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A Community-Led Approach to Enhancing Informed Consent for Individuals With Vision Impairment

Fleur O'Hare[1,2] | David Foran[3] | Tessa Saunders[4] | Lisa Eckstein[5] | Gudrun Wells[5] | Daniel Talko[6] | Kevin Lee[6] | Shane Somerville[6] | Debra Simons[7] | Grace King[8] | Michael Burmeister[9] | John Paul Cruz[10] | Camille Paynter[11] | Lauren N. Ayton[1,2,12]

[1]Department of Optometry and Vision Sciences, University of Melbourne, Parkville, Victoria, Australia | [2]Centre for Eye Research Australia, East Melbourne, Victoria, Australia | [3]Equalus Advisory, Noosa Heads, Queensland, Australia | [4]Evaluation and Implementation Science Unit, Melbourne School of Population and Global Health, University of Melbourne, Parkville, Victoria, Australia | [5]CT:IQ, Bellberry Limited, Adelaide, South Australia, Australia | [6]Expert by Lived Experience, Research Partner, Melbourne, Victoria, Australia | [7]Expert by Lived Experience, Disability Advocate, Melbourne, Victoria, Australia | [8]Expert by Lived Experience, Research Partner, Perth, Western Australia, Australia | [9]Expert by Lived Experience, Research Partner, Brisbane, Queensland, Australia | [10]Melbourne Social Equity Institute, University of Melbourne, Parkville, Victoria, Australia | [11]Department of Audiology and Speech Pathology, University of Melbourne, Parkville, Victoria, Australia | [12]Department of Surgery Ophthalmology, University of Melbourne, East Melbourne, Victoria, Australia

Correspondence: Fleur O'Hare (oharef@unimelb.edu.au)

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ABSTRACT

Participant Information and Consent Forms (PICFs) are critical documents that help promote informed decision-making about research participation. However, many PICFs remain inaccessible to people with diverse needs, including those experiencing print disability. Providing information in multiple accessible formats can enhance inclusivity and support equitable access to research opportunities. The "Meeting Access and Inclusion Needs" (MAIN) project was a four-part, community-engaged, formative study employing qualitative research methods. Part 1 involved focus groups with eight disability advocacy organizations ($n = 21$ individuals) to identify accessibility requirements. Part 2 comprised a co-design workshop series ($n = 11$ participants with lived experience) to develop accessible PICF templates. Part 3 included individual user experience sessions ($n = 6$ participants) employing the think-aloud methodology and the Theoretical Framework of Acceptability questionnaire. Part 4 involved an independent accessibility audit by Vision Australia against digital accessibility standards. The MAIN Project resulted in three co-designed PICF formats (print, audio, and video). The co-design team emphasized that two to three format options were essential, with one participant noting: "Everyone's need is unique, and accessibility is about more options for more people." The accessibility audit confirmed all templates met standards with minor modifications (e.g., metadata additions, caption pixelation resolution, text color adjustment). All templates conformed with accessibility standards and best practice guidelines following final revisions. Community-engaged co-design successfully produced formative, accessible, multi-format PICF templates meeting accessibility standards. Offering two to three information formats enhances accessibility and supports

Abbreviations: AI, artificial intelligence; CT:IQ, Clinical Trials: Impact and Quality; MP3, MPEG-1 Audio Layer 3 [compressed audio file format]; MP4, MPEG-4 Part 14 [multimedia container format that can hold both audio and video as well as other media like text and images]; PICF, Participant information and consent form; TDF, Theoretical Domains Framework; TFA, Theoretical Framework of Acceptability; WCAG, Web Content Accessibility Guidelines.

Camille Paynter and Lauren N. Ayton are co-senior authors for this study.

inclusive research participation. These templates and accompanying guidelines provide researchers with practical resources to tailor informed consent processes to diverse needs, particularly for people with vision impacts. Further research should focus on large-scale implementation and evaluation across research settings and populations.

1 | Introduction

An accessible informed consent process offers participants with equitable access to information, promoting autonomous decision-making. Rather than a singular event, consent is a continuous, interactive process designed to be supplemented with a Participant Information and Consent Form (PICF) that supports and maintains informed decision-making (ICH GCP 2025). However, as technology advances, with trials such as personalized genetic therapies becoming available, PICFs have grown increasingly long and complex. Despite ethical and legal mandates for clarity, informed consent remains inaccessible for substantial portions of society (Schenker 2011; Tam et al. 2015).

People living with disabilities regularly face barriers to information access during research and healthcare interactions (Kuper and Shakespeare 2024; Sabatello and McDonald 2024). These barriers are not inevitable. Proactive, tailored approaches can mitigate or eliminate access challenges, enabling broader participation and more representative research evidence (Swenor and Deal 2022). The imperative is clear: design and deliver flexible consent processes supported by information provided in multiple accessible formats to meet diverse needs and encourage participation across society.

Print disability affects people with visual, physical, perceptual, or learning disabilities, and represents a significant global challenge (Kuper and Shakespeare 2024). Whilst precise global figures are unavailable, the scale of vision-related impacts on print readability is substantial. The Marrakesh Treaty (2013), which aims to modify copyright laws to increase access to published works for people with print disabilities, estimated that 285 million people worldwide have vision impairments alone (World Intellectual Property Organization 2013). The World Health Organization (WHO) reports that 2.2 billion people (over 25% of the global population) have some form of vision impairment, including both treatable and untreatable eye conditions. The WHO also reports that 1.3 billion people (16%) live with significant disability impacting their ability to read and understand information (World Health Organization 2023a, 2023b).

The United Nations Convention on the Rights of Persons with Disabilities (especially articles 9, 21, and 24) states that people with print disability have the right to equal access to knowledge and information at the same time, cost, and quality as everyone else (United Nations 2007). Yet despite the Convention being in place for over two decades – and, in Australia, national and state-level anti-discrimination laws – people with disability continue to encounter information access barriers (McCallum 2020). Australia's Disability Royal Commission (published in September 2023) starkly acknowledged this reality: "despite obligations under international and domestic law, many people with disability in Australia still cannot access information and communications on an equal basis to people without disability" (Commonwealth of Australia 2023). People living with blindness or low vision were noted as communities who are particularly impacted, especially in the context of health and medical interactions where decisions are contingent on accessible information (Commonwealth of Australia 2023).

1.1 | The Call for More Inclusive Informed Consent Processes

Effective strategies to enhance participant engagement and information access include offering clear, concise information in accessible formats and languages tailored to individual needs (Chien and Wu 2024). A critical component is improving readability, ensuring the reading grade level of consent materials matches participants' literacy levels. This point cannot be underestimated given that participant information and consent forms are notoriously complex and commonly demand tertiary level education to understand (O'Sullivan et al. 2020; Symons and Davis 2022; Terblanche and Burgess 2010). Participant-centered adaptations to the informed consent process have shown promise in enhancing comprehension during informed consent (Flory and Emanuel 2004; Nishimura et al. 2013; Paramasivam et al. 2021; Pietrzykowski and Smilowska 2021), with growing evidence that varied formats, particularly audio-visual materials, improve information access (Gesualdo et al. 2021; Synnot et al. 2014). This approach is especially beneficial for people who require hearing support (Anderson et al. 2020; Wittich et al. 2023). However, evidence for the effectiveness of such adaptations for people who require vision support is lacking (Sabatello et al. 2019).

Beyond multimedia information aids, research teams should offer information in participants' preferred spoken or signed language and provide verbal consent options alongside written consent (Chien and Wu 2024; Paramasivam et al. 2021; Coleman et al. 2021; Rios et al. 2016; Watharow and Wayland 2022). Additionally, new resources such as the "Guidelines for Tailoring the Informed Consent Process in Clinical Studies" (developed by the i-Consent consortium) have emerged that aim to support researchers in adopting accessible and inclusive informed consent processes (Fons-Martinez et al. 2022). Our previous work demonstrates that research staff are motivated to provide accessible information formats during informed consent processes but often lack the necessary resources (O'Hare, Paynter, et al. 2026). This finding aligns with broader evidence showing that systemic barriers operate at both organizational and individual levels (Alemayehu et al. 2018; Djurisic et al. 2017). Two interconnected gaps undermine these efforts: research teams lack education on accessibility strategies tailored to specific access needs, including vision impairment (Markman et al. 2023; O'Sullivan et al. 2021; Trujillo Tanner et al. 2018), and staff are often unaware of available technologies and support services that could help implement these strategies (Bigby et al. 2023).

1.2 | Community Involvement in Implementing Change in Informed Consent Practices

One way to address gaps in knowledge and skills is to partner with communities to design solutions that meet their information access needs. Community-based participatory research emphasizes collaboration between researchers, people with lived experience, and community representatives as equal partners throughout the research process (Duran et al. 2019; Wallerstein et al. 2018). This approach prioritizes community priorities and drives positive change by centering those most affected by research outcomes. Researchers increasingly recognize the value that diverse perspectives and experiential knowledge bring to health research (Bailie et al. 2023). This shift reflects a broader movement towards genuine consumer and community involvement as standard practice. The principle of "nothing about us without us" now guides many research teams, who actively include people with lived experience as team members – not merely as data contributors. These individuals shape research direction and conduct by offering ideas and insights, distinguishing their role from that of traditional research participants. This represents true co-design and co-production: research conducted *with* or *by* communities, rather than *for* or *to* them (Research for Development Impact Network 2020).

Building on previous consumer and community-engaged research, we sought to enhance inclusion and accessibility in informed consent practice (Symons et al. 2022). We recognized that whilst researchers are motivated to offer accessible information formats, many lack the resources and capability to do so (Fons-Martinez et al. 2022; Markman et al. 2023; O'Sullivan et al. 2021; Trujillo Tanner et al. 2018; Bigby et al. 2023). Critically, empirical evidence is sparse regarding the impact of tailored information formats for people with vision impairment. Although a small number of studies have identified the perceived value of large font, braille, and screen-reader-compatible digital formats (Trujillo Tanner et al. 2018; Duckett and Pratt 2001; Kim and Sutharson 2022; McGrath et al. 2025; Williams 2009), direct evidence on implementation outcomes such as acceptability, accessibility, and appropriateness as experienced by recipients remains absent.

2 | Study Objectives

In response to these gaps, our team developed the "Meeting Access and Inclusion Needs" (MAIN n.d.) project: a four-part, formative, community-engaged study exploring inclusion and accessibility in informed consent processes. Building on prior work, we aimed to co-design information templates, tools, and resources that researchers could adapt to prospective participants' specific needs.

The study objectives were to:

1. Explore methods to support inclusive online participation via focus groups with senior staff from community and disability advocacy groups.
2. Co-design templates and tools through a workshop series with people with lived experience of disability, primarily visual disability.
3. Assess the acceptability and usability of templates and tools via user experience sessions.
4. Audit templates, tools, and guides against accessibility standards.

2.1 | Participant Roles

People with lived experience of disability undertook dual roles throughout the project. As research partners, they participated in co-design phases (Objectives 2–3), discussed findings, contributed to co-authorship, and engaged in community dissemination. As research participants, they provided data to measure implementation outcomes (Objective 3).

3 | Positionality

We adopt the social and human rights models of disability (Retief and Letšosa 2018) and use the term "challenge" to describe barriers imposed by the environment, not deficits inherent to disability. Information access challenges arise when barriers prevent equitable access; for example, when format or language choices limit readability, or when differing sensory, cognitive, language, and learning needs are not considered. In this study, it is considered that an information access challenge can be reduced or overcome by researchers by implementing accessibility and inclusion strategies in informed consent processes. We acknowledge that terminology can have an impact on a person's identity, well-being, and inherent dignity. Terminology is evolving, and presently, we have chosen to use person-first language throughout this manuscript.

3.1 | Community Engaged Project Team

The Principal Investigator (F. O. H.) is a clinician-researcher with over 25 years of experience collaborating with the low vision and blindness community. The lead co-investigator (D. F.) brings expertise in access and inclusion, a background in science and health, and identifies as a member of the blindness community.

3.2 | Core Co-Design Team

Six individuals with lived experience of chronic eye conditions formed the core co-design team and led decision-making. The onset of eye conditions ranged from congenital to middle adulthood. A further four individuals with lived experience of disability participated in selected phases of co-design. Together, this group contributed diverse skills and knowledge in access and inclusion, telecommunications, health service coordination, and education. Beyond data analysis and interpretation, the team aimed to collaboratively generate research evidence for public awareness and potential policy impact.

3.3 | Extended Research Team

Five researchers with expertise in vision research, implementation science, and qualitative methods provided design and

analytical support. Three of these researchers also bring lived experience of blindness, caring for someone with low vision or cancer, offering both internal (insider) and external (outsider) perspectives. Throughout the project, we consulted with clinical trials experts, disability advocacy leaders, and individuals with varied lived experiences (see Acknowledgments).

3.4 | Team Composition and Limitations

We intentionally built a team with diverse lived experiences, gender, educational backgrounds, and ages. Rather than employing a formal selection process, we promoted avenues to self-nominate (refer also to Section 6.1 below). We offered a flexible participation approach that allowed team members to opt in and out at each step, participate according to their individual capacity, and adjust their involvement based on personal circumstances.

4 | Methods

This project comprised four sequential parts utilizing qualitative research methods. We distinguished between two key approaches: focus groups, which gathered understanding of specific topics through structured questioning, and workshops, which facilitated interactive problem-solving, collaborative decision-making, and co-creation of solutions (Slattery et al. 2020). Workshops emphasized experience sharing, choice-making, and equal participation from all co-designers. We applied online experience-based co-design principles to structure our workshops (Eidenskog et al. 2024; Carey et al. 2025). Phone calls and emails supplemented communication.

Collaborators in this study preferred the term "research partner or collaborator" to consumer or advisor. This section will provide an overview of the methods undertaken at each stage.

4.1 | Ethical Approval and Reporting Standards

The study was approved by St Vincent's Hospital Melbourne human ethics committee (084/24) and the Centre for Eye Research Australia's research governance office. The protocol with Open Science Framework (OSF; identifier 10.17605/OSF.IO/B4ZWA). We followed the Standards for Reporting Qualitative Research (O'Brien et al. 2014), COnsolidated criteria for REporting Qualitative research Checklist (COREQ) (Tong et al. 2007), and the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) checklist (Staniszewska et al. 2017).

4.2 | Overarching Theoretical Models

We reviewed a range of possible candidate frameworks and identified the Theoretical Domains Framework (TDF) as best aligned with the research topic (Atkins et al. 2017; French et al. 2012). The TDF is an evidence-based model to identify barriers and facilitators towards change in healthcare implementation. This framework helped structure the inquiry into four phases relating to (1) the problem defined from varied stakeholder perspectives, (2) what factors contribute to the problem, (3) what strategies can help solve the problem, and (4) how change can be measured and understood. Additionally, the Theoretical Framework of Acceptability (TFA) was used to measure perceived acceptability of the information template set (Sekhon et al. 2022). Each information format was assessed using a 5-point Likert scale across the eight acceptability constructs: affective attitude, perceived burden, ethicality, perceived effectiveness, intervention coherence, self-efficacy, and overall acceptability. Qualitative insights were recorded verbatim as open text for each item.

5 | Part 1: Focus Groups With Industry Leaders and Experts

From November 2024 to January 2025, we conducted individual focus groups with 8 leading community organizations that support and advocate for people with disabilities, with 21 individuals participating. These organizations were national or state-based services, with a prioritization on supporting people living with visual disability encompassing low vision and blindness (listed in Acknowledgments).

We provided each organization with a focus group agenda and sought advice on three key questions:

1. What are the best ways to host an accessible workshop? For example, setting.
2. What current technologies and accessibility supports would work well in this setting?
3. What are the main access challenges in these settings, and what strategies address them?

5.1 | Focus Group Results: Communication Plan

Based on the focus group feedback, we developed a "Communication Plan" outlining accessibility accommodations for vision, hearing, sensory, emotional, and communication needs. Key elements included: optional camera use, disabled chat during key moments, no screen sharing, agenda and materials in varied accessible formats (provided 2 weeks prior to the meeting), individual pre-brief and debrief opportunities, and post-workshop transcripts and summaries.

6 | Part 2: Co-Design Workshop #1

6.1 | Recruitment and Eligibility

Workshop participants were recruited through organizations participating in Part 1. We designed invitation materials (e.g., Workshop Flyer) with co-researchers with lived experience and provided these in multiple formats: digital accessible Word documents (font sizes 14–18, black text on white background, headers and styles for screen reader compatibility), MP4 video with large open captions (white, bold, sans serif font on black bar), and MP3 audio file. Eligibility criteria were minimal, requiring only the availability to attend a 2–3 h online workshop and the ability to communicate comfortably in English. Attendees were advised that rest breaks were scheduled as part

of the workshop duration and that they would be compensated for their time.

6.2 | Ethical Procedures

The Principal Investigator contacted each candidate by phone to discuss the study, identify preferred information formats, and assess communication needs. Verbal consent was obtained following a comprehensive discussion process, which included repeated checks on willingness to participate, opportunities to clarify information and address questions, and explanations of options for ongoing involvement. Information on research ethics, privacy protection, and confidentiality was provided and discussed. Throughout the process, the Principal Investigator maintained ongoing dialog with each participant to develop relational accessibility and trust.

6.3 | Workshop Design and Structure

Participants resided across multiple Australian states; therefore, we selected an online Zoom workshop based on participant preferences. The Communication Plan from Part 1 and an ability-based, strengths-focused engagement model (Wobbrock et al. 2011) guided workshop planning and structure.

Two weeks prior to the meeting, participants received an agenda and a workshop guide that explained Zoom navigation, keyboard shortcuts, and camera options. Two lead investigators (F. O. H. and D. F.) facilitated the workshop and provided technical support. Participants were financially compensated for their time, including preparation time.

6.4 | Participant Information and Consent Templates

We made a strategic decision to create a "starting point" for discussion in the first workshop. We used the "InFORMed" project PICF template for written informed consent (version June 12, 2024), co-designed by the CT:IQ national working group with consumers across the clinical research sector (Symons et al. 2022). Prior work identified what researchers and research participants wanted changed in current consent forms (O'Hare, Paynter, et al. 2026; O'Hare, Ayton, et al. 2026). We created two print template versions, and an audio and video template for workshop discussion:

1. **Current format**: Standard InFORMed PICF template.
2. **Accessible format**: Revised design incorporating accessibility modifications based on VisAbility (VisAbility WA 2025), Vision Australia (Vision Australia 2024), and Centre for Accessibility Australia recommendations (Centre for Accessibility Australia 2025).
3. **Audio format**: Audio narration and summary of the project featured in the accessible format example.
4. **Video**: No graphics or footage of a person, instead, large open and high contrast captions were presented on a dark background.

Language was guided by the Suitability of Assessment Measures tool (Doak et al. 1996) and the Clear Communication Index checklist (Baur and Prue 2014). We calculated literacy and readability using Flesch-Kincaid and Flesch Reading Ease scores. Participants previewed the digital format examples before the workshop. Print templates were formatted in Microsoft Word (docx), videos in MP4, and audio in MP3.

6.5 | Workshop Facilitation

Section 1: Information access (approximately 1.5 h).

Each workshop participant was asked by a facilitator, "What stands out" from each format (Word, then audio, and video), focusing on perceived barriers and enablers to information access. Speaker order ("communication order") was coordinated by one of the facilitators (F.O.H), who introduced each member of the group and monitored speaking time to ensure each person was given the opportunity to share their thoughts.

Section 2: Broader experiences and co-design (approximately 1.5 h).

Participants considered four questions:

- What key information should be conveyed? (Prompt: information needed to decide whether to participate in research).
- What is important for the broader community? (Prompt: information needs of low vision, blindness, and disability communities).
- What else could be added? (Prompt: other ways to provide information).
- How could this be implemented? (Prompt: resources and feasibility).

Facilitators summarized key points during the workshop. The 3 h workshop included two rest breaks. We provided participants with a full transcript, discussion summary, and recommendations via email after the workshop. Member checking was encouraged (Urry et al. 2024). We used a modified Delphi approach (Khodyakov et al. 2020) via email to refine feedback and develop final recommendations for a second set of information prototypes.

6.6 | Workshop Results

Purposive sampling through community support agencies identified 17 people interested in the project. Of these, 11 participated in a workshop on March 19, 2025, while the other interested people were unavailable on that date.

Four key recommendations were made:

1. Enhance accessibility within the InFORMed PICF template.
2. Revise the audio template and develop a guide for researchers to develop their own audio PICFs.
3. Revise the video template and develop a researcher's instruction guide.

4. Create supplementary audio-visual materials showcasing positive research participation experiences, for example, a video featuring participants discussing their research involvement.

The first three recommendations are detailed below. The methods used to develop the fourth recommendation are not covered in this manuscript (see reference list to a co-created video and audio library: https://www.cera.org.au/consumer-resources/).

7 | Part 3: User Experience Sessions

7.1 | Template Development and Refinement

7.1.1 | Initial Review by Screen Reader Users

Two screen reader users reviewed the first draft of the revised prototype template set (version 1.0, July 20, 2025), which included:

- A vision-accessible InFORMed print template.
- A video with open captions.
- An audio narration template.

Online discussions were held via Zoom on July 25, 2025, and July 30, 2025, with the Principal Investigator and the two research collaborators. Feedback was incorporated to improve usability and screen reader compatibility, resulting in version 2.0 (July 31, 2025).

7.1.2 | Expert Review and Finalization

Interest holders and digital accessibility experts then reviewed the templates and suggested minor changes to the print template, specifically regarding brackets and the signature section presentation. This resulted in the final template set (version 3.0, August 01, 2025) used for user experience sessions.

7.2 | Audio and Video Format Creation

Audio and video formats were created using Descript (version 125.0.11, https://web.descript.com/). Descript is an all-in-one audio and video editing platform that uses artificial intelligence (AI)-powered tools to create content. We also conducted a Privacy Impact Assessment of the tool, which found no significant risks and confirmed that adequate mitigation strategies were in place. The process for creating audio and visual formats in Descript involved:

1. Writing a script in Word.
2. Importing the script into Descript.
3. Selecting two AI voices (one male, one female) for both formats.
4. Generating an audio MP3 file and a video MP4 file with large open captions.

7.3 | Format Specifications

- **Video design:** black background with large white open captions centered on screen.
- **Duration:** both formats were just under 4 min.
- **Captions:** centered open captions (burned into the video) appearing across two lines.

7.4 | Supporting Materials

The Principal Investigator developed accompanying instruction guides for each format, which were reviewed by the project team. The project team and two consumer representatives also reviewed the content and face validity (order, phrasing, clarity) of each of the acceptability (TFA) questions and response options.

7.5 | Participants

Six individuals from the first workshop participated in individual one-to-one user experience sessions between August 07 and 29, 2025. The Principal Investigator facilitated all sessions, which were conducted either via Zoom or in-person according to participant preference. Prior to each session, participants received phone-based education and training on the planned methods.

7.6 | User Experience Session Structure

7.6.1 | Think Aloud Method

The sessions were guided by the "think aloud" method (Ericsson and Simon 1980), a qualitative approach that uncovers cognitive processes and decision-making strategies as participants voice their thoughts whilst performing a task (Noushad et al. 2024). This method was combined with behavioral observation.

Participants received the following instructions:

> *Try to say everything that comes to your mind while you engage with the task. Even if your thoughts wander from the task, I want to hear them. Say as much as you feel comfortable saying. Don't try to plan or explain what you say, just act as if you were speaking to yourself.*

7.6.2 | Task and Participant Guidance

Participants were asked to:

1. Access their email,
2. Download the attached information set,
3. Access the information in their preferred order and manner.

Throughout the session, participants were encouraged to:

- Verbalize all thoughts, including those seemingly unrelated to the task.
- Speak continuously, as if thinking aloud to themselves.
- Describe their actions, decisions, and any problems encountered.

- Talk through their problem-solving process.

7.7 | Acceptability and Usability Assessment

At the end of each session, participants rated the acceptability of each of the three formats using the TFA questionnaire, which the Principal Investigator administered and recorded on a hard-copy form.

8 | Data Analysis

8.1 | Analytical Approach

Qualitative content analysis was used to analyze textual content from user experience sessions and open-ended TFA questionnaire responses (Elo and Kyngäs 2008). The Principal Investigator led the qualitative data analysis, with supervision and collaboration from two other researchers (T. S. and C. P.), each with extensive experience in evaluating qualitative data. NVivo software (QSR International Ptd Ltd., Melbourne) was used to support this analysis.

A modified Framework Analysis approach was employed (Ramanadhan et al. 2021). Top-tier categories were the format type (i.e., Word, Audio, Video). Under these subcategories were open codes derived using an inductive content analysis approach (Fereday and Muir-Cochrane 2006). Subcategories were informed by accessibility components, and data excerpts were organized under these open codes. These codes were subsequently synthesized into recommendations to support iterative format refinement.

8.2 | Results

Of the six individuals who participated in the user experience sessions, two were female and four were male (age range 32–63). Each person had a selection of communication preferences, assistive technology, and devices, and reported varying levels of sight to no sight (see Table 1). Acceptability scores (TFA) varied across formats, with the rating matrix and responses shown in Table 2 and a summary presented below.

8.2.1 | Word Print Format

The word format was generally "liked" by 4 of 6 participants. Half the group rated perceived burden as "no effort," and all participants considered it to be "fair" or "very fair" in its alignment with ethical principles and personal values. All participants agreed (strongly or somewhat) that the format effectively improved accessibility and felt "very confident" engaging with the document. None reported that the format interfered with other priorities or commitments. Overall acceptability was rated as "acceptable" (4/6) or "completely acceptable" (2/6).

8.2.2 | Audio Format

The audio format was similarly "liked" by four of six participants. Five participants rated perceived burden as "a little effort," and all rated the format as "fair" or "very fair." Most participants (5/6) strongly agreed that the format was broadly effective in improving accessibility and felt "very confident" engaging with it. All participants agreed it did not interfere with other priorities or commitments. Overall acceptability was split evenly: "acceptable" (3/6) and "completely acceptable" (3/6).

8.2.3 | Video With Open Captions Format

The video format showed the most varied ratings across all three formats. It was "liked" by three of six participants. Perceived burden ratings ranged from neutral to "no effort." Participants' rating of alignment with ethical principles and personal values ranged from "unfair" to "very fair." Opinions on accessibility effectiveness were evenly divided between agreement and strong agreement. Three participants felt "very confident" engaging with the format. Ratings on interference with priorities and overall acceptability were similarly varied.

8.3 | Summary of Findings

User experience data were coded by information format. This analysis identified eight improvement categories for the Word template (e.g., heading structure, language, links), four for the audio format, and two for the video format. The template set was subsequently updated based on these recommendations, with key changes including reconfiguring the Word consent form to allow manual entry of consent choices (Yes/No) and the use of unique table bookmarks.

Participant P7 highlighted the importance of accessible information for all:

> *The Word format is important because everyone gets this so we should as well. It basically normalizes the process, so non-sighted people get the same options that sighted people get.*

Participants also discussed voice characteristics for audio and video formats, noting difficulty in sourcing an AI voice with an Australian accent. Recommendations for the video format included featuring a speaker ("talking head") with open captions and ensuring voice speed is not too slow.

9 | Part 3: Co-Design Workshop #2

The co-design project team, comprising those who piloted the information set and those who participated in the user experience testing sessions, met for a follow-up collaborative workshop on September 19, 2025. The same methodology was applied as described above.

9.1 | Template Updates

Template changes were agreed through an iterative, co-design-led process involving workshop discussion, between-session refinement via phone and email, and review with the broader project team. All three file formats were updated accordingly, alongside minor wording revisions to the InFORMed template made in consultation with the CT:IQ working group.

TABLE 1 | User experience team demographics, communication, and information needs.

Participant #	Gender	Age	Self-described vision level	Communication preferences	Strategies for information access	Apps/Devices for information access
#1	M	43	Legally blind	Screen reader, screen magnifier, digital print, auditory	Screen magnification using the built-in software for short text, listen to a large body of text using a screen reader, or converting text into speech	MacOS and iOS devices with in-built assistive technology (e.g., VoiceOver, Zoom)
#2	M	52	Virtual blindness, some light perception	Auditory, digital print with screen reader	Text-to-speech, audio description	iOS devices with VoiceOver, NVDA, Narrator, Siri, and Be My Eyes
#3	F	39	Totally blind from birth	Accessible digital formats	Format screen reader user	JAWS screen reader, iPhone VoiceOver
#4	M	61	5% vision in each eye, no central vision, legally blind with some peripheral vision	Auditory, digital print with screen reader	Document magnification, Microsoft Word Read Aloud, taking a photo, and magnifying	Claro reader, Zoom text, Be My Eyes, and Metaglasses
#5	M	48	All field reduced (central and side), color is reduced, sensitive to glare, requiring more light to see	Auditory, verbal, digital print/ electronic, screen reader, trusted supporter	Document magnification, Microsoft Word Read Aloud, taking a photo, and magnifying	Apple, Zoom text
#6	M	51	Legally blind, narrow field of vision, requires ideal light and contrast.	Digital/electronic, auditory, verbal	Document magnification, VoiceOver, Read Aloud, color contrast conversion (light text, dark background)	Windows, Android, Ruby reader, DAISY reader
#7	F	63	Legally blind, can see print up close with one eye only	Digital print, verbal, auditory, electronic	Magnified print, enlarging font, contrast conversion on computer (light text, dark background)	Zoom text (iPad), Apple
#8	M	47	Difficulty seeing at night, central vision intact with restricted peripheral vision	Print, verbal, auditory	Plain language, font size 14 and above, black text on white background	Microsoft Suite in-built accessibility features

TABLE 2 | Theoretical Framework of Acceptability ratings from user experience sessions.

TFA construct	TFA item (The extend to which ... for each format)	Rating (*n*)
Affective attitude	You liked or disliked the:	
	Word/Print	Strongly like (3), like (3).
	Audio	Strongly like (1), like (4), neutral (1).
	Video	Strongly like (1), like (3), neutral (2), dislike (1).
Burden	How much effort did it take to access the information:	
	Word/Print	No effort at all (3), a little effort (2), neutral (1)
	Audio	A little effort (6).
	Video	No effort (2), a little effort (2), neutral (2).
Ethicality	How fair is the format for people with vision impairment:	
	Word/Print	Very fair (3), fair (3).
	Audio	Very fair (3), fair (3).
	Video	Very fair (2), fair (2), unfair (2).
Perceived effectiveness	The format has improved information accessibility:	
	Word/Print	Strongly agree (3), agree (3).
	Audio	Strongly agree (4), agree (2).
	Video	Strongly agree (2), agree (2), neutral (1), disagree (1).
Intervention coherence	It is clear how the format will improve information accessibility:	
	Word/Print	Strongly agree (3). agree (2). neutral (1).
	Audio	Strongly agree (3), agree (3).
	Video	Strongly agree (2), agree (3), neutral (1).
Self-efficacy	How confident did you feel engaging with the format:	
	Word/Print	Very confident (4), confident (2).
	Audio	Very confident (5), confident (1).
	Video	Very confident (3), confident (2), neutral (1).
Opportunity costs	Engaging with the format interfered with other priorities or commitments:	

(Continues)

TABLE 2 | (Continued)

TFA construct	TFA item (The extend to which ... for each format)	Rating (*n*)
	Word/Print	Strongly disagree (3), disagree (3).
	Audio	Strongly agree (4), disagree (2).
	Video	Strongly disagree (2), disagree (2), neutral (2).
Acceptability	How acceptable was the format for you:	
	Word/Print	Completely acceptable (2), acceptable (4).
	Audio	Completely acceptable (3), acceptable (3).
	Video	Completely acceptable (2), acceptable (1), neutral (2), unacceptable (1).

5-point Likert scale key

Rating	1	2	3	4	5
Affective attitude	Strongly dislike	Dislike	Neutral/no opinion	Like	Strongly like
Burden	Huge effort	A lot of effort	Neutral/no opinion	A little effort	No effort at all
Ethicality	Very unfair	Unfair	Neutral/no opinion	Fair	Very Fair
Perceived effectiveness	Strongly disagree	Disagree	Neutral/no opinion	Agree	Strongly agree
Intervention coherence	Strongly disagree	Disagree	Neutral/no opinion	Agree	Strongly agree
Self-efficacy	Very unconfident	Unconfident	Neutral/no opinion	Confident	Very Confident
Opportunity costs	Strongly agree	Agree	Neutral/no opinion	Disagree	Strongly disagree
Acceptability	Completely unacceptable	Unacceptable	Neutral/no opinion	Acceptable	Completely acceptable

9.2 | Co-Design Feedback on Template Formats

9.2.1 | *Word Format*

The co-design team was unanimous in their decision that the Word template ("InFORMed vision accessible PICF template") was acceptable, accessible, and appropriate, with no further format recommendations for improvement. In digital form, this format was perceived as universal because it allows users to manipulate the document to suit their needs (e.g., zoom text, enlarge font, convert print color, use screen reader software).

9.2.2 | *Audio Format*

Whilst Word's built-in "read aloud" function was useful, a separate audio format offered additional benefits, particularly the ability for people to "access anywhere anytime" and "on the go" (P1, P4, P5). The suggestion to embed chapter breaks in the content to enable the listener to move forward and backward across the content was supported by the group. The audio template and guide were updated accordingly.

Compared with video, the audio format has the advantage of being a smaller file size (MP3 file format) and therefore easier to download and access on mobile devices that support MP3 formats. These include mobile phones, iPads, and electronic readers (e.g., DAISY, Victor Reder Trek).

9.2.3 | *Video Format*

The video template, which featured an avatar speaker with large open captions (white captions surrounded by a black bar), received mixed appraisals. Generally, it was perceived as engaging with a broader community appeal. However, the voice-over occasionally did not synchronize with the movement of the avatar's lips, an issue noted as inherent when using generative AI avatars. Half of the group, who are regular screen reader users, routinely listen to auditory information between 1.6 and 1.8 times faster. At increased video speed, open caption display time shortened proportionally, causing co-designers to ignore captions and focus on the audio instead.

9.2.4 | *Multiple Format Options as a Design Principle*

Reflecting on broader community needs, the co-design team emphasized that offering multiple format options was essential to accessibility. This principle was articulated by Participant 4:

> *Everyone's need is unique, and accessibility is about more options for more people.*

The deluge of information and paperwork when first being informed about a research study or clinical trial was discussed. Some co-design members raised concerns about the paradox of choice (P1, P3, P5), questioning whether offering too many options might be overwhelming, particularly for people encountering research information for the first time. At the same time, the availability of two to three information format options was highly valued, as it extended the range of access options for diverse information and communication preferences. The intention to provide a limited range of options to support choice was articulated by Participant 2, who stated:

> *Choice and control are important and providing enough opportunity to get access to the information that best suits them, given we can't give everybody everything that they will want. I think we will meet the meat of the curve.*

9.3 | PowerPoint Video Template

Building on this commitment to multiple formats, the co-design group discussed creating videos using PowerPoint. The team agreed on the following specifications:

- Dark background with white or yellow text.
- Largest possible font size on each slide.
- Voiceover text must correspond identically to on-slide text.

PowerPoint was perceived as a familiar "tool in a researcher's wheelhouse," offering the practical advantage of bridging a skills gap. The format also permitted recording voiceover and converting content into a video format (MP4 file). This capability was seen as a means to mitigate the inaccessible features of the PowerPoint format itself.

9.3.1 | *Unresolved Design Considerations*

Two areas were identified during the workshops where consensus was not reached. The first is related to the voice for audio and video formats. The option of featuring a lead researcher or another project team member in these formats was discussed. Reported advantages included introducing prospective participants to key contacts, supporting trust and relational familiarity, and offering a natural voice cadence, inflection, and accent, with lip synchronization in video formats. However, concerns were raised regarding the resource burden of producing and reviewing human-voiced recordings. Co-designers noted that an AI-generated audio narration could be produced in under an hour using a prepared plain-language script, whereas recording and refining an audio narration made by the researcher may require several hours and multiple iterations.

A second unresolved area concerned how to accommodate accessible alternatives to written signature blocks within the print PICF template. While strong support was expressed for documenting consent verbally and/or via audio recording, further development of these approaches was deferred pending additional stakeholder consultation.

10 | Part 4: Accessibility Audit

Following co-design refinement and template updates, a set of three information templates, each with an accompanying user instruction guide, was submitted to Vision Australia for an independent accessibility audit.

10.1 | Audit Methodology

Two independent accessibility experts completed the audit and reporting for each format. The audit involved manual assessment of markup and visual design, identification of accessibility

issues, and evaluation of interactions with assistive technologies (e.g., JAWS and NVDA). For identified issues, relevant accessibility techniques were analyzed and referenced. Feedback was reported against Web Content Accessibility Guidelines (WCAG) Level 2 conformance criteria, assessed at levels A (2.1) and AA (2.2) (World Wide Web Consortium 2010), alongside content-specific recommendations aligned with recognized accessibility best-practice standards (Vision Australia).

10.2 | Summary of Findings

The audit identified minor modifications across formats. To conform to WCAG Level 2.2 guidance, the Word template and accompanying guide required adjustment to the document title label, removal of two blank spaces, and correction of the proofing language to ensure consistent spelling. To strengthen alignment with best practice accessibility standards, additional recommendations were made to enhance guidance on text color, line spacing, heading levels, table structure, and the use of headers and footers.

To meet WCAG requirements, the audio and video templates required an accompanying text transcription as an accessible media alternative. For audio formats, a best practice recommendation was also made to include chapter markers to support navigation by subject. The PowerPoint template required a minor adjustment to the title label to meet WCAG criteria, with auditors recommending a change from white to yellow text, as white can produce glare for people with certain eye conditions and refractive errors (e.g., halation associated with astigmatism).

Audio description was not deemed necessary for the video format, as the presentation featured a person speaking directly to the camera with no additional visual information conveyed. The video met WCAG criteria for pre-recorded content by having open, visible captions that included all spoken words and relevant sounds.

While WCAG does not specify a minimum caption size, Vision Australia recommends the use of a large, readable font synchronized with the spoken word. The audit report collated best practice guidance and recommended minor adjustments to caption presentation to ensure:

- One or two lines of captions per frame.
- Adequate spacing between lines when two are used.
- High contrast between captions and background bar.
- User-adjustable caption settings where platform functionality permits (e.g., YouTube).

This guidance was incorporated into the accompanying video creation guide.

11 | Final Assessment

All recommended minor changes were implemented. Following review, the project team confirmed that all templates conformed with accessibility standards and best-practice guidelines as of December 02, 2025.

11.1 | Implementation Workshop

A subsequent workshop (#3) was conducted with a group of research staff ($n = 8$) to explore attitudes, perceived barriers, and enablers to implementing the templates in practice. Results from this phase of the study are reported separately.

12 | Discussion

This study presents a formative, community-engaged exploration of how informed consent processes may be adapted to better support people with vision impairment. Its contribution lies in the involvement of a project lead and co-design contributors with lived experience of eye conditions, alongside consultation with consumer representatives and disability advocates across the design process. Together, these perspectives informed the development and refinement of accessible participant information and consent form formats.

Accessible communication and information are recognized as central to equitable participation in clinical research (Gedela et al. 2025; Hagopian 2024). Implementation of accessibility standards is important for three key reasons:

1. **Autonomy and agency:** enabling people to make adequately informed choices that promote autonomy, independence, and agency in consent decisions (Hagopian 2024).
2. **Research quality:** improved accessibility may facilitate greater diversity in research participation, strengthening research quality.
3. **Population level need:** vision impairment increases with age, and the population is ageing (Li et al. 2022). In addition, both disclosed and undisclosed disability are common across communities.

Together, these considerations underscore the importance of developing policies and practices that can accommodate a range of capacities and abilities.

Findings from our study suggest that creating accessible and effective PICF formats is feasible and may support more inclusive consent practices, particularly when information is offered in more than one format. Accessibility was conceptualized as extending beyond document layout to include language, format, and communication mode. Consistent with person-centered principles, the study highlights the importance of researchers proactively offering options early in the consent process, rather than placing responsibility on research participants to request alternatives.

There was no consensus on ranking format preferences, and acceptability ratings varied across print, audio, and video options. These findings reflect individual differences in information preferences rather than identifying a single approach. Some co-design contributors raised concerns about the paradox of choice, questioning whether too many options might be overwhelming and whether people in the broader community would know which formats suit them best in the research context. Whilst having six or more options may contribute to "decision paralysis" (Iyengar and Lepper 2001), two to three

options are generally well accepted in healthcare contexts (Szrek 2023).

Within informed consent practice, the optimal number of information formats has not been established (Kaltoft et al. 2015). Our study suggests that, given diverse information needs, offering two to three formats is perceived as acceptable and viewed as sufficient to support choice without excessive complexity. Co-design contributors generally favored the accessible digital print and Word format combined with either audio or video, depending on individual needs.

The digital Word format emerged as a versatile option, allowing users to customize the document to their needs. While Word's built-in "read aloud" function proved useful, a standalone audio format offered distinct advantages, including faster download speeds and the flexibility to access information while mobile (e.g., "anywhere anytime"). The video format enhanced engagement through visual elements, although challenges were noted when the playback speed increased. Despite these issues, some co-design contributors valued the video for its engaging nature, noting its potential for broader community appeal. These observations align with existing evidence indicating that videos can improve understanding of consent concepts and aid decision-making for some research participants (Gesualdo et al. 2021; Synnot et al. 2014; Nehme et al. 2013; Kirkham and Anderson 2020).

Alongside these format-related considerations, tension around voice selection emerged for both audio and video formats, balancing the perceived benefits of a human voice with the practical advantages of AI-generated narration. This was addressed by including guidance within the accompanying creation guides to support effective implementation of either approach, with Vision Australia recommending the use of a human voiceover where feasible.

Exploration of verbal consent strategies also emerged as an unresolved but salient issue. While this study did not extend to the development or testing of verbal consent pathways, current industry best-practice standards permit verbal consent under defined circumstances (ICH GCP 2025). Given its potential to reduce reliance on written signatures and proxy assistance, particularly for people with vision impairment, this represents an important next step for applied research and is the focus of subsequent work.

Empowered decision-making during informed consent practice is supported when individuals have choice and control over both the amount and the form of information provided (O'Hare et al. 2025). Accessible format options may also promote self-determination by reducing assistance from others (Griffith 2022). Through this study, we provide a set of accessible information templates, along with accompanying guidelines, to support researchers in tailoring informed consent practices to diverse needs.

Vision impairment rarely occurs in isolation. Print disability can be associated with visual, physical, perceptual, developmental, cognitive, or learning challenges. Whilst we recognize we cannot address all information access needs, this study represents a deliberate and considered step toward improving informed consent practice standards and expanding choice and control for future research participants.

12.1 | Study Limitations

This study has several limitations that should be considered when interpreting the findings. First, it was intentionally designed as a small, formative qualitative study. Sample sizes for the co-design workshops and user experience sessions were modest and purposively selected, in line with participatory design and usability research approaches that prioritize depth of engagement, specificity of experience, and iterative feedback over statistical generalizability (Slattery et al. 2020; Malterud et al. 2016; Sanders and Stappers 2008; Faulkner 2003). As such, findings should be interpreted as exploratory rather than representative.

Second, participation was based on self-selection, which may have contributed to greater representation of individuals with a strong interest in accessibility or research participation. Perspectives of people who are less engaged with research or experience additional barriers may therefore be under-represented.

Third, the study was conducted in an Australian context and involved only English-speaking participants. Differences in health systems, regulatory frameworks, and language access may limit transferability to other settings or multilingual populations.

Finally, some individuals contributed as both research partners and participants, a common feature of community-engaged and co-design research. While this overlap can strengthen relevance and insight, it may also influence perspectives through familiarity with the project's aims. To address this, findings were triangulated using multiple methods, including individual user experience sessions and an independent accessibility audit.

Despite these limitations, the study provides methodologically grounded, practice-relevant insights to inform the future development, implementation, and evaluation of accessible informed consent materials.

12.2 | Conclusions and Future Directions

This study demonstrates the feasibility of co-designing accessible PICF formats with people who have lived experience of vision impairment. By combining community-engaged co-design, user experience testing, and an independent accessibility audit, the work provides practical templates and guidance that researchers can adapt to support more inclusive informed consent practices.

The findings emphasize the importance of offering information in multiple formats to accommodate diverse access needs and preferences, and of proactively providing these options as part of person-centered consent processes. Rather than identifying a single preferred format, the study highlights the value of offering a manageable range of options that support choice and control.

Further research should focus on implementation and evaluation at scale, including assessment of adoption, uptake, feasibility, and appropriateness across different research settings and populations. Extending this work to multilingual contexts and exploring adaptable PICF formats for differing literacy levels, cultural expectations, and modes of communication will be important. As digital tools and assistive technologies continue to evolve, sustained collaboration with people with lived

experience remains essential to ensuring informed consent processes are both accessible and meaningful.

By making these templates and guides developed through this work publicly available (Clinical Trials: Impact and Quality CT:IQ, InFORMed Project 2026; Centre for Eye Research Australia 2025), this study contributes practical resources for the research community and supports broader capacity-building toward more equitable and inclusive research participation.

Author Contributions

Fleur O'Hare: conceptualization, methodology, investigation, validation, formal analysis, writing – original draft, writing – review and editing, resources, data curation, project administration, funding acquisition. **David Foran:** conceptualization, methodology, validation, investigation, writing – review and editing, formal analysis, project administration. **Tessa Saunders:** investigation, formal analysis, methodology, writing – review and editing, supervision, data curation. **Lisa Eckstein:** investigation, writing – review and editing, project administration, formal analysis, resources, validation. **Gudrun Wells:** investigation, writing – review and editing, formal analysis, project administration, resources, validation. **Daniel Talko:** conceptualization, writing – review and editing, validation, methodology, formal analysis, investigation. **Kevin Lee:** conceptualization, investigation, methodology, validation, formal analysis, writing – review and editing. **Shane Somerville:** conceptualization, investigation, methodology, validation, formal analysis, writing – review and editing. **Debra Simons:** conceptualization, investigation, methodology, validation, formal analysis, writing – review and editing. **Grace King:** conceptualization, investigation, methodology, validation, formal analysis, writing – review and editing. **Michael Burmeister:** conceptualization, investigation, methodology, validation, formal analysis, writing – review and editing. **John Paul Cruz:** investigation, methodology, validation, formal analysis, writing – review and editing. **Camille Paynter:** investigation, methodology, writing – review and editing, formal analysis, data curation, supervision. **Lauren N. Ayton:** funding acquisition, investigation, methodology, writing – review and editing, formal analysis, project administration, supervision, resources.

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Ethics Statement

Ethical approval was granted by St Vincents Hospital Melbourne Ethics Committee on May 28, 2024 (REF: 084/24). Research Governance approval was granted by the Centre for Eye Research Australia office on July 31, 2024. Participants in this study provided verbal consent before participating in the workshops and user experience sessions. A plain language summary of the project with links to a copy of the Participant Information and Consent Form was available. A link to the study website was also available, which provided additional information about the study.

Consent

All authors have read and approved the final manuscript and give their consent for publication. The participants in this study have provided verbal or written informed consent for the publication of their anonymized data and any potentially identifiable information included in this article.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Supplementary materials are attached, and links to download additional tools and resources are provided.

Additionally, this research will be made available in a public repository provided by the University of Melbourne. The research can be found here: https://figshare.unimelb.edu.au/ and https://minerva.unimelb.edu.au/.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.
Supporting File 1: dvr270058-sup-0001-S1_template.docx.
Supporting File 2: dvr270058-sup-0002-S2_template.docx.