Published in final edited form as:

Comput Inform Nurs. 2017 November ; 35(11): 556–564. doi:10.1097/CIN.0000000000000356.

User-centered Design, Experience, and Usability of an e-Consent User Interface to Facilitate Informed Decision Making in an HIV Clinic

S. Raquel Ramos, PhD, MSN, MBA, FNP-BC

Postdoctoral Fellow, Yale University School of Nursing, 400 West Campus Drive, West Haven, Connecticut, USA

Abstract

Health information exchange is the electronic accessibility and transferability of patient medical records across various health care settings and providers. In some states, patients have to formally give consent to allow their medical records to be electronically shared.

The purpose of this study was to apply a novel user-centered, multi-step, multi-framework approach to design and test an electronic consent user interface, so patients with HIV can make more informed decisions about electronically sharing their health information.

This study consisted of two steps. Step one was a cross-sectional, descriptive, qualitative study that employed user-centric design interviews to create the user interface. This informed step two. Step two consisted of a one group post-test to examine perceptions of usefulness, ease of use, preference and comprehension of a health information exchange electronic consent user interface.

More than half of the study population had college experience, but challenges remained with overall comprehension regarding consent. The user interface was not independently successful, suggesting that in addition to an electronic consent user interface, human interaction may also be necessary to address the complexities associated with consenting to electronically share health information.

Comprehension is a key factor in the ability to make informed decisions.

Keywords

health information exchange; informatics; HIV; user interface; user-centered design; user experience

Introduction

User-centered design is an interactive and iterative process that incorporates end-user feedback to facilitate tailored, usable interfaces, products, or systems^{1,2}. End-users are

*Corresponding Author: S. Raquel Ramos, Raquel.ramos@yale.edu, Telephone: 203-737-2312 Fax: 203-785-3554.

Disclosures

The author reports no real or perceived vested interests that relate to this article that could be construed as a conflict of interest.

individuals who will be the actual users and benefiter of this design process and its impact on product outcomes¹. User-centered design should result in products that are intuitive, intelligible, and not cumbersome^{1,3}. Moreover, user-centered design methodologies are advantageous on a variety of influential levels. This design methodology has the potential to inform recommendations at state and national levels about the benefits of integrating stepwise, iterative, user-centric procedures in areas such as healthcare, industry, and academia.

In this study, a user-centered design approach was used to create an electronic consent (e-Consent) user interface (UI) that would inform persons living with HIV (PLWH) about the risks and benefits of electronically sharing their personal medical records via a health information exchange (HIE). Health information exchange facilitates the electronic access and sharing of an individual's medical records between HIE participating providers and organizations⁴. In the United States, there are no standardized processes for consenting to electronically share medical records, as some states automatically share and others require an individual to formally sign a consent.

In general, consent forms and other medical communications are written by medical experts or attorneys. Without medical or legal expertise, patients have been chronically misinformed as to the purpose, risks, benefits and procedures described on consent forms⁵. Most consent documents are worded for individuals with post-high school reading levels and are written in complex legal language. This is neither helpful nor applicable to populations with varying levels of literacy⁶, since the information is not meaningful or actionable.

In contrast, user-centered design engages intended users in the design process. A user-centered design approach⁷ was selected to facilitate comprehension of the risks and benefits of consenting to HIE using interactive tools to improve decision making ability⁵. Findings from phase one of this study published elsewhere⁸ suggested that there was: (1) limited understanding about HIE, (2) an inability to distinguish HIE from the Health Insurance Portability and Accountability Act (HIPAA)⁹, and (3) fragmented clinical workflow that prevented HIE consent from being discussed and obtained.

To address these findings, an e-Consent UI was designed and tested with patients at an HIV clinic in New York City. The purpose of this study was to apply a novel user-centered, multistep, multi-framework approach to design and test the usefulness, ease of use, preference, and comprehension of an HIE e-Consent UI.

Overview

Step one of this study was a cross-sectional, descriptive, qualitative study that employed semi-structured interviews to determine which icons and simple text phrases best described features important to HIE consent. Icon examples using health-related clip art and simple text about HIE were presented to participants. Their feedback informed the iterative design of a UI. Step two of this study consisted of a one group post-test design to examine PLWH's perceptions of the usefulness, ease of use, and preferences regarding a UI when compared to the clinic's paper consent form. We did not conduct a pre-test examination, as findings from

the previous work described the low variability of pretest knowledge among clinic patients about the risks and benefits of HIE ⁸.

Design

Setting

This study was conducted at an urban, academic, hospital-based clinic in New York City. The clinic provides HIV care to patients receiving federal and state medical coverage.

Sample

The study sample consisted of 25 participants, five of whom participated in icon selection and 20 of whom participated in e-Consent UI testing. Inclusion criteria for participants were: (1) receiving care at the HIV clinic, (2) English-language literate, and (3) willingness to participate. For the purposes of this study, English-language literacy referred to the ability to read words with three syllables and sentences with at least 10 words ⁶. The ability to read this study's informed consent and agree to participate demonstrated an appropriate level of literacy to participate. Exclusion criteria were: (1) severe visual impairment, (2) cognitive impairment, and (3) inability to read or communicate in English.

Recruitment

Prior to initiation of study procedures, institutional review board approval was obtained through Columbia University Medical Center. Multiple strategies were used to recruit participants. First, flyers containing study information and a contact number were posted in the clinic waiting room. Interested prospective participants contacted the study's confidential voicemail system and the researcher returned their calls. Second, the researcher recruited patients directly from the clinic's common area. Third, study participants informed other clinic patients about the study (snowball sampling).

Methods – Step One

Data collection

In step one, five semi-structured interviews that lasted no more than 60 minutes were completed with the clinic patients. Because previous research suggested that there was no baseline knowledge of HIE or HIE-related concepts ⁸, a small sample was used. The interviews concentrated on icon selection and simplified text headings to represent the concepts of electronic sharing via HIE. Simplified text headings refer to wording with fewer than three syllables and sentences with no more than 10 words ⁶.

During the interviews, participants were presented with an e-Consent UI icon prototype. Each icon heading had four examples for each consent topic and was used to stimulate discussion. Icons were selected by the researcher after viewing recommended clip art links on the Sage Bionetworks Web site ^{10,11}. Icons were selected from clip art to represent concepts related to HIE (Figure 1). Icons selected were matched with simplified text headings (e.g., "What is HIE?" or "How is my information protected?") to ascertain whether the icon and simplified text headings were comprehensible and clearly walked patients

through the risks and benefits of HIE consent using the same concepts as the currently used paper consent.

Simplified text headings were structured according to the U.S. Department of Health and Human Services (DHHS) and the Office of the National Coordinator (ONC) eConsent Video Trial Project¹². The DHHS/ONC study presented a narrative in video format as educational material about HIE. After every screen's title was presented (e.g., "What is HIE?"), the narrative would define the topic¹². In the DHHS/ONC study, it meant defining HIE. All scripts used for the topic narratives were reviewed for readability by the ONC, the Office of General Counsel, and the Office for Civil Rights prior to DHHS approval¹². With the intent of improving consistency in language and incorporating the necessary legal clauses, this resulted in unintended higher readability levels¹².

In step one of this study, only the headings and simplified text were used for the e-Consent UI prototype to decrease reading complexity and cognitive burden of presented concepts. Participants were asked to select icons that best represented a set of questions and to describe their rationale for the selection. The questions were as follows:

- What is HIE?
- What health information can be accessed?
- Who can access my information?
- How is my information protected?
- What are my choices for consent?

All interview data were audio recorded and subsequently de-identified. The selected icons were documented, and once analyzed, they were included on the UI.

Analysis

In step one, five icon-selection interviews were transcribed by the researcher, and the responses to the chosen icons were noted. Select quotes regarding the rationale for choosing a specific icon or ideas about a similar topic were documented. These data were also used to provide context on how to improve the design of the UI.

Results Step One

Four iterations of the e-Consent UI prototype were created with the icons selected from the participant interviews. All UI prototypes were created using Microsoft PowerPoint (Microsoft, Redmond, WA) to simulate application functionality. An informatics expert in UI design was consulted for all prototype iterations and revisions. The final e-Consent included 16 screens, a five-icon home page, and highlighted icons with simplified text headings that guided the user (Figure 2).

Methods - Step Two

Approach

Two approaches guided the study. The first approach was Wilbanks' three-layered stacked approach^{13,14}. The second approach was Mayer's Multimedia Principles¹⁵. Lastly, UI heuristics were assessed¹⁶.

Wilbanks' three-layered stacked approach to electronic application (app) design consists of: (1) visual animations and icons that convey important elements, (2) simplified text headings designed to easily describe information, and (3) an electronically generated document as a PDF file^{13,14}. Wilbanks and colleagues used the three-layered stacked approach to design electronic apps with an e-Consent feature for those with chronic illnesses, such as Parkinson's disease, diabetes, and asthma¹⁴. Once consented via the e-Consent, individuals were able to track their symptoms, report new symptoms, and access resources regarding their health¹⁴.

The second approach was Mayer's Multimedia Principles¹⁵, and five of the 12 principles were utilized in this study. The principles included were: (1) coherence, (2) signaling, (3) spatial contiguity, (4) multimedia, and (5) personalization¹⁵.

The coherence principle refers to the omission of extraneous words and information, which may act as a barrier to information delivery¹⁵. Signaling utilizes cues to highlight information that inform the user as to the organization of the material, such as the icons used in the UI¹⁵. In this study, this was demonstrated by participants that used icons referring to simplified text headings and described the risks and benefits of electronic sharing via HIE. Spatial contiguity referred to the close alignment between icons and text¹⁵.

In general, multimedia utilizes more than one medium for learning, such as pictures and text, instead of relying on solely one method¹⁵. This study is novel and innovative because it utilized both. Finally, personalization refers to presenting words in an informal, lay format that reduces the complexity of formally worded information¹⁵.

Additionally, a heuristic assessment was conducted on the e-Consent UI. In this study, the heuristics consisted of assessing the e-Consent UI for: (1) simple dialogue, (2) end-user language, (3) minimal cognitive effort, (4) consistent wording, (5) and a home page navigation icon¹⁶. A heuristic decreases decision-making time and permits individuals to continue working through a task without much cognitive effort¹⁷. It can be thought of as a mental shortcut.

Recognition, a form of memory retrieval, allows individuals to navigate familiar information with the assistance or cues to respond to an answer or to make a decision¹⁸. Thus, a recognition heuristic refers to the ability to make quick and efficient decisions using low cognitive effort by making inferences based on partial recognition¹⁷. For instance when designing the e-Consent UI, a recognition heuristic supported ease of use and usability through navigation of highlighted icons and visible user functions, such as 'home page' and 'next' buttons.

Procedures – Step Two

Step two participants (n = 20) (Table 1) were randomly assigned to complete either the UI or paper consent first. This was done using a random number generator. Participants then switched to the alternate consent format not initially assigned.

The e-Consent UI is an interactive app composed of a home screen with five icons that led to simplified text headings describing the risks and benefits of consenting to electronically share via HIE. The e-Consent UI was designed to facilitate a better understanding of HIE through the use of icons, colored backgrounds, simple wording, and on a touch screen tablet. This was intended to guide the user step-by-step using multiple visual formats^{13–15,19}.

Each visit took approximately 30 minutes to complete, and participants were given a \$30 gift card for their time. As in a previous study, all participants completed a demographic survey that included information on age, gender, race, ethnicity, duration of living with HIV, and usage and comfort using the Internet²⁰. Once participants completed both the e-Consent UI and the paper consent form, a 4-item Likert-scale survey (strongly agree to strongly disagree) was completed. The Technology Acceptance Model (TAM)²¹ guided the creation of the following four survey items: (1) the icons let me know what content would be displayed when I clicked them, (2) the text under each icon was easy to understand, (3) the icons and simple text prepared me to read the HIE consent document, and (4) the electronic HIE consent app was easy to use.

Lastly after participants completed reading the paper consent and the UI, semi-structured interviews were conducted to assess comprehension of HIE concepts. The open-ended questions explored the following areas: (1) comprehension of HIE by defining it in their own words, (2) perceptions about the paper version in comparison to the e-Consent UI, and (3) preferred format.

Analysis – Step Two

Quantitative analysis

Data were processed using IBM SPSS Statistics version 23 (IBM, Armonk, NY). Sample characteristics were summarized using descriptive statistics (proportions, means, and standard deviations), and the Likert-scale data was analyzed for frequencies. From the qualitative interview data, the proportions of consent format (paper or UI) preference among the participants were calculated.

Qualitative analysis

Semi-structured interviews were audio recorded and transcribed. A thematic analysis was used for all 20 interviews to assess if the clinic participants were able to better comprehend the risks and benefits of HIE and why a particular format (paper or UI) was preferred. The TAM²¹, which guided the Likert-scale items, also guided the open-ended questions for participant responses on ‘perceived usefulness’ and ‘ease of use’ regarding the UI (Figure 3). It was also important to capture the number of participants who were able to articulate the components of HIE (e.g., electronic access, all protected health information being

shared, different from HIPAA). Themes or ideas about a similar topic that provided context on how to improve the design of the user interface were also categorized and noted in the researcher notes.

Results Step Two

Table 1

Participant characteristics – Step Two

Characteristics (N=20)	n	%
Gender		
Male	15	75
Female	5	25
Nativity Status		
U.S. born	15	75
Non U.S. born	5	25
Ethnicity		
Non-Hispanic	12	60
Hispanic/Latino	8	40
Race		
White	3	15
African American	11	55
Multi-racial	1	5
Other	5	25
Sexual Orientation		
Heterosexual	9	45
Bisexual	2	10
Gay or Lesbian	8	40
Unsure	1	5
Education		
Some high school no diploma	4	20
High school diploma/GED	2	10
Some college/no degree	3	15
Trade/vocational school	1	5
Associate degree	3	15
Bachelor degree	6	30
Graduate or professional degree	1	5
Income		
No income	1	5
Between \$5 – \$10K	7	35
Between \$10,001 – \$20K	4	20
Between \$20,001 – \$30K	3	15
Between \$30,001 – \$40K	3	15
More than \$40,000	1	5
Medical Coverage		

Characteristics (N=20)	n	%
Medicare	3	15
Medicaid	5	25
Medicaid & Medicare	9	45
Ryan White	1	5
Private/Other	2	10
Age		
Mean 54.60 (SD 10.8)		

Comprehension

Semi-structured interviews

Thirty-five percent of participants (n = 7) verbalized more than one essential component of HIE (i.e., high level of comprehension), such as: (1) all medical information is shared electronically, (2) HIE is different from HIPAA, (3) HIE is accessible by participating providers and organizations, and (4) written consent is required in order to share. Those with high comprehension included: two with some college but no degree, one with a trade degree, one with an associate degree, two with bachelor's degrees, and one with a graduate degree. Listed below are selected quotes from those that demonstrated high comprehension by verbalizing more than one component of HIE:

"It's a program where your medical doctors have access to your medical records whether it's at the clinic or outside of the hospital and lists the health conditions that I have and what treatments I have gotten. You must sign a consent form to have the doctors' access my information."

"Health information exchange, it provides electronic access to treatment providers. This can be anywhere that the HIE exists."

"It's about the whole process of how if I were injured another hospital my doctors can always check back on the information from the other hospital. They can always access what was done what was administered to me if I was outside of my healthcare circle."

Twenty percent of participants (n = 4) were able to verbalize one essential component of HIE in their responses when asked. The education level of those PLWH with moderate comprehension included: one with some college but no degree, two with an associate degree, and one with a bachelor's degree. Examples of their responses are as follows:

"Easier way to access your information, especially if you're not in a way to coherently speak for yourself."

"It provides electronic information to the clinic you go to. To the doctors that takes care of you. Can understand more of what they're dealing with."

Forty-five percent of the participants (n = 9) were unable to verbalize any essential components of HIE in their comprehension interview when asked. The education level of those PLWH with no comprehension included: four with some high school experience but

no diploma, two with a high school diploma/GED, and three with a bachelor's degree. Selected quotes include the following:

"It's about my status my sickness, my medications and my doctors."

"HIE is when you have privacy. The way I understood it, when you have privacy in the facility where you receive the medical care and you decide you want medical care elsewhere you would get a consent."

"It's about your health, your HIV status, your TCells and uh viral and TCells. It tells you about your health. What meds to take. Helps you stay healthy with your HIV status."

Preferred Consent Format

With regard to the paper and e-Consent UI assignment, 75% (n = 15) were initially assigned to read the paper consent, and the remainder used the UI first. Over half of the participants (n = 14) were in favor of using the UI over the paper consent. Those favoring the e-Consent included: two with some high school but no diploma, two with a high school diploma/GED, three with some college but no degree, one with a vocational/technical diploma, three with an associate degree, and three with a bachelor's degree. Selected quotes from participants in response to the user interface are as follows:

"It [user interface] was less intimidating and more to the point. Less is more and this was more.

This delivers more in less time and is not as intimidating [as a paper consent]. Since we live in an age of technology, people are just more familiar with it and even people that aren't are going to find it [e-Consent] easier."

"Honestly, I would never read this much information. Um, if I see it I would just sign it – yeah that's too many words for me right there. I generally do not read those types of things. I think the electronic version is simple to use. I would read that because they're more simple, concise paragraphs. I guess more interactive and I'm used to that. All of the information is essentially given. I use the computer. I have an iPad and all that so um to me it's very convenient and it's less paper to deal with. I prefer electronic because I think that's where most things in life are going in general."

Thirty percent of the participants (n = 6) preferred using a paper consent instead of an e-Consent UI. Those favoring paper consent included: two with some high school but no diploma, three with a bachelor's degree, and one with a graduate degree. Selected quotes are as follows:

"It [paper consent] was very understanding. It [user interface] is also understanding. I like it. But, I'd pick the paper because I could take my time reading it."

"I think the paper version explains it better because it gives you the words instead of just the icon. You have a better understanding with the words. The electronic is good. I guess I would do better with the paper because I'm used to it. The electronic is easy but I'm used to paper even though it is more tedious."

Perceived Usefulness and Ease of Use of the User Interface

Results suggested that 65% of participants (n = 13) agreed or strongly agreed that the icons informed them of upcoming UI content. Ninety percent (n = 18) reported (agreed or strongly agreed) that the text represented by each icon was easy to understand. Seventy percent (n = 14) reported that they strongly agreed the UI icons prepared them to read the HIE consent PDF file on the iPad tablet. Eighty-five percent (n = 17) reported that they strongly agreed the UI was easy to use.

Consent Preference Based Upon HIE Comprehension Assessment

Triangulated interview and survey data (Table 2) suggested that the majority of those who demonstrated high or low levels of comprehension and all who demonstrated a moderate level of comprehension preferred the UI. Four of the six participants who preferred the paper consent demonstrated low comprehension of HIE.

Discussion

This study's approach was novel because the three-tiered layering process that starts with an icon has been used in electronic apps having to do with asthma, diabetes, and Parkinson's Disease ^{11,19,22}, but it has never been used in the context of HIE consent. This portion of the study has set the foundation and illustrated the importance of integrating patients into the early design stages of an HIE e-Consent UI. Interventions are most beneficial when they are tailored and guided by the needs of the end-user population ⁷, which in this instance was PLWH at the HIV clinic.

In terms of a general approach to the design of the UI, the primary influence was Wilbanks' work on a three-tier approach to electronic consent that was subsequently adapted for inclusion in the Apple Research kit ^{10,11,19}. Multimedia Principles ¹⁵ provided important information to guide the creation of a simple, intuitive, and interactive HIE e-Consent UI. Heuristic assessment ¹⁷ conveyed preliminary usability of the UI, and the principles of user-centered design were used with participants in the selection of icons that were suitable for inclusion in the first step of our approach.

Implications for improvement of the user-centric user interface

This study utilized a user-centered design approach in the creation of the UI. Patients provided feedback on which icons they perceived best visually represented the risk/benefit concepts of HIE. A three-tiered approach that started with an icon resulted in the Patient-centered Consent Toolkit ¹¹, and subsequently guided this study's HIE e-Consent UI design.

Because there is not one standard model that facilitates comprehension of consent documents, this study used approaches from a variety of frameworks to best meet the needs of this HIV clinic's diverse population. Icons were used as part of the three-tiered approach ¹¹. The concept of simplified text headings were used from the three-tiered approach, but the simple text was used from the UI video study ¹² guided the wording for our e-Consent. The principles of coherence, signaling, multimedia and personalization ¹⁵ supported the e-Consent design. Heuristic assessments supported the e-Consent's low

cognitive effort during navigation of the UI ¹⁷. Aggregating these frameworks was a novel approach in the overall design process, as each approach complemented the other.

The qualitative UI comprehension testing yielded three participant rankings: (1) those that were able to verbalize more than one component of HIE, (2) those that were able to verbalize one component of HIE, and (3) those that were not able to verbalize any components of HIE. Despite incorporating simplified text headings and content, study findings suggested that after completion of both consent formats, there remained confusion and a lack of understanding about electronically sharing via HIE. Interestingly, of the participants that were unable to demonstrate comprehension, five out of nine participants preferred the UI, while the other four preferred the paper consent. Although small changes to simplify wording may improve understanding ²³, it is uncertain if this would be beneficial, given that there was no meaningful difference in the number of those with low comprehension that preferred one format over the other.

Most of study participants were ethnic or racial minorities, of which more than half had some college with no degree or greater. This does not support comprehension testing results, as most were college educated and almost half of the participants had some high school experience or high school diplomas. However, this finding does support that factors other than educational achievement, such as social, economic, psychological, and linguistic may contribute to lower levels of comprehension and the ability to be informed ²³.

Of those who were college educated (i.e., having some college training with no degree, having an associate, bachelor or graduate degree), 35% verbalized more than one essential component of HIE and 20% were able to verbalize one component of HIE when asked. The majority of those that were not able to verbalize any components of HIE included four persons with some high school with no diploma, two high school graduates, and three persons with a bachelor degree. This suggests that the UI was not adequate as an independent means to facilitating comprehension. In addition to the UI, human interaction may be needed to better address the complex topic of electronic sharing via HIE.

Currently, Food and Drug Administration guidelines suggest that consent wording should not exceed an eighth-grade reading level ²⁴, and Doak and colleagues suggest that literature is most appropriate when it is written at the fifth-grade level ⁶. Although legally required, paper consents provide weighty information that distracts individuals from having a clear explanation of study procedures ^{5,25}. Because of this, the feasibility of moving towards an easy to read, user-centered UI remains a critical issue, yet there is no current standard of measuring if patients who have consented are fully informed. Since there is limited literature available on the issue of consent comprehension, further research is warranted on exploring the best approaches to facilitate the delivery of HIE consent using validated, comprehensible formats and user-centered approaches that incorporate knowledgeable, dedicated persons to assist in the consent process.

Conclusion

Health information exchange is a complex construct, and an individual's health literacy may not necessarily align with their overall functional literacy. Thus, the inability to comprehend information may decrease informed decision-making. Comprehension is a key factor in the ability to make informed decisions.

Acknowledgments

S. Raquel Ramos is funded by Self and Family Management of Chronic Illness T32NR008346. PI: Nancy Reynolds. This work was funded by Reducing Health Disparities Through Informatics (RHeaDI) T32NR07969. PI: Suzanne Bakken.

The author would like to thank Drs. Barbara J. Guthrie, Trace Kershaw, and Alonso A. Alvaro for their assistance with manuscript preparation.

References

1. Abras, C., Maloney-Krichmar, D., Preece, J. Bainbridge, W Encyclopedia of Human-Computer Interaction. Vol. 37. Thousand Oaks: Sage Publications; 2004. User-centered design; p. 445-456.
2. Witteman HO, Dansokho SC, Colquhoun H, et al. User-centered design and the development of patient decision aids: protocol for a systematic review. Systematic reviews. 2015; 4(1):1. [PubMed: 25554246]
3. Norman, DA., Draper, SW. User centered system design.
4. Downing NL, Adler-Milstein J, Palma JP, et al. Health information exchange policies of 11 diverse health systems and the associated impact on volume of exchange. Journal of the American Medical Informatics Association. 2016;ocw063.
5. Rothwell E, Wong B, Rose NC, et al. A Randomized Controlled Trial of an Electronic Informed Consent Process. Journal of Empirical Research on Human Research Ethics. 2014; 9(5):1-7.
6. Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. AJN The American Journal of Nursing. 1996; 96(12):16M.
7. Årsand E, Demiris G. User-centered methods for designing patient-centric self-help tools. Informatics for Health and Social Care. 2008; 33(3):158-169. [PubMed: 18850399]
8. Ramos SR, Gordon P, Bakken S, Schnall R. Sociotechnical Analysis of Health Information Exchange Consent Processes in an HIV Clinic. Journal of the Association of Nurses in AIDS Care. 2016
9. Annas GJ. HIPAA regulations-a new era of medical-record privacy? New England Journal of Medicine. 2003; 348(15):1486-1490. [PubMed: 12686707]
10. Bionetworks, S., editor. Sage Bionetworks. Mobile consent walkthrough I PD APP. 2015.
11. Sage Bionetworks. [Accessed June 3, 2015] Participant-centered consent (PCC) toolkit. 2015. <http://sagebase.org/e-consent/>
12. DHHS, ONC. eConsent video trial project: Patient educational material/text for stories. 2013.
13. Friend SH. App-enabled trial participation: Tectonic shift or tepid rumble? Science Translational Medicine. 2015; 7(297):297ed210-297ed210.
14. Wilbanks J. Portable approaches to informed consent and open data. Privacy, Big Data, and the Public Good: Frameworks for Engagement. 2014
15. Mayer, RE. Multimedia learning. Cambridge university press; 2009.
16. Nielsen, J., Molich, R. Heuristic evaluation of user interfaces. Paper presented at: Proceedings of the SIGCHI conference on Human factors in computing systems; 1990;
17. Goldstein, Gigerenzer G. Simple heuristics that make us smart. Oxford University Press; 1999. The recognition heuristic: How ignorance makes us smart; p. 37-58.
18. Nielsen, J. [accessed December 19, 2013] Ten usability heuristics. 2005. <http://www.nngroup.com/articles/ten-usability-heuristics/>

19. Ritter S. Apple's Research Kit Development Framework for iPhone Apps Enables Innovative Approaches to Medical Research Data Collection. *J Clin Trials*. 2015; 5:e120.
20. Whiddett R, Hunter I, Engelbrecht J, Handy J. Patients' attitudes towards sharing their health information. *International journal of medical informatics*. 2006; 75(7):530–541. [PubMed: 16198142]
21. Davis, FD, Jr. A technology acceptance model for empirically testing new end-user information systems: Theory and results. Massachusetts Institute of Technology; 1986.
22. John Wilbanks, Hermosilla M. [Accessed July 3, 2015, 2015] Improving informed consent through design to advance science. Ideas Lunch. 2015. <http://thegovlab.org/john-wilbanks-improving-informed-consent-through-design-to-advance-science/>
23. Jadad, AR., Enkin, MW. Randomized controlled trials: questions, answers and musings. John Wiley & Sons; 2008.
24. Alper, J. Informed Consent and Health Literacy:: Workshop Summary. National Academies Press; 2015.
25. Kass NE, Chaisson L, Taylor HA, Lohse J. Length and complexity of US and international HIV consent forms from federal HIV network trials. *Journal of general internal medicine*. 2011; 26(11): 1324–1328. [PubMed: 21748435]

1. What is HIE? (Which, if any, best describes a person thinking about the definition of HIE?)

2. What health information can be accessed? (Which, if any, best describes this?)

3. Who can access my information? (Which, if any, best describes this?)

4. How is my information protected? (Which, if any, best describes this?)

5. What are my choices for consent? (Which, if any, best describes this?)

Figure 1.
Illustration of Patient Icon and Simplified Text

Figure 2.
Screenshots of User Interface, Icon Home Page, and HIE Information

Figure 3.

Technology Acceptance Model.[21] Reprinted with permission.

Note: Attitude toward using, behavioral intention to use, and actual system usage were not assessed.

Table 2

Illustration of triangulated responses to consent preference by level of comprehension

	# that preferred user interface on an iPad	# that preferred paper HIE consent	Selected Quotes
¹ High level of comprehension	5	2	<p>"Honestly, I would never read this much information. Um, if I see it I would just sign it – yeah that's too many words for me right there. I generally do not read those types of things. I think the electronic version is simple to use. I would read that because they're more simple, concise paragraphs. I guess more interactive and I'm used to that. All of the information is essentially given. I use the computer. I have an iPad and all that so um to me it's very convenient and it's less paper to deal with. I prefer electronic because I think that's where most things in life are going in general."</p> <p>[preferred user interface]</p> <p>"The iPad was easier to read. I would want it blown up a little more [the words] but it was fine. I grew up reading 3 papers a day. It's nice to have the electronic. Growing up we never had computers or phones....so I still prefer paper."</p> <p>[preferred paper consent]</p>
² Moderate level of comprehension	4	0	<p>"It [user interface] was less intimidating and more to the point. Less is more and this was more."</p> <p>[preferred e-Consent]</p> <p>"This delivers more in less time and is not as intimidating [as a paper consent]. Since we live in an age of technology, people are just more familiar with it and even people that aren't are going to find it [e-Consent] easier."</p> <p>[preferred e-Consent]</p>
³ Low level of comprehension	5	4	<p>"It [paper consent] was more confusing but I got to know where I stand. "It [user interface] helped me out in a way to understand what was going on. For me, the words I didn't really understand how to read it, but I felt like I needed help and some words I didn't know, you know? Even though I was doing it on a computer, I would really do it on a paper. The paper helped me sound the words out." In some ways I understand and some ways I didn't [the user interface]."</p> <p>[preferred paper consent]</p> <p>"I was surprised because of the difference [paper consent]. I like the electronic version because sometimes they ask you and you don't have to go through those stages. It was simpler."</p> <p>[preferred user interface]</p>

¹High comprehension = ability to report one or more essential component of HIE

²Moderate comprehension = ability to report one essential component of HIE

³Low comprehension = unable to report any essential component of HIE