

Assessing the usability of a novel toolkit for creating visual key information pages for informed consent for research: a mixed methods study

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Submitted to: JMIR Formative Research
on: April 29, 2025

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Abstract

Background: Key information pages for informed consent require a concise summary of information to improve participant understanding but have not widely incorporated health literacy best practices.

Objective: We previously developed a visual key information template to improve informed consent. This study conducted usability testing of this customizable one-page key information template.

Methods: Participants (n = 15) were asked to spend about 20 minutes using the visual key information template, engaging in a think-aloud protocol. They then responded to qualitative debrief questions about the template and validated measures of acceptability, appropriateness, and feasibility. Interviews were recorded, transcribed, and analyzed with a usability-focused codebook and thematic analysis.

Results: The toolkit was positively received. Common usability challenges included: interpreting instructions, condensing consent content, replacing/resizing icons, and fitting information into template boxes. Participants had positive experiences with toolkit elements, especially the icon library, and generally felt the toolkit was easy to use and encouraged simplification of information. Some participants noted not fully reviewing instructions before the study and discussed specific technical abilities as potential limitations of widespread use. We documented suggestions and made changes to the toolkit in response to feedback received.

Conclusions: Overall, participants considered the toolkit appropriate, acceptable, and feasible. Further research should investigate changes to format and software that balances functionality with ease of use.

(JMIR Preprints 29/04/2025:76740)

DOI: <https://doi.org/10.2196/preprints.76740>

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Original Manuscript

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Keywords: informed consent, health literacy, key information, usability testing, think-aloud protocol, qualitative mixed-methods



Introduction

Background

Informed consent documents for research studies aim to introduce research participants to important topics including research design, risks and benefits, data privacy, and participant rights. Research and regulatory oversight teams often struggle to clearly present these complex details, which results in consent forms that are lengthy, repetitive, and difficult to understand.¹⁻⁵ The introduction of the key information (KI) page in the 2018 Federal Common Rule sought to address these challenges by requiring a “concise and focused summary” of information most important to potential participants who are deciding whether to join a study.⁶ Although evidence-based recommendations for how best to use KI pages are limited to date, the guidance that does exist encourages flexibility to adapt information to the audience.^{7,8} However, recommendations frequently do not include health literacy best practices. Our research team developed and tested options for a one-page KI template incorporating health literacy best practices: icons, color, white space, and bulleted lists of information.^{9,10} After selecting and refining our approach, we developed a customizable toolkit in Microsoft PowerPoint.^{9,11} The toolkit includes an editable version of the template, instructional documents and videos, an icon library, and best-practice examples to empower study teams to use the proposed template.

Objective

We conducted mixed-methods usability testing of the toolkit elements and template to ensure the toolkit is acceptable, appropriate, and feasible for research teams.

Methods

Participant Eligibility and Recruitment

We invited principal investigators and research staff at three large research universities to join the usability testing procedures via direct emails. Potential participants were identified from previously compiled lists of potential participants, as well as via snowball sampling and word-of-mouth referral.¹² Eligible participants included principal investigators of human subjects research

studies, research team members (e.g., coordinators, project managers), or research support staff with a focus on protocol development or recruitment. Based on standard sample sizes for usability testing¹³, we planned to recruit 10-15 participants in an initial round of recruitment. If new usability considerations were identified in the last 5 interviews, the research team would have recruited additional participants.

Data Collection

We designed a think aloud protocol for usability testing based on examples from past related processes.¹⁴⁻¹⁶ We sent study materials (the visual KI toolkit described above, a brief summary document, and a 5-minute introductory video) to participants in advance of scheduled interviews for their review and preparation. Participants spent approximately 20 minutes filling out the visual KI template based on an existing consent form (their own or an example provided by the study team, per participant preference) before the research team asked them to stop to minimize participant burden. Participants were asked to screenshare using video conference software as they completed the task. Interviewers prompted participants with a pre-determined list of questions if they were silent for more than 20 seconds (Appendix 1). Participants completed as much of the template as they were able during the allotted time; there was no necessary minimum completion. After testing, interviewers collected responses to debrief questions and validated measures of acceptability, appropriateness, and feasibility.¹⁷

Data Analysis

Interviews were recorded, transcribed, and divided into two parts for coding: the observational portion, and the debrief portion. The observational portions of the interviews were independently coded by one of two coders (EG, ZT). A third coder (KC) was consulted to reach consensus for each code. A usability-focused codebook was developed by three research team members (EG, KC, MP) based on anticipated challenges and challenges that emerged from the first five participant interviews and refined as needed throughout the coding process. Codes were

organized based on four usability constructs for computer-based tools: navigation, content, functionality, and layout.^{14,16} A challenge was considered frequent if at least eight (53.3%) of participants experienced it one or more times in their interview.

Several research team members (EG, MV, VC, KC) developed additional codes to analyze the broader scope of the debrief portion of the interviews, using an inductive methodology described by Naeem et al (2023).¹⁸ Debrief portions were coded collaboratively by two research team members (EG, ZT) with consultation from a third member (KC). Acceptability, appropriateness, and feasibility scores were calculated based on standard methodology for the validated measures.¹⁷

Ethics Approval

The Washington University in St. Louis Institutional Review Board approved this study as exempt research (IRB #202405126).

Results

Participants

Fifty-one eligible potential participants were invited to participate. Of those, 16 agreed to participate, two declined, and 33 were unable to be reached. Fifteen participants completed fourteen total interviews (Table 1). In one interview, two participants working on the same research project requested to be interviewed simultaneously, with one participant controlling the visual KI template while the other offered suggestions and commentary.

Table 1. Participant Demographics (n = 15)

Age (years)	
Mean (SD)	44.2 (12.57)
Range	27-76
Gender	
Woman/female	10 (66.7%)
Man/male	4 (26.7%)
Another response	1 (6.7%)
Ethnicity	
Latino/a/Latine or Hispanic	1 (6.7%)
Not Latino/a/Latine or Hispanic	14 (93.3%)
Race	
White	14 (93.3%)
Asian	1 (6.7%)
Institutional Role	
Principal Investigator (PI)	6 (40.0%)
Research Support Team Member (e.g., clinical trial oversight, recruitment enhancement)	3 (20.0%)
Research Team Member (e.g., coordinators, managers)	6 (40.0%)

Observational Period Findings

We assessed the number of participants who reported each identified usability challenge (Table 2). Five frequently observed challenges were noted. Two were related to content in the toolkit: participants had difficulty interpreting instructions and participants had difficulty condensing content from the full consent document into the visual KI template. Two were categorized as functionality issues: participants had technical issues updating information in boxes and participants had trouble replacing or resizing icons. One was a layout challenge: participants had challenges fitting study information into the boxes provided. There were few navigation challenges other than navigating between pages, which occurred among four participants.

Table 2. Usability Challenges Reported (n = 15)

Usability Challenge	Participants (n, %)	Adaptation(s) to Address Challenge
<i>Content</i>		
Participant had difficulty interpreting instructions.	8 (53.5%)	Clarified instructions; developed demonstration video resource
Participant had difficulty condensing content from full consent into bullets.	8 (53.3%)	Developed demonstration video resource
Participant had difficulty splitting content across boxes.	7 (46.7%)	Developed demonstration video resource
Icon not available for participant's desired image.	4 (26.7%)	Maintaining list of suggested icons
Participant expressed desire to include information beyond the recommended scope of visual KI.	3 (20.0%)	n/a
Participant indicated specific information was unavailable/missing.	2 (13.3%)	Clarified instructions; developed demonstration video resource
<i>Functionality</i>		
Participant had trouble replacing or resizing icons.	10 (66.7%)	Reviewed formatting to ensure appropriate layering of elements; developed demonstration video resource
Participant had technical issues updating information in boxes.	9 (60.0%)	Reviewed formatting to ensure appropriate layering of elements; developed demonstration video resource
Participant had other technical issues.	3 (20.0%)	n/a
Participant discussed a goal/functionality that cannot be achieved in PowerPoint.	2 (13.3%)	Maintaining list of suggested future functionalities
Participant had difficulty manipulating size of boxes or box headers.	1 (6.7%)	Developed demonstration video resource
<i>Layout</i>		
Participant said they could not fit desired study information in the boxes provided.	8 (53.3%)	Developed demonstration video resource
Participant expressed that the text is too small.	4 (26.7%)	Developed template version with larger font size
Participant had trouble creating text wrap.	3 (20.0%)	Reviewed formatting to ensure appropriate layering of elements; developed demonstration video resource
Participant had trouble reading side instructions.	1 (6.7%)	n/a
<i>Navigation</i>		
Participant had difficulty moving from page to page in toolkit.	4 (26.7%)	n/a
Participant unintentionally moved items around.	3 (20.0%)	Reviewed formatting to ensure appropriate layering and grouping of elements
Participant unintentionally changed format.	3 (20.0%)	Reviewed formatting to ensure appropriate layering and grouping of elements
Participant had difficulty finding desired icon.	2 (13.3%)	n/a
Participant initially had difficulty	1 (6.7%)	Developed demonstration video resource

determining which template to use (6 vs. 8 box).		
Participant expressed unfamiliarity with PowerPoint.	1 (6.7%)	n/a

Debrief Period Findings

In the debrief portion of the interviews, participants indicated that the toolkit was overall easy to use. They noted that the templated boxes made the task straightforward and encouraged them to simplify some information:

“Having these headings at the top of each [box] helps to also organize the information just mentally before you’re getting started. You can already start thinking about what goes where and what might make sense to a potential participant or patient who’s reviewing this.” – P10, research support team member

“I think that having a toolkit like this forces you to write things fairly simply and directs you exactly what to do.” – P14, principal investigator

Some participants referred to their experience as “intuitive” (P06, research team member; P14, principal investigator). Others highlighted that the “inherent flexibility” (P08, principal investigator) of the toolkit met their needs and speculated it would meet others’. However, some noted that the template by itself did not necessarily solve all challenges with the content of informed consent forms, like a high volume of desired content or a tendency toward jargon:

“It’s hard, especially the goal of the study, if there’s a lot involved, it was hard for me to figure out what to put there.” – P12, research team member

“I like the idea, but I think what...everybody has to do...is that you need to check the level of language. Because all of us are wrong all the time.” – P01, principal investigator

Participants also responded positively to the resources in the toolkit, particularly the icon library.

“I love that [the icon library] is there...it’s easy to get lost in a rabbit hole of looking for the right icon and then trying to figure out any copyright privileges...knowing that there’s a

library of things that I can select from was nice.” – P07, principal investigator

Not all participants used all resources provided. For example, multiple participants noted that they had not read through the instructions. Some felt the instructions were too long, but others appreciated inclusion of background and technical details:

“These first two pages being so dense...I was like ‘Oh, I just want to know what I need to do right now.’” – P06, research team member

“I’ve never really seen anything really like it other than just templated fliers...but [with those] you’re sort of just on your own. I think it’s important to...have that instruction and...an educational piece.” – P11, research support team member

Participants noted that users’ technical ability or experience could limit feasibility of use. One participant was also concerned about the possibility of users inadvertently creating unappealing materials with the template:

“People who know how to do it, right, they’re going to do it. If this is required to be used, they’re going to hate it. People who don’t—if they don’t have that skill in design principles anyway, they’re going to [mess] it up.” – P09, research support team member

Suggestions and Adaptations

Suggestions that arose throughout the interviews were documented and iteratively considered for implementation. In addition to the changes made to address usability issues (Table 2), several revisions were made based on specific recommendations from participants:

- Updated the “default” set of icons on template pages to ensure they are as broadly applicable as possible
- Moved the icons to the bottom right of boxes to minimize issues with text wrapping
- Added further guidance about options for customization
- Clarified best practices for using icons in payment box to minimize sources of confusion

Large-scale changes to the format of the template (e.g., adding new visual elements like arrows

between boxes, migrating toolkit to a platform that would allow dropdown selection of icons) were beyond the scope of this testing, so were documented for potential future work but not implemented in the current toolkit. We are also maintaining a list of suggested additions to the icon library for future iterations of the icon library.

Toolkit Acceptability, Appropriateness, and Feasibility

The toolkit was generally positively received, with most participants rating it highly across 5-point acceptability, appropriateness, and feasibility scales (mean acceptability score = 4.28 (range: 1.50-5.00; SD = 0.87); mean appropriateness score = 4.32 (range: 3.00-5.00; SD = 0.57); mean feasibility score = 4.35 (range: 2.75-5.00; SD = 0.63)).¹⁷

Discussion

Principal Results

These usability interviews affirmed previous findings that the proposed visual KI template is an acceptable tool for researchers conducting human subjects research.⁹ Participants generally found the toolkit both straightforward and flexible. Participants in our prior research suggested that the boxes in the toolkit would be useful for participants' comprehension and experience;⁹ in this work, we found they are also helpful for researchers thinking through how to write and summarize key consent information. However, it is important to make sure that the flexibility of the template is clear and that instructions are modular so that users can customize the content to fit study-related needs and preferences while meeting overall key information best practices. We refined instructions and created a demonstration video resource to ensure users have access to clear information about when and how to customize major elements of the template.

Although the toolkit addresses many of the formatting issues that can make informed consent forms unappealing or intimidating, participants continued to report that selecting appropriate content for key information remains a challenge (i.e., what information is appropriate to include, how to "translate" from jargon-filled protocols to plain language). The template helps to suggest some

overall content categories, but does not provide a complete solution to helping individuals summarize important study-related material. This research provided a first step focusing on usability challenges specific to a previously developed informed consent toolkit; future research could explore how to select the most appropriate content for the toolkit within the box headings.

Our selection of Microsoft PowerPoint as the platform for this toolkit has meant that we are unable to address some of participants' specific functionality desires such as including drop-down menus for icon selection. However, we chose to use this program given its broad accessibility in the United States and users' overall comfort with it. Many told us in previous work that introducing new software would create steep learning curves for those less familiar with technology.⁹ Future work could explore the best software to balance ease of use with functionality.

Limitations

These usability interviews were conducted with a limited number of participants working at similarly-resourced academic institutions in the United States; results might not generalize to participants in other institutions. In addition, participants may have worked through challenges that if they were not being observed, may have caused them to give up while using the toolkit on their own. However, we did not note any participants expressing significant frustration during the interview period. About half of participants worked on the task based on their own study protocols or consents (n = 8 participants with 7 unique protocols), but many used a sample consent for a previous decision support intervention project. This could have limited the number of study type-specific challenges encountered, particularly because only one protocol included a medication intervention.

Conclusion

Test users generally found the proposed KI toolkit appropriate, acceptable, and feasible. Some usability issues were addressed with enhanced instructional resources, and other suggestions related to the toolkit content were considered and incorporated. Future research could explore further guidance for selecting the right content for KI pages and technology platforms (e.g., generative

artificial intelligence integration) that provide more tailored support for users developing visual KI pages.



Acknowledgements

The qualitative interviews for this project were supported by the Agency for Healthcare Research and Quality (AHRQ, Grant R01 HS029310).

Conflicts of Interest

Dr. Politi was a consultant for UCB Biopharma in 2024 and EpiQ, Inc. in 2023 on topics unrelated to the content of this manuscript.

Abbreviations

KI: key information

Data Availability

Deidentified transcripts will be available through the Qualitative Data Repository (QDR) at Syracuse University (DOI: 10.5064/F6XJ82VS).

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Supplementary Files

Multimedia Appendixes

Think aloud prompts used with participants after approximately 20 seconds of silence.

URL: <http://asset.jmir.pub/assets/e1cc8385448531eacfa008cdf7b58c01.docx>