2019). The scale includes 5 subscales: Uncertainty subscale (feeling assured and clear about the choice), Informed subscale (feeling informed about the options, advantages, and disadvantages), Values Clarity subscale (importance of advantages and disadvantages), Supported subscale (having enough support, advice, and lack of pressure), and Effective Decision subscale (being satisfied with the decision and planning to follow through). (Appendix B.)

- Satisfaction with Decision Scale (SWD)
Patient satisfaction was measured using the ten-item Satisfaction with the Decision-Making Process Scale. The SWD scale measures satisfaction with health care decisions. This scale was selected because it has excellent reliability and validity (Holmes-Rovner, et al., 1996). The SWD scale captures satisfaction with the health care decision at the time when a decision has been made but the consequences have not yet occurred in medical treatment situations. The brief scale provides an efficient measure that can be easily used in healthcare settings to evaluate decision-assisting technologies or patient-provider interactions aimed at involving patients in decision-making. (Appendix C.)
- State-Trait Anxiety Inventory (STAI)
Anxiety levels were assessed using a 6-item short form of the State-Trait Anxiety Inventory (STAI). The STAI is the definitive instrument for measuring decisional anxiety in adults (Metzger, 1976). It distinguishes between a brief state of anxiety and the more chronic condition of "trait anxiety (depression)". The inventory's simplicity makes it ideal for evaluating individuals with various educational backgrounds. (Appendix D.)
- The utility, design, and acceptability of the EC were assessed via a purpose-designed questionnaire for post-EC participants only. This survey includes patients' ratings of the following: 1) ease of use/interface, 2) balance of the presentation related to the options of participating or not participating in the procedure, 3) clarity of the information presented, 4) length of the EC, 5) the amount of the information included in the EC, and 6) preference for traditional consent vs EC. (Appendix E.)

Note: If anxiety is detected or communicated by the patient, normal protocols will be followed. The study would be stopped, clinical staff would be alerted, and a nurse or physician would evaluate the patient.

Data Analysis

Scales, as described in the design section, were used based on the suitability for this study and alignment with federal requirements. Responses from both groups were captured in a secure server and downloaded to SAS 9.4 (SAS Institute, Cary NC). Both total group scores were summed, assigned an average score against which the groups were compared. Mean scores were compared using the two-sample t-test with a significance level of 0.05. The following describes the questionnaires and how they were calculated:

- Quality of Informed Consent (QuIC)
 - QuIC Part A (range 0 – 100, a high value indicates better understanding) had 18 questions. For each question, correct answers are assigned a score of 100 points, incorrect answers are assigned a score of 0 points, and "unsure" is assigned a score of 50 points. The final scores are obtained by averaging the scores of all completed questions.
 - QuIC Part B had 13 questions (range 0 -100, a high value indicates better understanding). The responses are first averaged to obtain raw average (range, 1-5), then final score = (raw average - 1)*25 (Joffe et al., 2001).
- Decisional Conflict Scale (DCS)
 - DCS had 16 questions (range 0 – 100, high value indicates high decisional conflict). The total score is obtained according to the User Manual:
 - 0 = “strongly agree”; 1 = “agree”, 2 = “neither agree nor disagree”, 3 = “disagree”; 4 = “strongly disagree”.
 - Sum scores of all 16 questions;
 - Divided by 16;
 - Multiplied by 25
- Ease of Use
 - EC survey had 8 questions
 - 4 = “Excellent”; 3 = “Very good”, 2 = “Good”, 1 = “Fair”; 0 = “Poor”.
 - Sum scores of all 8 questions;
 - Divided by 8;
 - Multiplied by 25

- Satisfaction with Decision Survey
 - 6 questions (range 0 – 100, high value indicates high satisfaction)
 - 4 = “strongly agree”; 3 = “agree”, 2 = “neither agree nor disagree”, 1 = “disagree”; 0 = “strongly disagree”.
 - Sum scores of all 6 questions;
 - Divided by 6;
 - Multiplied by 25
- State-Trait Anxiety Inventory (STAI)
 - 17 questions. To calculate the total STAI score (range 20 – 80, a high value indicates high anxiety):
 - Reverse scoring of the positive items so that 1=7, 2=6, 3=5, 4=5, 5=3, 6=2 and 7=1;
 - Rescale the score by multiply 4/7 so that the scale of the study, 1-7 becomes the standard 1-4;
 - Sum all 17 scores;
 - Multiple total scores by 20/17.

To analyze the results of our experiment, we used two sided, two-sample t-tests with a significance level of $\alpha=0.05$. All computations were performed using SAS 9.4 (SAS Institute, Cary NC).

RESULTS

Other studies have shown that “females have higher donation rates than males among African Americans and Hispanics. For whites, the blood donation rate for males exceeds females beginning at age 30” (Shaz et al., 2011). Additionally, these studies have reveal that ethnic minorities are underrepresented in blood donation.

In the study, there were a larger number of non-white female subjects with college degrees among the study participants. Further analysis may be needed to determine to what extent these demographic characteristics may have influenced the responses to survey questions.

Table 3 Subject Demographics

Variable	Value	#(% of n)	n(% of N)	SD	EC
Gender	Female	38 (66)		17	21
	Male	20 (34)	58 (100)	10	10
Education	Associate degree	6 (10)		4	2
	Bachelor degree	23 (40)		16	17
	Graduate degree	3 (5.2)		2	1
	High school degree or equivalent	11 (19)		6	5
	Less than a high school degree	5 (8.6)		2	3
	Some college but no degree	10 (17)	58 (100)	5	5
Race	Asian	4 (6.9)		2	2
	Black or African-American	13 (22)		6	7
	From multiple races	4 (6.9)		1	3
	Latino/Latina	14 (24)		7	7
	White	23 (40)	58 (100)	13	10
Age	25 to 34	18 (31)		9	9
	35 to 44	24 (41)		14	10
	45 to 54	5 (8.6)		2	3
	55 to 64	11 (19)	58 (100)	5	6
Group	Electronic consent	28 (48)	58 (100)		28
	Standard document	30 (52)		30	

Table 3 illustrates the subject demographics for the study. Although the larger proportions of the population were female, white, college-educated, and between the ages of 35 and 44, it is not immediately clear what impact that had on their responses to the surveys.

Table 4 Summary of Survey Scores

Variable	N	Mean \pm SD	25/50/75 Percentile
STAI_score	58	37.2 \pm 13.5	26.7/38/48.6
QuIC A_score	58	67.3 \pm 10.3	60.4/66.7/75
QuIC B_score	58	69 \pm 23	49.5/69.2/90.9
DCS_score	58	34.7 \pm 23.5	19.1/27.3/57.8
SWD_score	58	60.4 \pm 26.9	37.5/68.8/75
iPad_score	28	77.8 \pm 21.4	53.9/78.1/100

For STAI, subjects who score 20 to 40 fall within normal or tolerable limits, 40 to 60 represent mild problems, and 60 to 80 are severe. As shown in Table 4, the subjects from this study average 37.2, which is normal or tolerable.

The QuIC scoring was based on a 0-100 scale. Ideally, patients scoring higher or closer to 100 reflected a higher Comprehension and understanding of the informed consent content. The average score was 67.3 meaning the subjects had an acceptable level of Comprehension and understanding.

The DCS scoring was also based on a 0-100 scale. In this, it would ideal for the subjects to score closer to 0. This would indicate lower decisional conflict or greater comfort with the decision to participate in a given study or procedure. The average score was 34.7, which represents low decisional conflict.

The Satisfaction scoring was based on a 0-100 scale. Ideally, patients scoring higher or closer to 100 reflected a higher satisfaction with the consent process. The average score was 60.4 meaning the subjects had an acceptable level of satisfaction with the informed consent process.

The EC survey was a subjective questionnaire to determine how easy the app was for the EC group to use and provide insight into what improvement might need to be made. Ideally, a higher score from 0-100 would subject the device and the app performed well. This group scored an average of 77.8, which suggests that the device and app performed well.

Table 5 Comparisons of the 5 scores

	Standard Document			Electronic Consent			
Variable	N	Mean \pm SD	25/50/75 Percentile	N	Mean \pm SD	25/50/75 Percentile	P
STAI_score	30	40.6 \pm 13	28.2/45.4/51.8	28	33.5 \pm 13.3	23.9/30.3/40.8	.039
QuIC (A)_score	30	62.1 \pm 8.8	54.9/63.9/69.4	28	72.8 \pm 8.99	66.7/72.2/77.8	<.0001
QuIC (B)_score	30	54.7 \pm 18.8	39.9/51.9/69.2	28	84.2 \pm 16.6	71.6/88.5/100	<.0001
DCS_score	30	47.3 \pm 20.7	27.7/53.9/63.3	28	21.2 \pm 18.3	2.34/25/26.6	<.0001
SWD_score	30	50 \pm 22	29.2/41.7/70.8	28	71.4 \pm 27.6	67.7/75/97.9	.001

Table 5 illustrates that the EC group outperformed the SD group in each survey, which suggests that there is a significant benefit to the patient when using the electronic consent. P values computed with a t-test.

Table 6 Pearson Correlation Coefficients

	STAI_score	QuIC A_score	QuIC B_score	DCS_score
QuICA_score	-0.39 0.0025			
QuICB_score	-0.38 0.0033			
DCS_score	0.40 0.0017	-0.70 <.0001	-0.86 <.0001	
SWD_score	-0.43 0.0007	0.43 0.0008	0.57 <.0001	

The first number of each cell is the Pearson correlation coefficient and the second number is the p-value. For example, the correlation between the STAI score and QuIC (A) score is -0.39.

Table 6 indicates that the 5 instruments were highly correlated. The following highlights the specific correlations:

- High anxiety score was associated with a worse understanding of consent (Pearson = -0.39 and -0.38 to QuIC Part A and B. The p-values were 0.0025 and 0.0033 respectively), high decisional conflict (Pearson = 0.40. The p-value was 0.0017) and the low satisfaction score (Pearson = -0.43. The p-value was 0.0007) (See the first row of **Error! Reference source not found.**).

- Poor understanding of consent was associated with high decisional conflict and low satisfaction scores (See the second row of **Error! Reference source not found.**).
- The high decisional conflict was associated with a low satisfaction score (See the third row of **Error! Reference source not found.**).

DISCUSSION

Informed consent for public health research participants can be complicated by comprehension, anxiety and decision-making issues. Uncertainty around the risks or aspects of complications and recovery also fuel confusion or hesitation in decision-making. The complexity of informed consent information and, in some cases, the conditions under which it's presented can interfere with the comprehension and retention needed to make informed decisions. These concerns are common in public health research settings and have to be accounted for when planning a study. As previously described, the EC solution aims to mitigate these types of concerns. In the public health context, the application specifically targets reducing the likelihood that the informed consent process results in a decision that negatively impacts the study participant or the research. The following are common perceptions of study participants about informed consents:

- Time-consuming and cumbersome – While the EC cannot alone promise to eliminate this concern, it was designed to be flexible. The value of its flexible design is that it can be altered or customized based on the nature of the research or operative procedure so that it provides a tailored experience for each setting.
- Content is too complex or hard to read – Literacy levels vary across various demographics. As such, the literacy level for the targeted community must be considered during the design phase, as does the prevailing spoken language. Using the standard document approach can make printing, revising, filing, and retrieving documents costly. EC virtually eliminates this as a concern and allows language conversation to happen more easily.
- The study setting was suboptimal – When utilizing a standard document consent, it is common for there to be a lengthy discussion between the participant and someone from the research team. This requires a suitable space and lots of time. That dynamic is often costly in time, staff resources, and space. The EC is designed with interfaces that respond to likely questions and store others to reduce the time both a room and a researcher may be needed.

- Couldn't relate to the content – The nature of static or standard documents is that you must read it in a manner in which it is provided. Unfortunately, not everyone learns the same way or relates to information in the same manner. The EC addresses this by incorporating multimedia tools with educational material to present the information in a more engaging and accessible fashion. “Multimedia education use has shown promise among physical and behavioral health patients with increased understanding, comprehension and interest towards treatment and care.” (Bennett, Aronson, Guarino, Bania, & Marsch, 2016)

Similar to research, hospitals can also benefit from EC. Specifically, hospitals can see improved patient safety, patient satisfaction, and quality of care. As noted above, medical settings must keep pace with patients that have more sophisticated expectations as a result of access to vast amounts of information from the internet. They expect faster and larger amounts of information about the diagnosis they receive and procedures for which they are prescribed. Moreover, patient and research study participants are entitled to fully understand what they can expect following any treatment regime, recovery experience, or lifestyle changes they may have to make.

Hospitals may also experience administrative benefits when incorporating EC into their operations. Specifically, they may see:

- Improved Informed Consent Management - EC offers digital signature capture to ensure the validity of the consent documents.
- Reduced Transcription Time and Errors – Paper handling, filing, and storing is virtually eliminated when the documents are digitized.
- Greater Regulatory Compliance - The use of EC applications enables greater compliance with Federal, state regulators and other requirements.

As mentioned in the literature review section, previous studies to evaluate and improve the informed consent process yielded mixed results. Each fell short in determining what specific modalities and in what combination would successfully improve informed consent. Beyond the interactive features to deliver the research or medical consent information, the challenge was establishing a relationship between how it was delivered and comprehension. While the previous studies suggest there were greater benefits to using electronic mechanisms to deliver informed consent, they failed to establish that it would lead to better patient understanding, retention, and satisfaction.

The survey results of this study revealed that the EC group had significantly less anxiety (STAI score), a higher understanding of the consent (QuIC Part A and Part B), less decisional conflict (DCS score) and higher satisfaction (Satisfy score) (see Table 3). These findings ultimately support the study hypothesis that the EC had improved understanding and retention, reduced decisional uncertainty, lowered anxiety, and yielded greater satisfaction.

CONCLUSION

The chief finding is that the SD and EC groups differed in a statistically significant way in all of their responses to the surveys. The study also found a high degree of correlation between the instruments.

The response returned "significant" ($p < 0.05$) values between SD and EC groups, which suggest that this difference is primarily attributable to the format employed to deliver the content. Specifically, the EC group performed better on each instrument. It is not clear if demographics played a role in responses to the survey, that determination would require a follow-up study with a larger sample.

Conventional standardized consent forms have significant deficiencies and errors. The new system of electronic informed consent is easy to deliver, legible and understandable. Furthermore, it assists researchers as well as providers with fully informing patients about the treatment, risks, benefits and alternative therapies, thereby supporting ethical and legal standards, and improving the quality of care. Standardized electronic informed consent should be the new standard of care.

APPENDICES

Appendix A: Quality of Informed Consent

APPENDIX: QUALITY OF INFORMED CONSENT (QuIC), PART A

INSTRUCTIONS: Below you will find several statements about cancer clinical trials (otherwise known as cancer research studies). Thinking about your clinical trial, please read each statement carefully. Then tell us whether you agree with the statement, you disagree with the statement, or you are unsure about the statement by circling the appropriate response. Please respond to each statement as best you can. We are interested in your opinions.

A1.	When I signed the consent form for my current cancer therapy, I knew that I was agreeing to participate in a clinical trial.	Disagree ₁	Unsure ₂	Agree ₃ [*]
A2.	The main reason cancer clinical trials are done is to improve the treatment of <u>future</u> cancer patients.	Disagree ₁	Unsure ₂	Agree ₃ [*]
A3.	I have been informed how long my participation in this clinical trial is likely to last.	Disagree ₁	Unsure ₂	Agree ₃ [*]
A4.	All the treatments and procedures in my clinical trial are standard for my type of cancer.	Disagree ₁ [*]	Unsure ₂	Agree ₃
A5.	In my clinical trial, one of the researchers' major purposes is to compare the effects (good and bad) of two or more different ways of treating patients with my type of cancer, in order to see which is better. [†]	Disagree ₁	Unsure ₂	Agree ₃ [*]
A6.	In my clinical trial, one of the researchers' major purposes is to test the safety of a new drug or treatment. [‡]	Disagree ₁	Unsure ₂	Agree ₃ [*]
A7.	In my clinical trial, one of the researchers' major purposes is to find the highest dose of a new drug or treatment that can be given without causing severe side effects. [‡]	Disagree ₁	Unsure ₂	Agree ₃ [*]

A8.	In my clinical trial, one of the researchers' major purposes is to find out what effects (good and bad) a new treatment has on me and my cancer. [§]	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A9.	The treatment being researched in my clinical trial has been proven to be the best treatment for my type of cancer.	Disagree ₁ ⁺	Unsure ₂	Agree ₃
A10.	In my clinical trial, each group of patients receives a higher dose of the treatment than the group before, until some patients have serious side effects.	Disagree ₁ ^{**}	Unsure ₂	Agree ₃ ^{††}
A11.	After I agreed to participate in my clinical trial, my treatment was chosen randomly (by chance) from two or more possibilities.	Disagree ₁ ^{‡‡}	Unsure ₂	Agree ₃ ^{§§}
A12.	Compared with standard treatments for my type of cancer, my clinical trial does not carry any additional risks or discomforts.	Disagree ₁ ⁺	Unsure ₂	Agree ₃
A13.	There may <u>not</u> be direct medical benefit to me from my participation in this clinical trial.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A14.	By participating in this clinical trial, I am helping the researchers learn information that may benefit future cancer patients.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A15.	Because I am participating in a clinical trial, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could review my medical records.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A16.	My doctors did not offer me any alternatives besides treatment in this clinical trial.	Disagree ₁ ⁺	Unsure ₂	Agree ₃
A17.	The consent form I signed describes who will pay for treatment if I am injured or become ill as a result of participation in this clinical trial.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A18.	The consent form I signed lists the name of the person (or persons) whom I should contact if I have any questions or concerns about the clinical trial.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A19.	If I had not wanted to participate in this clinical trial, I could have declined to sign the consent form.	Disagree ₁	Unsure ₂	Agree ₃ ⁺
A20.	I will have to remain in the clinical trial even if I decide someday that I want to withdraw.	Disagree ₁ ⁺	Unsure ₂	Agree ₃

* Correct answer

† Scored for phase III subjects only

‡ Scored for phase I subjects only

§ Scored for phase II subjects only

** Correct answer for patients on phase II and III trials

†† Correct answer for patients on phase I trials

‡‡ Correct answer for patients on phase I and II trials

§§ Correct answer for patients on phase III trials

APPENDIX: QUALITY OF INFORMED CONSENT (QuIC), PART B

When you signed the consent form to participate in your clinical trial, how well did you understand the following aspects of your clinical trial? *If you didn't understand the item at all, please circle 1. If you understood it very well, please circle 5. If you understand it somewhat, please circle a number between 1 and 5.*

		I Didn't Understand This at All	⇒	I Understood This Very Well	
B1.	The fact that your treatment involves research	1	2	3	4 5
B2.	What the researchers are trying to find out in the clinical trial	1	2	3	4 5
B3.	How long you will be in the clinical trial	1	2	3	4 5
B4.	The treatments and procedures you will undergo	1	2	3	4 5
B5.	Which of these treatments and procedures are experimental	1	2	3	4 5
B6.	The possible risks and discomforts of participating in the clinical trial	1	2	3	4 5
B7.	The possible benefits <u>to you</u> of participating in the clinical trial	1	2	3	4 5
B8.	How your participation in this clinical trial may benefit <u>future patients</u>	1	2	3	4 5
B9.	The alternatives to participation in the clinical trial	1	2	3	4 5
B10.	The effect of the clinical trial on the confidentiality of your medical records	1	2	3	4 5
B11.	Who will pay for treatment if you are injured or become ill because of participation in this clinical trial	1	2	3	4 5
B12.	Whom you should contact if you have questions or concerns about the clinical trial	1	2	3	4 5
B13.	The fact that participation in the clinical trial is voluntary	1	2	3	4 5
B14.	Overall, how well did you understand your clinical trial when you signed the <u>consent form</u> ?	1	2	3	4 5

Appendix B: Decisional Conflict Scale

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
	[0]	[1]	[2]	[3]	[4]
1. I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I am clear about which risks and side effects matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Total DCS score incorporates all 16 items. Uncertainty subscale is derived from items 10-12. Perceived efficacy subscale is derived from items 13-16.

Appendix C: Satisfaction with Decision Scale

You have been considering whether to consult your health care provider about hormone-replacement therapy. Answer the following questions about your decision. Please indicate to what extent each statement is true for you AT THIS TIME.

Use the following scale to answer the questions.

1 = strongly disagree

2 = disagree

3 = neither agree nor disagree

4 = agree

5 = strongly agree

- () I am satisfied that I am adequately informed about the issues important to my decision.
- () The decision I made was the best decision possible for me personally.
- () I am satisfied that my decision was consistent with my values.
- () I expect to successfully carry out (or continue to carry out) the decision I made.
- () I am satisfied that this was my decision to make.
- () I am satisfied with my decision.

Appendix D: State-Trait Anxiety Inventory (STAI)

	Not at all	Somewhat	Moderately	Very much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Appendix E: Utility, Design and Acceptability Questionnaire

iPad Utility, Design, and Acceptability Questionnaire

1. The quality of the VIDEO was...
Poor Fair Good Very Good Excellent
2. The quality of the SOUND was...
Poor Fair Good Very Good Excellent
3. The quality of the information/training was...
Poor Fair Good Very Good Excellent
4. My comfort with using the device was...
Poor Fair Good Very Good Excellent
5. The ease of moving through the content was...
Poor Fair Good Very Good Excellent
6. The ease of reading the content was...
Poor Fair Good Very Good Excellent
7. The ease of holding and interacting with the application and device was...
Poor Fair Good Very Good Excellent
8. The explanation of how to use the device/application was...
Poor Fair Good Very Good Excellent

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