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Accelerating implementation of visual key information to improve informed consent in research: a single-institution feasibility study and implementation testing

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ABSTRACT

Objective Current consent processes often fail to communicate study information effectively and may lead to disparities in study participation. The 2018 Common Rule introduced a mandatory key information (KI) section as a means of improving consents; however, it frequently remains lengthy and prohibitively complex. We conducted a feasibility study of an accessible visual KI template for use in routine studies.

Design Parallel feasibility study and implementation testing.

Setting Single Midwestern US academic centre, between July 2023 and July 2024.

Participants To develop and implement the visual KI template, we used rapid implementation science methods and recruited decision-making and clinical experts, patients and community partners to iteratively adapt the KI template. To assess its efficacy, we surveyed patient participants eligible to enrol in one of four clinical trials that used the visual KI template as part of informed consent.

Primary and secondary outcome measures The primary outcome was participant knowledge about clinical trial details. Secondary outcomes included decisional conflict about joining the trial (validated SURE measure), KI template acceptability (validated Acceptability of Intervention Measure) and perceived self-efficacy communicating about trial details with researchers/clinicians (items adapted from the Perceived Efficacy in Patient/Physician Interaction measure). Feasibility was evaluated based on reach, number of modifications needed to tailor the intervention to each pilot trial, and time required for ethics reviews.

Results Of 85 study participants across the four clinical trials using the visual KI page, the weighted mean knowledge score about trial details was 87.4% correct (range 77.8%–88.9%). Few (n=9; 10.6%) reported decisional conflict about whether to participate. Almost all (n=82; 96.5%) participants stated they approve using the visual KI template. 79 (92.9%) participants reported feeling confident asking clinicians or researchers questions about the trial.

Conclusions Visual KI templates can improve potential participant comprehension and in doing so, may reduce barriers to participation in research. Parallel feasibility studies and implementation science methods can facilitate the rapid development and evaluation of evidence-based interventions, such as improved informed consent templates.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study used implementation science methods that balanced the need and enthusiasm for visual key information (KI) template implementation with iterative testing to maximise participant benefit.
⇒ Initial testing was performed within one institution; however, early results will guide a future multi-institutional trial of visual KI templates.

INTRODUCTION

Obtaining informed consent for research studies is a priority to advance transparency and integrity in human subjects research while upholding patient autonomy.[1] The multifaceted nature of informed consent necessitates an approach that balances standardised procedures while engaging participants and minimising burden.[1] Despite attempts to improve consent procedures, current processes often fall short in effectively communicating important information about study protocols to potential research participants.[2] Individuals and researchers report that the length, complexity and technical wording on informed consent forms paradoxically hinders participant understanding of study details.[3 4] The COVID-19 pandemic further highlighted existing shortcomings of informed consent forms: COVID-19 vaccine consents were on average 21.8 pages, which would take at least half an

hour to read without stopping.[5] As the pandemic limited non-essential face-to-face encounters, requiring a shift to remote recruiting, the length and complexity of informed consent forms were even more pronounced, significantly impacting research staff's ability to clarify study details and engage with participants to correct misunderstandings.[6] Ineffective informed consent forms have not only affected clinical trial enrolment broadly but also have led to disparities in participant recruitment, particularly among those who are typically underrepresented in clinical trials relative to study disease populations.[7 8]

In 2018, the US Federal Policy for the Protection of Human Subjects, or the Common Rule, began requiring that informed consent forms begin with a key information (KI) section to summarise the studies.[9] KIs should be 'focused and concise' and convey information that is 'most likely to assist … in understanding the reasons why one might or might not want to participate in the research'.[10] The introduction of the KI section is a result of decades of research intent on improving the informed consent process. Current best practices include writing below an 8th grade reading level, using plain language,

Table 1 Expert Recommendations for Implementing Change (ERIC) strategies as selected by end-users

Selected strategies used and how they support behaviour change	Operationalised in this study
Access new funding (increase opportunity for end users)	► Secured institutional funds to revise template and test in pilot studies ► Obtained federal/external funding to conduct qualitative interviews and develop training for key end users
Assess for readiness, identify barriers/facilitators (increase motivation and capability to adopt visual KI pages)	► Meetings with principal investigators and research team members to prepare for implementation in clinical research studies ► Meetings with key end users (principal investigators, research team members, IRB members and community members) to identify workflow barriers and facilitators ► Identified existing consent workflow procedures and tailored visual key information procedures to meet study team and IRB needs
Audit and provide feedback (increase capability to adopt visual KI pages)	► Provided interim data reports to research teams about participants' attitudes towards the visual key information templates and their knowledge of key information in studies ► Collected feedback from PIs, IRB members and research team members to assess feasibility and workflow considerations
Build a coalition (increase motivation and capability to adopt visual KI pages)	► Identified and engaged with key end users throughout the study (IRB members, community members, PIs, research staff) ► Worked with graphic designers and plain language experts
Capture and share local knowledge (increase capability to adopt visual KI pages)	► Shared data updates via presentations to potential and engaged end users to discuss emerging themes, challenges and showcase iterative prototypes of the key information pages
Conduct educational meetings (increase motivation and capability to adopt visual KI pages)	► Facilitated meetings before and during implementation to discuss project aims, timeline, budget, logistics, scope of work, staff roles, project needs and expectations, concerns and allow for feedback
Develop and implement tools for quality monitoring (increase capability and opportunity to adopt visual KI pages)	► See the 'audit and provide feedback' section about sharing data reports ► Created standardised assessment processes for each study including knowledge, decisional conflict, feasibility, acceptability and appropriateness of the visual key information template
Obtain and use patient/family feedback (increase motivation to adopt visual KI pages)	► Collected feedback from participants to assess feasibility and acceptability of visual key information templates ► Shared information with community advisory boards for additional input from potential patients/family members of those who might consider studies
Promote adaptability (increase capability to adopt visual KI pages)	► Offered six box and eight box versions of the templates ► Optimised and customised key information template for physical or electronic dissemination (printed materials or e-consent process) ► Tracked and implemented feedback from end users using FRAME
Provide ongoing consultation (increase capability and opportunity to adopt visual KI pages)	► Project coordinators and PI are always available via phone, email ► Held regular check-ins between project staff and clinical staff for progress updates and to address workflow challenges
Purposely re-examine the implementation (increase capability and opportunity to adopt visual KI pages)	► Conducted monthly data summaries to track participant survey responses, identify gaps and proactively assess acceptability
Tailor strategies (increase motivation and capability to adopt visual KI pages)	► Adapted strategy for implementation based on local needs; tracked using the FRAME-IS

FRAME, Framework for Reporting Adaptations and Modifications to Evidence-based Interventions; FRAME-IS, Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies; IRB, institutional review board; KI, key information; PIs, principal investigators.

short sentences and bullet points to improve patient comprehension.[11] However, most KIs in practice still rely heavily on minimum federal regulations and contain similar information, format, complexity and wording as longer, text-based consent documents.[12]

Although the KI section was intended to improve the informed consent process, they are often written at an advanced reading level (higher than 8th grade), without important information such as the rationale for study enrolment, and without following plain language principles.[12 13] Given these challenges and the importance of clear, ethically appropriate consent processes to advance medical and human subjects research, we developed, refined, adapted and implemented a visual, plain language KI template to improve informed consent processes.[6] The visual KI template was modified for four ongoing research studies (two cancer treatment studies, one biobank study and one study on memory and ageing). The purpose of this paper is to: (1) summarise the processes used to develop our KI template and accelerate its translation into practice and (2) report the results of our pilot studies testing the feasibility, acceptability, satisfaction and preliminary efficacy of this promising KI intervention.

METHODS

Setting and approach

We conducted our research at a Midwestern academic medical centre between July 2023 and July 2024, with plans to scale up our intervention to two other institutions in different regions of the country. Based on consent limitations we previously reported,[6] we engaged key end-users and adopted a flexible approach responsive to the context for routine use of visual KI pages based on implementation science principles.[14] Our end-users included faculty experts across the fields of decision-making and ethics, clinicians, institutional review board (IRB) staff, research coordinators, community partners and potential research participants. This initial engagement helped the research team identify opportunities to improve the KI template and prioritise incorporating health literacy principles, such as plain language and visual designs.[15 16] With this promising approach for improving institutional KIs, and the welldocumented inequities in clinical trials, institutional champions were motivated to accelerate the implementation of strategies. Therefore, the research team launched a concurrent process for conducting both a feasibility study with efficacy and implementation testing.[17 18] This approach is distinct from other implementation science hybrid research designs as we collected both the iterative efficacy for the intervention and clinical implementation evaluation outcomes in parallel.

Recruitment into the survey study to test the KI template

Patient participants eligible to enrol in one of the four participating clinical trials were approached in the clinic with the visual KI page as part of consent to their specific trial. Research coordinators and research team members reviewed the visual KI template as part of the regular consent procedures for the participating clinical trials. This study team then contacted all participants that were approached for the participating clinical trials to complete surveys about trial knowledge, decisional conflict, acceptability and satisfaction with using the visual KI template.

In three of the pilot trials, participants were not provided compensation for their completion of the study survey about the visual KI template. In the fourth trial, patient participants were offered a parking voucher for completing the study survey.

Measures

The study team and research staff used six and eight items to assess participants' knowledge of trial-related procedures, risks and benefits, with true/false/unsure response options (eg, 'I will be asked to complete some tests on paper and the computer to check my memory and thinking'; 'I will need tests and an exam to see if I am eligible for the study'; 'I will definitely benefit directly from being in this study'). Incorrect and unsure responses were coded as incorrect and a total percentage correct was calculated per standard scoring guidelines for knowledge measures.[19] Next, we assessed decisional conflict or uncertainty related to decision-making about joining the trial, using the validated 4-item SURE measure.[20] Scores less than or equal to 3 indicate the presence of decisional conflict. We used the validated, 4-item Acceptability of Intervention Measure to evaluate the acceptability of visual KI pages.[21] Higher scores indicate greater acceptability. We also used items adapted from the Perceived Efficacy in Patient-Physician Interactions short form, which evaluates patients' self-efficacy or confidence in obtaining medical information and attention to their medical concerns, to understand participants' confidence in asking clinicians or research staff questions about study details.[22 23] We also explored attitudes with the consent information in the template using items adapted from the NIH Health Information National Trends Survey.[24]

To evaluate feasibility, we recorded the reach of the intervention within the pilot trials and time to IRB approval of protocol amendments to approve the visual KI page. We also assessed the number of modifications that were necessary to ensure the visual KI was appropriate for each pilot's unique consent process.

Patient and public involvement

Patients and community partners were involved in the conduct of this research. Specifically, we had a community advisory board from the Center for Collaborative Care Decisions and community advisory board members from the Institute for Clinical and Translational Sciences programme review the study materials, visual KI pages and measures.[25 26] We also included patients and community partners in a qualitative study to explore perceptions of the visual KI pages in more depth.[6]

RESULTS

We adapted three implementation science approaches and frameworks for our project and the local clinical research context.

Table 2 FRAME and FRAME-IS modifications

Modification type	What was modified	Nature of modification	When modification occurred	Who suggested modification	At what level of delivery	Fidelity consistent	Intent/goal
Content	Refining Colour scheme used in the templates	Changed colours to be engaging without being informal	Pre-implementation (pilot)	Community members; research team; design team	Network (system/ community)	Yes	Increase satisfaction Increase reach or engagement Single colour described as monotonous or 'institutional' but multiple colours were seen as informal and inconsistent
Context: format	Refining Orientation of visual template	Changed page orientation from landscape to portrait orientation	Pre-implementation (pilot)	Study participants (recipients); IRB members	Target intervention group	Yes	Increase satisfaction Increase reach or engagement Landscape documents are not easily incorporated into the rest of the format of consent, and not easily viewed in the e-consent platform
Context: format	Refining Delivery of visual consent	Printed and laminated copies of the visual consent for participants	Pre-implementation (pilot)	Research team	Clinic/unit level	Yes	Improve effectiveness (improve success of visual consents). Some e-consent procedures made visuals too small on a tablet or iPad. Some participants prefer reading on paper
Content	Refining Icons: distribution of icons on the page, types of icons/visuals used, number of icons used	Integrated visuals/ icons within the text to contextualise content versus in one location, standardising the look and feel of icons, limiting icons to 1–2 per box	Pre-implementation (pilot)	Study participants (recipients); community members; research team; design team	Network (system/ community) Target intervention group	Yes	Increase satisfaction Increase reach or engagement Limiting the number of icons avoids confusion about what each represents, avoids overwhelming and ensures enough white space; integrating icons throughout the page helps to associate the visuals with the content; standardising the look and feel of icons helps establish uniformity and consistency
Context: format	Tailoring Number of boxes available for content	Created six box and eight box formats for the template	Pre-implementation (pilot)	Research team; design team	Target intervention group	Yes	Improve effectiveness/outcomes Some study designs may be able to fit study information in six boxes, while more complex studies may have additional information that requires more boxes
Content	Refining Readability of template	Considered reading level, avoided legal/medical jargon, used plain language, increased white space, used bullet points to break up text, broke up lengthy sentences	Pre-implementation (pilot)	Community members; research team; design team	Target intervention group	Yes	Increase reach or engagement Improve effectiveness Clear, easy to understand, readable content can improve participant engagement and understanding of study procedures
Context: format	Refining Accessibility of template	Incorporated universal design principles (consider font type, font size, colour of text (avoided red/green))	Pre-implementation (pilot)	Community members; research team; design team	Target intervention group	Yes	Increase reach or engagement Improve effectiveness Promotes uptake of the template in multiple, diverse contexts and communities

Continued

Table 2 Continued

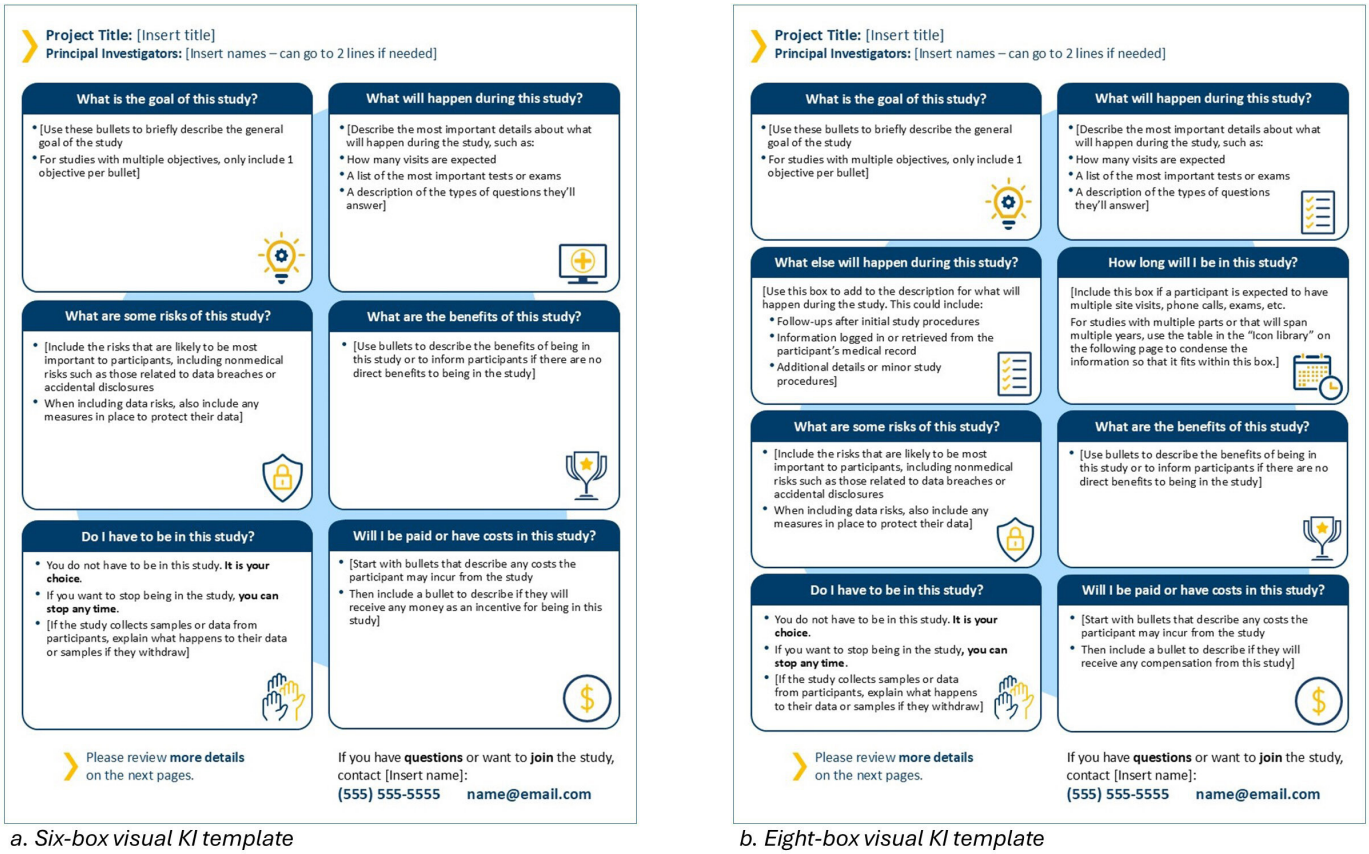
Modification type	What was modified	Nature of modification	When modification occurred	Who suggested modification	At what level of delivery	Fidelity consistent	Intent/goal
Content (BioBank)	Refining Study-specific content in the visual	Clarified whether or not more samples are needed for the study and emphasised there are no additional visits required for the study	Pre-implementation (pilot)	Team; study staff	Target intervention group	Yes	Improve effectiveness/outcomes Research team periodically performs interim data checks with study staff to make sure the visuals effectively condense content in the main consent and that study procedures (ie, cost, withdrawal from the study and requirements for study participation) are clear for study participants
Context: format	Refining Usability of templates	Updated text input to text boxes instead of typing directly in shapes	Pre-implementation (aim 2)	Research team	Target intervention group	Yes	Simplify creating text wrapping
Content	Refining Developed an icon library	Compiled icons with the support of Health Literacy Media for common study procedures, risks, benefits, payment, etc to include in the toolkit	Pre-implementation (pilot-aim)	IRB members	Target intervention group	Yes	Improve fit with recipients Improve reach or engagement Creating an icon library improves standardisation across studies and reduces the burden for research teams to independently figure out what icons to use for complex study information (ie, risks, benefits, etc). Standardisation also improves the likelihood of offering balanced visuals for benefits and risks to avoid unintentional coercion
Content	Refining Updated icon library	Created additional icons for study goals, study procedures, study risks and unique participant characteristics with the support of Health Literacy Media	Pre-implementation (aim 2)	Study staff; research team	Target intervention group	Yes	Increase reach or engagement Diversifying the types of icons available in the icon library promotes the use of visuals within broader contexts (ie, study types and study populations)
FRAME-IS							
Implementation strategy: conduct ongoing training	Added element: training video	Recorded a 5-minute training video to orient users to the project and explain how to navigate using the toolkit and its components	Pre-implementation (aim 2)	Community members; IRB members; research staff	Network (system/ community)	Yes	Increase the reach of visual KIs; increase adoption of visual KI pages Offering users a brief, virtual training video can help increase dissemination efforts by reducing the burden of study staff to offer live, in-person trainings
Implementation strategy: conduct educational meetings	Adding element: onboard 'super users'	Introduce visual KIs to protocol committee members, clinical trials design teams, and recruitment and enhancement teams	Implementation	Funder; IRB members	Network (system/ community)	Yes	Increase reach of visual KIs Onboarding additional personnel to be familiar with visual KI templates and procedures

Continued

Table 2 Continued

Modification type	What was modified	Nature of modification	When modification occurred	Who suggested modification	At what level of delivery	Fidelity consistent	Intent/goal
Implementation strategy: conduct ongoing training	Adding element: train 'super users'	Train additional staff including protocol committee members, clinical trials design teams, and recruitment and enhancement teams	Implementation	Funder; IRB members	Network (system/ community)	Yes	Increase adoption of visual KIs Training personnel outside of research teams and IRB members promotes uptake of visual KIs and promotes engagement from diverse end user groups involved in the conduct of human subjects research
Implementation strategy: capture and share local knowledge	Adding element: 'super users' and research team trainers supporting dissemination	Protocol committee members, clinical trials design teams, and recruitment enhancement teams supporting visual KI development and implementation	Implementation	IRB members	Network (system/ community)	Yes	Improve sustainability of visual KIs Removes burden from the study staff to individually support visual KI development. Super users can support dissemination efforts by helping local research teams based on others' experiences
Implementation strategy: conduct ongoing training/ capture and share local knowledge	Adding element: local conference or group meeting	Proposed hosting a conference or group meeting to share current findings and discuss implementation	Implementation	Study staff	Organisational	Yes	Increase reach of visual KIs Increase adoption of visual KIs Research teams and IRBs can routinely train new members. Conference will serve as an additional training opportunity for new team members and share lessons learnt and project progress to guide implementation discussions
Implementation strategy: mandate or incentivise changes	Tailoring	IRB encourages use of visual KIs as a recommendation versus required template	Pre-implementation	IRB members; study staff	Network (system/ community)	Yes	Increase adoption of visual KIs IRB support is an important factor in the feasibility of implementation. Visual KIs are encouraged by IRB reviewers, which supports implementation efforts and adoption of visual KIs
Implementation strategy: promote adaptability	Refining	Supporting research teams in numbering boxes and adapting risk section to suit study needs (ie, separate risks of standard treatment from risks of intervention/ study)	Pre-implementation (pilot)	Research teams; IRB members	Network (system/ community)	Yes	Improve the acceptability, appropriateness or feasibility of visual KI pages; increase the reach of visual KIs Promotes uptake of the template for multiple study types/contexts

FRAME, Framework for Reporting Adaptations and Modifications to Evidence-based Interventions; FRAME-IS, Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies; IRB, institutional review board; KI, key information.



a. Six-box visual KI template

b. Eight-box visual KI template

Figure 1 (A) Final six-box visual key information template. (B) Final eight-box visual key information template.

Implementation approach: Expert Recommendations for Implementing Change strategies

To lay the groundwork for effective implementation, we used selected Expert Recommendations for Implementing Change (ERIC). ERIC is a consensus document of 73 discrete strategies for effective implementation built by an expert panel of implementation scientists and clinicians. We started by *accessing new funding* and *building a coalition* of end-users (principal investigators (PIs) and research staff, IRB members and community members). With our end-users' feedback, we identified 12 applicable strategies to inform our implementation strategies (table 1).[27]

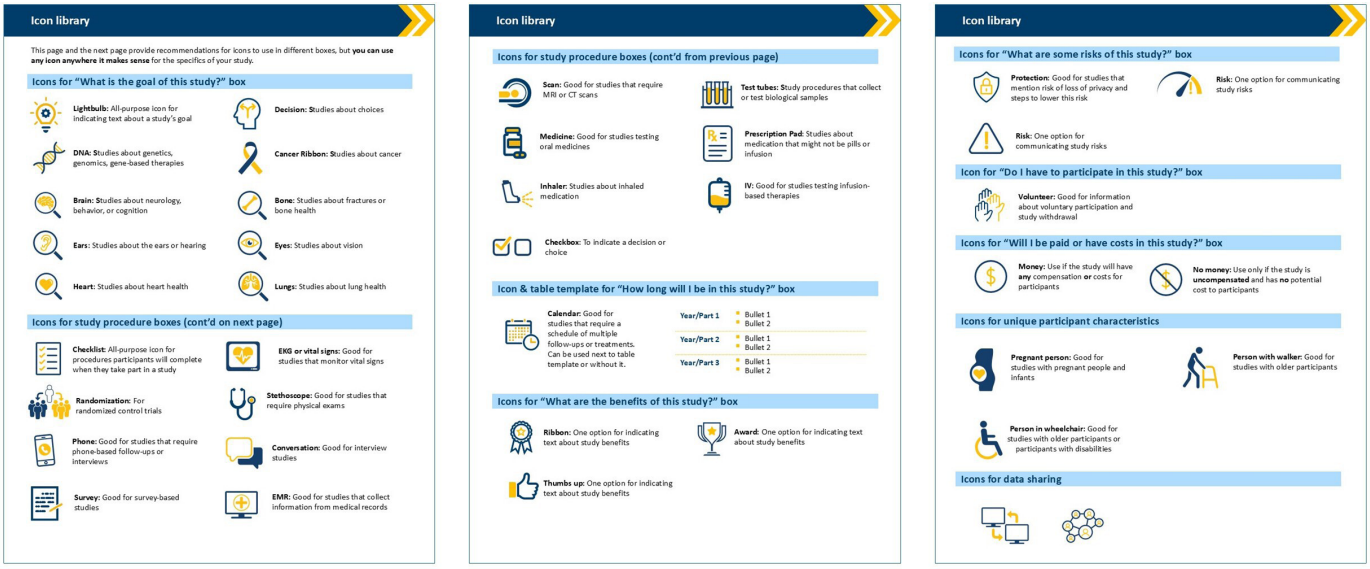
The 12 selected ERIC strategies facilitated our close collaboration with end-users throughout the pre-implementation and implementation phases. In the pre-implementation phase, we *conducted education meetings*, meeting on three occasions with two community advisory boards, holding two meetings with the IRB, presenting at institutional Work in Progress meetings, and meeting with the Washington University Bioethics Research Team over the course of 1 year to share updates, troubleshoot logistic challenges in real time and solicit feedback. Acknowledging clinical demands and workflow, we included online training modules, in-person didactics, group meetings, and conference calls to describe our KI template drafts and gather feedback. Our team *promoted adaptability* by collaborating with Health Literacy Media, a non-profit community partner with expertise in health communication, to incorporate end-users' feedback into the visual KI template.

In the implementation phase, the research team *audited and provided feedback* by providing interim data reports and assessing workflow considerations using audit and feedback to facilitate quality monitoring and improve adaptability. We also *obtained and used patient/family feedback* by generating monthly data summaries to track participant responses and proactively adapt implementation strategies.

Framework: Framework for Reporting Adaptations and Modifications to Evidence-based Interventions and Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies

To systematically record modifications and adaptations, we employed the Framework for Reporting Adaptations and Modifications to Evidence-based Interventions (FRAME[28]) for the intervention and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS[29]) for the implementation process (table 2). FRAME ensures that all relevant aspects of each modification are considered and addressed, including the modification itself, the reason for the modification, its timing and the magnitude of the modification, whereas FRAME-IS tracks modifications to the strategies used to implement change.

All changes made were fidelity-consistent and kept the original intent of the KI template with modifications made to improve the flow of the content. Most modifications proposed by end-users focused on increasing



a. Icon library page 1 b. Icon library page 2 c. Icon library page 3

Figure 2 Icon library.

participant engagement, especially via language, visuals and overall design. Building on the feedback of community members, the research team and design team, the KI section was written in plain language and incorporated health literacy-informed design principles such as increasing white space, using easily readable fonts and avoiding red/green colours to design for those with colour blindness. Colour schemes were selected that were neither too monotonous (described by one community partner as 'institutional'), nor overly colourful, which were perceived by some community partners as 'informal' or 'cartoonish'. We chose two colours, blue and yellow, to add visual interest without overwhelming readers. We also simplified and consolidated the number of icons and placed them near the text to which they referred so it did not appear to require a 'figure key' or 'legend' which could create confusion, as one community partner cautioned.

For studies with more extensive information for participants, several changes were made to optimise readability. Templates with both six and eight sections were created, allowing increased text, and visuals were rearranged throughout the consent to be integrated with relevant text information. By arranging visual aids with each text box, end-users and research and design teams improved readability while standardising the format of consents.

We also tracked edits to address logistical hurdles that could impact effective implementation. For example, per IRB members' feedback, KI templates were transformed from landscape to portrait orientation so that they could be incorporated with other consent sections and easily viewed when administered on electronic data collection platforms. Consent copies were printed and laminated for easier viewing in some studies, especially for those with visual impairments, those using a smartphone or those with limited computer self-efficacy to view documents on a screen. In one study, study-specific risks were separated from risks from standard treatment in the KI template to differentiate the two.

Notably, there were some features of the KI template that we were unable to change due to local context. Specifically, documents were required to be in a Rich Text Format (RTF) for the IRB submission system. The RTF format and use of the e-consent platform required converting the template to an image format, which limited alt-text for each icon and could not be read by a screen reader for those with visual impairments. While these features were due to our local context and could not be changed currently, we will monitor changes to policy and regulations at our site and others to adapt features as policies evolve or become more flexible over time.

Framework: Designing for Accelerated Translation

To accelerate the implementation of our improved KI templates, while dynamically incorporating real-time feedback, we used the Designing for Accelerated Translation (DART) framework. DART consists of three strategies for iterative innovation implementation and testing: prioritising early and meaningful partnerships across all stakeholders; user-centred design; and healthcare system buy-in.[30] In addition to developing strong, diverse partnerships with end-users as previously described, we executed user-centred design by dynamically seeking and incorporating user feedback during the implementation period. We sought institutional buy-in with key leaders who helped identify appropriate studies and PIs willing to quickly refine and adapt their consent forms.

KI template

Our final KI, a one-page, portrait-oriented template, is shown in figure 1. The body of the template consists of a grid, customisable for study-specific details, written in bolded white font against a navy background.[31] The highlighted template study sections include those

Table 3 Survey respondent demographics (N=85)

Age	n=83
Mean (SD)	65.7 (12.6)
Range	27–87
Gender	
Female	53 (62.4%)
Male	32 (37.7%)
Non-binary	0 (0.0%)
Prefer not to say	0 (0.0%)
Prefer to self-describe	0 (0.0%)
Ethnicity	
Latino/a/x or Hispanic	1 (1.2%)
Not Latino/a/x or Hispanic	83 (97.7%)
Not reported	1 (1.2%)
Race	
Caucasian or White	76 (89.4%)
Black or African-American	6 (7.1%)
Asian	1 (1.2%)
Native American or Alaskan Native	0 (0.0%)
Native Hawaiian or other Pacific Islander	0 (0.0%)
More than one race	2 (2.4%)
Education	
≤HS degree	13 (15.3%)
>HS degree	72 (84.7%)
Geographic location	
Rural	12 (14.1%)
Urban	58 (68.2%)
Suburban	14 (16.5%)
Missing	1 (1.2%)
Health literacy (SILS)[34]	
Limited	8 (9.4%)
Adequate	76 (89.4%)
Missing	1 (1.2%)

SILS, Single Item Literacy Screener.

recommended by the Common Rule and the local IRB as KI needed to consider study participation, such as the study goal, procedures, important risks, important benefits, voluntary participation and compensation or costs. One to three relevant icons are incorporated into the text in each box, which can be selected from a carefully curated library of simplified icons in the template's toolkit (figure 2). Blank space is allocated judiciously outside the boxes for IRB stamps, and inside the boxes for ease of reading. Details about how to use the template and adapt it for studies are provided to research staff, such as how to save the file and how to submit the file as part of the informed consent process for the IRB.

Feasibility, acceptability, satisfaction and preliminary efficacy

Across our four ongoing research studies, 85 participants completed surveys (table 3). Participants' average age was 65.7 years, and the majority of participants were female (n=53; 62.4%), white (n=76; 89.4%) and non-Hispanic (n=83; 97.7%). 58 (68.2%) stated that they live in an urban environment. All potential participants in each pilot study received the visual KI once it was approved by the IRB, resulting in an intervention reach of 100%. IRB approvals of amendments took under a week and required minimal to no edits to the proposed visuals.

The weighted mean of correct knowledge questions was 87.4 (range 77.8%–88.9%). The study aspects most frequently answered incorrectly were whether participants could withdraw from the study or whether they would directly benefit from participation (particularly in the cancer studies). Overall, participants found the template to be acceptable. Almost all (n=82; 96.5%) of survey respondents stated that they approved of their doctor using visual KI pages and 88.2% (n=75) of participants liked that their doctor used the visual KI page. Very few (n=9, 10.6%) participants reported experiencing decisional conflict about joining the study after reviewing the visual KI (table 4). Most participants expressed confidence in asking clinicians or research team members about study information. For example, 92.9% (n=79) reported feeling very confident asking their doctor questions about study details and 94.1% (n=80) reported feeling very confident asking for more information if they did not understand study details. Finally, participants had positive attitudes about consent information in the templates. 90.6% (n=77) of participants felt satisfied with the consent information while only 10.6% (n=9) of participants reported taking a lot of effort to understand the consent information. Only 2.4% (n=2) of participants found the consent information hard to understand.

DISCUSSION

This parallel feasibility study tested the feasibility, acceptability, satisfaction, preliminary efficacy and implementation process of using a visual KI template as part of informed consent for research at an academic medical centre ready for wide-scale implementation. The DART approach was an especially effective means of accelerating the implementation of our visual KI template. As we introduced the visual KI template and process, many additional study principal investigators and research coordinators requested that we support its use for their specific studies. The research team balanced continued testing with implementation in the local context. For example, the IRB teams and other institutional leaders were supportive of rapid implementation, but required time to prepare, train and equip reviewers and those overseeing human subjects research to understand the new process. ERIC strategies supported the implementation process by providing training, resources and identifying champions to support the process. In addition, PIs and

Table 4 Primary and secondary study outcomes

Study-specific knowledge Weighted mean=87.4%; range 77.8%–88.9%	
SURE: decisional conflict[20]	
Yes, experiencing conflict	9 (10.6%)
No, not experiencing conflict	76 (89.4%)
Acceptability of Intervention Measure (AIM)[21]	
1. I approve of my doctor using this visual consent form	
Agree	82 (96.5%)
Disagree	3 (3.5%)
2. Having my doctor use this visual consent form is appealing to me	
Agree	72 (84.7%)
Neutral	10 (11.8%)
Disagree	3 (3.5%)
3. I like that my doctor used this visual consent form	
Agree	75 (88.2%)
Neutral	7 (8.2%)
Disagree	3 (3.5%)
4. I welcome my doctor using this visual consent form	
Agree	73 (85.9%)
Neutral	7 (8.2%)
Disagree	3 (3.5%)
Did not answer	2 (2.6%)
Perceived Efficacy in Patient-Physician Interactions (PEPPI)[23 24]	
1. How confident were you in your ability to ask your doctor questions about study details?	
Very confident	79 (92.9%)
Less than very confident	6 (7.1%)
2. How confident were you in your ability to explain your concerns about study details to your doctor?	
Very confident	75 (88.2%)
Less than very confident	10 (11.8%)
3. How confident were you in your ability to understand what your doctor tells you about study details?	
Very confident	75 (88.2%)
Less than very confident	10 (11.8%)
4. How confident were you in your ability to ask your doctor for more information if you did not understand what they said about study details?	
Very confident	80 (94.1%)
Less than very confident	4 (4.7%)
Did not answer	1 (1.2%)
Attitudes toward the consent information, adapted from the Health Information National Trends Survey (HINTS)[24]	
1. It took a lot of effort to understand the consent information	
Agree	9 (10.6%)
Disagree	68 (80.0%)
Neutral	8 (9.4%)
2. You felt frustrated when viewing the consent information	
Agree	2 (2.4%)
Disagree	75 (88.2%)
Neutral	8 (9.4%)
3. You were concerned about the quality of the consent information	
Agree	6 (7.1%)
Disagree	75 (88.2%)
Neutral	4 (4.7%)
4. The consent information was hard to understand	
Agree	2 (2.6%)
Disagree	78 (91.8%)
Neutral	5 (5.9%)
5. You were satisfied with the consent information	
Agree	77 (90.6%)
Disagree	5 (5.9%)
Neutral	2 (2.4%)
Did not answer	1 (1.2%)

research coordinators suggested adaptations to the KI page to fit their study needs. For example, one cancer treatment study requested that we separate the risks of standard cancer treatment from the risks associated with a study-related procedure. We used FRAME to track this adaptation and supported this visual display to meet the needs of the specific end-user. However, only three substantial formatting modifications were necessary to tailor the original visual KI to study-specific contexts, suggesting that the template was highly feasible for implementation at baseline. Importantly, we continued testing outcomes of the intervention and reviewed data at regular intervals to ensure that we were not doing any harm by rapidly implementing the KI templates. Although any implemented programme can require further optimisation when executed, interventions are likely 'ready' when evidence suggests increased benefit with minimal harm, and end users are requesting implementation.

Results of the participant-level survey indicated that there was high knowledge (weighted mean=87.4% across trials). We analysed specific questions that individuals missed on the knowledge items and found that participants endorsed misunderstandings similar to those reported in the literature. These included logistics (eg, some participants in the biobank study were unsure about whether additional samples would be needed) and therapeutic misconception (individuals' overestimation of direct benefit by study participation when a study is aimed to assess future benefit, such as in one cancer treatment study, some participants were not sure about whether there would be direct benefits to themselves from the

investigational cancer treatment).[32] As we conducted interim analyses, we were able to adapt the knowledge questions and the KI templates with support from community partners and research teams to improve the clarity of these key study details. Our iterative edits may provide a replicable means of addressing widely prevalent, ethically problematic misunderstandings, such as therapeutic misconception, which has been well documented in the literature, especially in early investigational studies.[33]

The strengths of our study include its unique design, through which we have been able to simultaneously and iteratively improve and test our visual KI template. Adopting this approach has accelerated its implementation in a replicable fashion. Furthermore, our intervention reach was high: 100% of people used the consent intervention on implementation. Limitations of our study include its single institution and sample across varied studies. Its design, while conducive to rapid implementation, did not allow for a comparative control group. We also only tracked immediate responses to the KI page of consent, rather than a large multisite study also looking at enrolment (and diversity in enrolment). We plan to use these initial results towards a future larger multi-institutional randomised controlled trial, which may further validate our initial findings and build evidence for the impact of these forms on enrolment diversity and retention over time.

Conclusion

Informed consent documentation has become lengthier and more confusing over time, and frequently uses language that is at a significantly higher reading level than recommended. We developed a visual KI template to be used to improve informed consent, support participant engagement and understanding, and reduce barriers to study participation. Participants demonstrated high knowledge about studies, template satisfaction and rated it as acceptable for routine use. Other implementation measures including reach, ethics approval timelines and necessary functional modifications suggested a high degree of feasibility. Future work can test the impact of this KI template in diverse settings and institutions, using hybrid effectiveness/implementation study designs, to support widespread use.

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Contributors AH: drafting the work, substantial contributions to interpretation of data for work and final approval of publishable version; AJH: substantial contributions to conception/design of work, revising it critically for important intellectual content; KC and EG: substantial contributions to acquisition and analysis of data and revising it critically for intellectual content; JM: substantial contributions to the conception/design of work, interpretation of data, revising work critically for intellectual content; MP: substantial contributions to conception/design of work, acquisition, analysis and interpretation of work, revising work critically and approving final version for publication. Guarantor is MP.

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Competing interests MP was a consultant for UCB Biopharma in 2024 and EpiQ in 2023 on topics unrelated to the content of this manuscript. All other authors have no competing interests to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Washington University in St. Louis IRB 202405126, 202306057, 202310117, 202312076, and 202312073. All participants in this feasibility study reviewed a consent information sheet and agreed to the study prior to completing the survey. The visual KIs were approved as a modification to each study's existing consent documents in their respective IRB applications. Importantly, IRB reviewers recommended that the visual key information page be included as page 1 of the informed consent document for each study, rather than as a miscellaneous attachment or recruitment material, since it was being used as part of consent.

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