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Cognitive Testing of an Electronic Consent Platform: Researcher Perspectives

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Abstract. This study focuses on feedback from domain experts to assess usability and acceptance of the E-Consent electronic consent platform. Quantitative and qualitative data were captured throughout the usability inspection, which was structured around a cognitive walkthrough with heuristics evaluation. Additional surveys measured biobanking knowledge and attitudes and familiarity with informed consent. A semi-structured qualitative interview captured open-ended feedback. 23 researchers of various ages and job titles were included for analysis. The System Usability Scale (SUS) provided a standardized reference for usability and satisfaction, and the mean result of 86.7 corresponds with an 'above average' usability rating in the >90th percentile. Overall, participants believe that electronic consenting using this platform will be faster than previous workflows while enhancing patient understanding, and human rapport is still a key component of the consent process. Expert review has provided valuable insight and actionable information that will be used to further enhance this maturing platform.

Keywords. Research consent, patient-facing technology, patient participation, system implementation, usability

1. Introduction

The E-Consent platform is a flexible framework designed to accommodate a wide variety of research consent workflows using electronic devices [1]. The platform has now experienced multiple iterations of development, based on several prior usability studies and lessons learned from working with a wide variety of potential users [2-3]. Formative development of the immature platform relied on subject matter experts to finalize the feature set and general workflow. After many cycles of improvement focusing on end-users, the platform has now matured into a new version with considerable changes. To ensure the application remains focused and lean, and to consider any rare cases, the next development cycle should rely on feedback from another sample of experts with domain knowledge in the field.

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2. Methods

2.1. System Design

The system has been built according to user-centered design principles, with an emphasis on ease-of-use and minimizing cognitive load [4].

Content displayed by the platform is organized into two main 'modules': an Education Module, and a Consent Module. The Education Module delivers study-relevant background information intended to assist users as they make an informed choice about consenting, whereas the Consent Module delivers the content of the informed consent form section by section (Figure 1). Each module is divided into a series of 'chapters', organized around a main menu that acts like a table of contents. Within each chapter, information is presented as paraphrased 'tips,' which are one to two sentences of text supported by multimedia. Content is edited by subject matter experts to reduce medical jargon and esoteric terms where possible. Short multiple-choice quizzes based on the content of tips appear periodically, and these quizzes require a correct answer to progress to the next page. Wrong answers prompt users to try again.

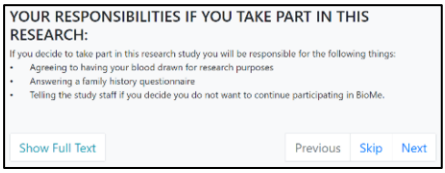

Figure 1. Example of a section from Consent Module.

By default, users begin in the Education Module and progress through each chapter in sequence. After completing this first module, users then enter the Consent Module. The interface is consistent from module to module, however, the structure of the Consent Module is modeled closely on the structure of the approved consent form. Content is again paraphrased into smaller tips that may or may not include multimedia. Regardless, the full text of each section of the consent form is available on all pages through a 'Show Full Text' button. The Consent Module concludes by showing the full text of the consent form one final time, followed by an electronic signature page (Figure 2).

Figure 2. Electronic signature page.

Users may progress through the chapters in sequence, or they may skip to the full consent form at any time. Ultimately all users will be presented with the full text of the consent form and the electronic signature page, which they may choose to sign. For this

study, an actual Biobanking consent form written in American English was used to model all content.

2.2. Study Design

This study focused on feedback from research experts. Participants were considered experts if their role directly involves clinical research, based on self-reported job description.

Subjects were sequestered one-at-a-time into a quiet testing room equipped with either a desktop workstation or a tablet computer with touchscreen. Upon sitting down, participants were instructed to complete a package of pre-test surveys that included sociodemographics questionnaire and the Rapid Estimate of Adult Literacy in Medicine (REALM). The cognitive walkthrough then began as subjects were instructed to use the E-Consent system to complete three representative tasks. Post-task surveys captured both quantitative and qualitative data. Following that, participants completed a heuristics evaluation, a Biobanking Attitudes and Knowledge Survey (BANKS), and a Process and Quality of Informed Consent for Clinical Research (P-QIC) form. The session concluded with a semi-structured qualitative exit interview.

The three tasks of the cognitive walkthrough were as follows: Task 1 asked users to progress through the educational module, Task 2 required users to navigate through the consent module and sign the consent form electronically, and Task 3 requested that users complete the System Usability Scale (SUS) as presented through the electronic platform. Although all tasks could be completed without assistance, users were advised that they could request help at any time. Any requests for help were noted.

Post-task surveys asked participants to rank each task on a Likert-like scale of 1 (very difficult) to 5 (very easy). Survey questions for Tasks 1 and 2 included: 1) How difficult or easy was it to review the content and finish the sections? 2) How difficult or

Table 1. Task self-assessment.

Task Self-Assessment	Mean (SD)
Task 1: Progress Through Education Module	
Content Difficulty	4.7 (0.6)
Questions Difficulty	4.9 (0.6)
Satisfaction	4.3 (0.8)
Amount of Time	4.1 (1.1)
Visually Appealing	4.1 (1.0)
Easy to Navigate	4.6 (0.8)
Task 2: Complete Consent Module	
Content Difficulty	4.5 (0.8)
Questions Difficulty	4.7 (0.7)
Satisfaction	4.3 (1.0)
Amount of Time	4.0 (1.1)
Visually Appealing	4.3 (1.0)
Easy to Navigate	4.7 (0.6)
Task 3: Complete E-Questionnaire	
Satisfaction	4.8 (0.5)
Amount of Time	4.4 (1.1)
Visually Appealing	4.7 (0.6)
Easy to Navigate	4.9 (0.3)

easy was it to answer the questions? 3) How satisfied are you with using this system to complete this task? 4) How would you rate the amount of time it took to complete this task? 5) Is the system visually appealing? 6) Is the system easy to navigate? These were followed by two open-ended questions that ask the participant to describe any problems and offer additional feedback. As Task 3 was just the System Usability Scale presented electronically, its post-task evaluation included only questions that were relevant to this section.

3. Results

Data was collected from 23 researchers for this phase of the study. Ages ranged from 22 to 58 years old. 14 of the 23 participants described their roles as either Research Coordinators or Research Assistants. Other job titles included Physician-Researchers, Research Administrators, and Analysts, among others. Average REALM score was 64/66, which equates to the highest category 'high school or better'. All participants rated their English proficiency as either 'Excellent' (19/23) or 'Good' (4/23).

Table 2. Heuristics evaluation means.

Heuristics Evaluation Means	
Heuristic	Mean Score (SD)
Visibility	4.7 (0.6)
Match (system to real world)	4.8 (0.4)
Control	4.4 (1.2)
Consistency	4.6 (0.7)
Error Prevention	4.6 (0.6)
Recognition	4.7 (0.9)
Flexibility	4.4 (0.7)
Aesthetics	4.6 (0.8)
Error Recovery	4.6 (0.9)
Help & Documentation	4.0 (1.1)

Task self-assessment results (Table 1) are presented as averages, with a score of 5 indicating highest satisfaction. Content difficulty for Tasks 1 and 2 was found to be 4.7 and 4.5, respectively. Questions difficulty was 4.9 and 4.7, whereas satisfaction was 4.3 for both. Ease of navigation was rated at 4.6 and 4.7. One participant required help to complete tasks 1 and 2. The heuristic evaluation's highest mean score was 4.8 for 'Match (between system and real world)', whereas the lowest mean score of 4.0 was attributed to 'Help and Documentation' (Table 2). System Usability Scale (SUS) scores were normalized in the usual fashion; SUS mean was 86.7, which corresponds with an 'above average' usability rating and places this system at greater than the 90th percentile for usability. The semi-structured qualitative interview captured multiple pieces of actionable feedback about the system (Figure 3).

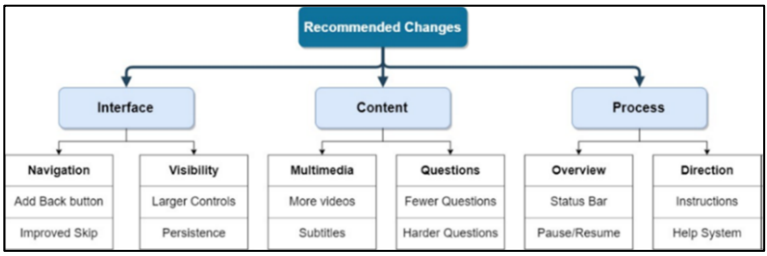

Figure 3. Usability Concept Map of experts' suggestions.

4. Discussion

While expert review continues to be used effectively with specific methodologies during product development, we engaged our subgroup of experts for the entire battery of this usability evaluation. Feedback from this cohort yielded multiple actionable points, especially during the semi-structured qualitative interview. The experts shared valuable insight from their long history of working in research. Interestingly, they offered exceptionally useful information about usability in edge cases, such as the need for optimized font size, color, emphasis, subtitles, controls, and the like, for users with a variety of visual, auditory, or motor disabilities**.**

Human rapport was mentioned as an important aspect of the consent process. One expert said, "I think this will get more people to consent, but I think some people will just click through without reading. Having a [Clinical Research Coordinator] present actually ensures understanding." The need to accommodate various workflows with involvement from a Clinical Research Coordinator (CRC) was described more than once.

Regarding the traditional paper workflow for consents, the experts generally agree that this electronic system is preferable; as one participants said, "The app is more useful in explaining the research in comparison to reading it", and "it adds to the chance for people participating." Another researcher explained, "people will learn more thanks to the interactivity, and they're better informed so more likely to sign the form."

CRCs were extremely enthusiastic about the platform: "It's fun, it's fast, it saves a lot of CRC's time." Another coordinator said, "[It's] good that you can go straight to 'consent now' and skip education, if a coordinator already explained everything."

The heuristics evaluation revealed the highest score for 'Match (between system and real world)', implying that the system is intuitive. The lowest score for 'Help & Documentation' emphasizes user expectations for a robust and obvious Help system.

Limitations of this study are primarily related to the focused user group. This expert subset of participants is already familiar with informed consent procedures, and they have a high self-reported English literacy and medical literacy, which correspond with their high REALM score average. Thus, they do not necessarily reflect the patient population that will ultimately use this platform. Future usability studies will need to refocus on the target audience in most likely settings. Regardless, these experts have provided valuable insight into their research consent workflows.

5. Conclusion

Expert review represents a valuable source of feedback for development, beginning with the formative usability evaluation and recurring with later product refinement. This group of experts provided multiple actionable points that will be incorporated for the next development cycle.

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