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OPTIMISE-ing consent in clinical trials: recommendations for designing accessible consent processes to address communication and decision-making needs as a barrier to participation

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Abstract

Background

People with communication and decision-making needs often encounter barriers to participating in research, particularly trials, due to complexity of study information and lack of appropriate support. With greater accessibility and the right support, people with impaired communication and decision-making are better able to make, or contribute to, decisions about participating in research. This protects their right to make their own decisions, ensures their views are heard, and potentially improves inclusivity of research. However, researchers are often uncertain about how to make consent more accessible. The aim of OPTIMISE was to develop a set of recommendations for designing more accessible trial consent processes.

Methods

OPTIMISE comprised a literature review and consultation with key stakeholders including those with lived experience, supported by two advisory groups. Searches of MEDLINE were conducted April-June 2025 and examples of enhanced consent processes for research or clinical practice were identified (n=26) alongside online searches for relevant regulatory, policy and guidance documents. Insights to inform inclusive consent recommendations were coded, summarised, and organised into preliminary domains.

A workshop was held with stakeholders (n=21) purposively sampled based on their experience of either research, practice, or a lived experience perspective. World Café, an inclusive participatory method for reducing power imbalance was used to facilitate dialogue and seek agreement on key domains to be included. Recommendations were collated and refined to develop an overarching framework and linked to practical resources from the wider CONSULT research programme and other sources.

Results

OPTIMISE recommendations consist of three guiding principles that underpin inclusive consent - collaboration, ethics and reflection - and seven domains across which consent processes can be made more accessible, if appropriate action is taken. These include the content, language and format of information provided, as well as design, environment, and timing considerations, and communication and decision supports, with links to practical tools and examples. The recommendations can be accessed online: www.capacityconsentresearch.com/optimise

Conclusions

OPTIMISE developed a comprehensive framework of recommendations to ensure consent processes are ‘accessible by design’. The recommendations aim to support researchers, and those reviewing and approving studies, to conduct more inclusive research that reduces communication and decision-making barriers.

Introduction

Clinical trials play a vital role in helping reduce the disparities that exist in health outcomes caused by factors such as age, socio-economic disadvantage, ethnicity and disability [1]. Routinely excluding populations means that the healthcare delivery that follows from research is not designed for them, which builds in inequity and can result in treatments that are less effective for the very people who most need support, leading to poorer outcomes [2]. As a result, improving inclusivity and diversity in clinical trials is now a policy priority in the UK [3–5], including research funders [6, 7] and the pharmaceutical industry [8], and internationally such as through the World Health Organisation (WHO) guidelines for best practice in clinical trials [9]. As issues around communication, language and literacy are barriers to inclusion in trials [10], people with communication and decision-making needs are recognised as a group who are currently under-served by research [11, 12].

Communication and decision-making needs can be associated with conditions such as dementia, acute events such as stroke, or be associated with a range of disabilities including learning disability. The degree to which they affect different components of communication and cognition and an individuals' needs will vary. People with communication and decision-making needs are excluded either explicitly, due to concerns about their ability to provide informed consent [13], or because information about the study is not accessible to them. This is seen systematically across the full spectrum of impairing conditions and disabilities, for example in stroke [14], learning disabilities [15], palliative care [16, 17], older peoples [18], oncology [19], neurological conditions [20] and beyond.

Importance of including people with communication and decision-making needs

Around 20% of the UK population will experience communication disabilities at some point in their lives [21], and over 2 million people have significantly impaired decision-making [22]. Together with an estimated 18% of adults having very poor literacy skills [23], and nearly a million people in the UK not able to speak English well or at all [24], this is a sizeable population who are currently underserved by research. Studies that are not accessible may struggle to recruit participants and to meet their statutory equality and accessibility requirements. In the UK (with international equivalents) there are several legal and regulatory instruments that enshrine equality rights and accessibility requirements which may also be considered to extend to the design and conduct of clinical trials. For example, the UN Convention on the Rights of Persons with Disabilities (UNCRPD) recognises communication accessibility as a fundamental human right, and requires appropriate measures to be taken to ensure that people with disabilities are able to access information and communications [25]. The UK Equality Act 2010 protects individuals with protected characteristics, such as disability, from receiving unfair treatment and requires public sector organisations to make reasonable adjustments [26]. Organisations that provide NHS care or adult social care in England have a duty to ensure that people with impairments or disabilities can access and understand information and receive the communication support they need [27]. There are

also statutory requirements that people should be ‘given all practicable help’ before it is deemed that they are not able to make their own decisions [28].

Previous studies have highlighted the significant gap between legal and ethical obligations related to informed consent and participants not being able to understand the unfamiliar, complex information that is provided to them [29]. International guidelines for the conduct of clinical trials such as ICH E6 (R3) require that participation in trials should be voluntary and based on a consent process that ensures that they (or their legally acceptable representatives, where applicable) are well-informed [30]. WHO guidance on best practice proposes that consent information should be widely accessible and readily understandable (for example with respect to readability) and avoid legalistic or other technical language [9]. There are also requirements for inclusive trial design, in particular when designing participant information and informed consent processes, as highlighted by the Health Research Authority’s Design and Review Principles [31].

Calls to optimise consent processes to ensure trials are more accessible

The increasing length and complexity and poor readability of participant information sheets is considered a persistent and prevalent problem, common to trials across the world [29]. This has led to international calls to ‘optimise’ informed consent [32] and to mandate the use evidence-based informed consent practices [33]. It has also led to the development of tools to improve participant understanding during the informed consent process [34], and recommendations for developing more accessible participant information sheets and consent forms [35–37]. However, these primarily focus on information provision, rather than wider aspects of communication and decision-making, and don’t necessarily take account of populations with additional communication and decision-making needs who require support in order to understand and use decision-related information. Improving accessibility could improve the quality of informed consent processes and improve inclusivity by ensuring that participants with support needs are more likely to be able to consent for themselves or, if deemed to lack capacity, communicate their views about participation to their consultee or legal representative. A systematic review of strategies to improve participation of people with cognitive impairment identified the need for targeted, tailored and multi-pronged consent strategies [38], and a project to develop accessible consent processes for autistic people and people with a learning disability called for more work to help design inclusive practices for all populations with additional considerations [39]. More recently, a study to explore current practices and perspectives of staff involved in informed consent processes for clinical research in Australia found that staff are motivated to employ a range of strategies to support their informed consent practice [40]. However, researchers often report that they lack the knowledge and skills to design trials to be accessible for people with communication and decision-making needs [40–42].

Conducted as part of an ongoing research programme which explores the ethical, legal and methodological issues in research involving adults with impaired capacity to consent (CONSULT), the

OPTIMISE project aimed to develop evidence-based recommendations to help researchers design trial consent processes to ensure they are equitable and accessible for people with communication and/or decision-making needs.

Methods

The OPTIMISE project was conducted by an interdisciplinary team with expertise in clinical trials involving different populations with communication and decision-making needs including people with dementia, learning disabilities, stroke, and older people living in care homes, and in co-production with under-served groups. It was supported by two groups who provided advice throughout the project: a Lay Advisory Group consisting of seven people with a broad range of lived experience, and a Researcher Advisory Group which included an academic with expertise in inclusive research and co-production and experience of recruiting people with learning disabilities into a variety of study designs (AMR), a trials methodologist with expertise in inclusive trial design (ST), a trials methodologist with expertise in optimising understanding for informed consent and clinical experience working with people with communication impairment (JW), a clinical academic with expertise in informed consent, supported decision-making, inclusive communication, and acquired communication disability (MJ) and a clinical academic speech and language therapist with expertise in inclusive research involving people living with dementia including primary progressive aphasia (AV).

A stakeholder analysis was conducted using the '3i' framework [43] to identify key parties (e.g. UKCRC CTU network, UK Trial Managers Network (UKTMN), HRA) who, based on their relevant interests, influence and impact, would be key to engage with in order to help disseminate the invitation to join the workshop and to support uptake of the recommendations.

In line with similar previous projects (e.g. MAPLE [35]), as the project involved working with professionals and members of the public to develop recommendations it was conducted as an involvement and engagement activity, rather than as a research project, and ethical approval was therefore not required [44].

The project was conducted in four stages (see Fig. 1) which are described in more detail below, which led to: 1) the development of an evidence-based framework for optimising informed consent methods for adults with communication and/or decision-making needs, applicable to all populations and settings where difficulties with communication and decision-making may arise and reflecting that consent is an ongoing process rather than a one-off event, and 2) the development of an implementation toolkit of resources to help researchers and other groups use the OPTIMISE recommendations in practice.

Stage 1. Identifying candidate domains of inclusive consent

A focused review of literature reporting enhanced consent processes for research (or healthcare) decisions was conducted in April 2025 to identify the candidate domains - defined as a component of the consent process - to be included in the recommendations for optimising informed consent

processes. As the review was intended to capture the range of potential domains of enhanced consent, rather than to map all available literature or identify gaps in the literature which might be the aims of a systematic review. One database (MEDLINE) was searched using keywords including informed consent and communication barriers (see **supplementary file** for search strategy). The results from the search were reviewed for inclusion by one researcher (VS). Articles were included if they reported enhanced consent processes for research and/or healthcare decisions, including systematic reviews, and excluded if they were not available in English. Articles were not critically appraised or excluded based on perceived quality. Included articles were imported into NVivo 14. As a literature review, the protocol was not eligible for registration on a systematic review database (e.g. PROSPERO).

Alongside this, online searches were conducted to identify regulatory, policy and guidance documents which related to accessibility requirements for informed consent for research and were relevant to the UK. A Google search was conducted April-June 2025 using the search terms ‘guidelines’, ‘policy’ and ‘informed consent’ ‘access*’, together with focused searches of the websites of research governance organisations (e.g. HRA). Entries were examined for relevance by one researcher (VS), and the document imported into NVivo 14 for synthesis.

Text from the included articles and policy and guidance documents were then coded using inductive coding and organised into candidate domains and discussed with the Researcher Advisory Group and Lay Advisory Group for initial refinement ahead of the stakeholder consultation stage.

Stage 2. Expert consultation to develop OPTIMISE recommendations (dup: abstract ?)

A workshop to seek agreement on the key domains to be included in OPTIMISE recommendations was held with key stakeholders. They were purposively sampled based on their expertise in conducting research involving adults with impaired communication and decision-making, or as members of clinical mental capacity teams, or from a lived experience perspective. Workshop participants were identified through the project team and Researcher Advisory Group’s networks and recruited via organisations identified in the stakeholder mapping (e.g. UKCRC CTU network) and an open invitation via LinkedIn. Members of the Researcher Advisory Group and Lay Advisory Group were also invited to attend. The day-long workshop was held in July 2025 in person at a community venue in South Wales. Where required, attendees’ travel costs and costs for a replacement carer were provided.

The workshop used a World Café approach which is designed to ‘explore questions that matter’ through connecting diverse perspectives based on a number of core design principles including the creation of a hospitable space [45]. A World Café approach was chosen as it is known to be effective in accessing and connecting diverse and multiple stakeholder groups [46], and being accessible for people with communication and decision-making difficulties [46, 47]. To support participation, attendees were provided with a briefing summary prior to the workshop which explained the background to the project, the purpose of the workshop and outlined the three key questions to be explored during the workshop:

Q1) when along the consent pathway do we need to consider designing more inclusive processes, Q2) what are the key elements (domains) of the consent process that we need to consider in order to optimise accessibility, and Q3) how can we support researchers to use the OPTIMISE recommendations to design more inclusive consent processes.

The workshop started with a short 'scene setting' presentation from the research team which included a brief overview of the literature and the draft set of domains. Participatory methods were used to facilitate dialogue, including interactive polls (via Mentimeter) to encourage attendees to share their perspectives at the start and end of the workshop. As is common in World Café methods, each of the tables had a 'tablecloth' of oversize sheets of paper and were strewn with coloured pens and 'Post It' notes, and the walls had large sheets of blank paper attached. For each of the three questions, the question and an accompanying illustration was printed on a tablecloth. Participants were asked to note down recommendations on the tablecloth. To support inclusion, they could do this through writing and/or drawing their responses, and the co-hosts of the workshop (VS and MS) provided support for communication, including re-explaining the task using simplified language where required.

One person at each table was then invited to verbally summarise the table's responses to the wider group. After each round, a new tablecloth was revealed with the next question. Attendees were encouraged to move to a different table for each round if they were happy to do so to facilitate new connections and conversations. After the third round, the key domains identified by each group were transferred to the blank sheets on the wall and organised by the wider group into an agreed set of domains. Following the workshop, a draft framework of recommendations was circulated to the attendees and a wider group of stakeholders who expressed interest in the workshop but could not attend the event and to the two advisory groups, before being finalised based on additional feedback from these groups.

Stage 3. Mapping practical tools and resources to the OPTIMISE recommendations

In order to provide researchers and other groups with the practical tools and resources needed to implement the OPTIMISE recommendations in practice, the recommendations were mapped by one researcher (VS) to resources from the wider CONSULT programme which includes a website of collated information and resources on capacity and consent in research (www.capacityconsentresearch.com) and stakeholder-informed e-learning (CONSULT Training) which contains case studies and other illustrative examples. This was supplemented by updated online searches for relevant content, and through advice from the Researcher Advisory Group and other networks. A document with the framework of recommendations and linked resources was circulated to the Researcher Advisory Group for review prior to being finalised based on their feedback.

Stage 4. Implementation of the OPTIMISE recommendations

An implementation toolkit was developed to help raise awareness of the OPTIMISE recommendations and to support uptake. The toolkit was co-produced with experts in accessible design and with lived experience (Thinklusive Advisory Group) and consisted of an interactive infographic to raise awareness of the recommendations, easy read guides to support public involvement when research teams are using the recommendations to design studies, and case studies to illustrate how the recommendations could be applied in practice.

The OPTIMISE recommendations and implementation toolkit were launched at a webinar in December 2025. A post-webinar survey was used to collect initial feedback from attendees on their views about OPTIMISE as well as key takeaway messages from the webinar (see **supplementary file** for survey questions), with ongoing informal feedback sought through presentations at research network events and conferences. Based on the post-webinar feedback, a follow-on practical workshop was held to support researchers to develop accessible participant information. Researchers were asked to complete pre- and post-workshop questionnaire (see **supplementary file** for questionnaires) to help evaluate the workshop.

Results

Stage 1. Identifying candidate domains of inclusive consent

Searches identified 579 articles that were reviewed for inclusion, with 26 articles included in the final synthesis. See **Table 1** for characteristics of the included articles, which included systematic reviews (n = 6) and randomised controlled trials of strategies or interventions to enhance consent (n = 8) and a range of other methods including qualitative and consensus approaches. They captured diverse conditions and disabilities including people with neurodegenerative conditions (n = 8), mental health conditions (n = 4), intellectual (or learning) disability (n = 3), or those at the end of life (n = 1), as well as non-specific impaired decision-making capacity. The articles were geographically diverse (e.g. systematic reviews reporting international literature), however six studies were conducted solely in the UK.

Table 1 Characteristics of included articles

Authors (year)	Location	Study or article type	Main study population	Aim
Badenhoop et al (2023)	Germany	Cohort study	People with dementia	Investigate the associations of different aspects of communication behavior and relationship aspects with the capacity to consent to treatment in people with dementia
Brady et al (2012)	UK (international studies included in review)	Review	People with aphasia	Explore the exclusion of people with aphasia from stroke research in a recent Cochrane review, enabling more accessible research information and consent processes
Dunn et al (2001)	USA	Randomised controlled trial	Older people with psychosis	Evaluate whether a novel consent procedure improved the comprehension of consent for older patients with psychosis
Dunn et al (2023)	Australia (international studies included in review)	Systematic review	People with intellectual disability	Identify factors acting as barriers or enablers to the process of healthcare consent for people with intellectual disability and to understand how to make this process equitable and accessible
Evans et al (2020)	UK (international studies included in review)	Systematic review and transparent expert consultation	People with impaired capacity nearing the end of life	Develop evidence-based guidance on how best to include individuals with impaired capacity nearing the end of life in research, by identifying the challenges and solutions for processes of consent across the capacity spectrum.
Eyler and Jeste (2006)	USA (international studies included in review)	Review	People with impaired decision-making capacity	Explore issues related to the definition of decision-making capacity, review strategies to improve aspects of the informed consent process, and outline areas in need of future studies

Fields and Calvert (2025)	USA (international studies included in review)	Review	People with cognitive impairment	Explore considerations for assessing capacity to consent to research and supportive measures when determining cognitively impaired patients' ability to consent
Fons-Martinez et al (2021)	EU (international studies included in reviews)	Reviews and stakeholder consultation	Adults and children involved in clinical research	Develop a set of guidelines that offer ethical recommendations and practical tools aimed at making the informed consent process in clinical studies more comprehensive, tailored, and inclusive
Gillies et al (2021)	UK (international studies included in review)	Core outcome set	People with capacity to consent to research	Develop a core outcome set for the evaluation of interventions that aim to improve how people make decisions about whether to participate in randomised controlled trials
Harmell et al (2012)	USA	Randomised controlled trial	People with schizophrenia	Feasibility of a web-based tool for enhancing the informed consent process in schizophrenia research
Harris et al (2021)	USA	Systematic review	People with serious mental illness	Review rates of research exclusion from studies for psychiatric conditions through a systematic review of relevant clinical trials
Hostiuc et al (2018)	Romania (international studies included in review)	Systematic review and meta-analysis	People with schizophrenia	Evaluate the degree of impairment in each dimension of decision-making capacity in schizophrenia patients and whether enhanced consent forms are associated with a significant increase in decision-making capacity
McDonald et al (2024)	USA	Systematic review	People with intellectual disability	Identify approaches to consent in US-based social-behavioral research with adults with intellectual disability
Mittal et al (2007)	USA	Randomised controlled trial	People with mild cognitive impairment or	Evaluate the feasibility, acceptability, and preliminary efficacy of two enhanced consent

			mild Alzheimer disease	procedures for research with patients with Alzheimer disease or mild cognitive impairment
Normahani et al (2021)	UK	Review	People with capacity to consent to clinical procedures	Identify processes and measures for consideration when engaging in consent-based discussions with competent patients undergoing elective procedures
Palmer et al (2018)	USA	Randomised controlled trial	People with mild-to-moderate Alzheimer's disease	Evaluated the effectiveness of an enhanced research consent procedure, compared with routine consent, in improving decisional capacity for research
Poth et al (2023)	Germany	Randomised controlled trial	People with dementia	Developing and test supportive measures to enhance the informed consent process for people with dementia
Pyer and Ward (2023)	UK	Qualitative	People with dementia	Explore the experiences of gaining and giving consent for people living with dementia in research, enabling the development of user-friendly approaches
Rubright et al (2010)	USA	Randomised controlled trial	People with mild-to-early moderate Alzheimer's disease	Evaluate whether a memory and organizational aid structured to support recognition memory and executive function can improve the capacity of a patient with mild to early moderate AD to provide an informed consent
Sacco et al (2021)	France	Review	People with neurocognitive disorders	Determine a pragmatic, ethical and regulatory correct approach to seek the informed consent of patients with neurocognitive disorders in 'Living Labs' research
Stiles et al (2001)	USA	Randomised controlled trial	People with mental health conditions	Evaluate alternative procedures for improving the understanding of research consent disclosures

				by people with mental illness
Swan et al (2025)	Australia (international studies included in review)	Systematic review	Older people with cognitive impairment	Review evidence for strategies to support the inclusion and participation of older people with cognitive impairment in clinical research
Wade et al (2017)	UK	Randomised controlled trial	People with capacity to consent to research	Development and evaluate the Participatory and Informed Consent (PIC) measure which evaluates the breadth and clarity of information provision for consent to research and evidence of patient understanding
Wark et al (2016)	Australia	Descriptive case study	Older people with intellectual disability	Explore the use of complementary consent methodologies to support people aging with intellectual disability to facilitate meaningful participation in the development of personal health care plans
Wasserman and Navin (2018)	USA	Descriptive case study	People with compromised decision-making	Explore efforts to help patients who lack decision-making capacity provide input into decisions about their care
Wied et al (2021)	Germany	Feasibility study	People with dementia	Development and implementation of support tools to enhance informed consent processes for people with dementia on whether to undergo lumbar puncture

<Table 1 Characteristics of included articles>

Online searches identified a (non-exhaustive) range of relevant regulatory, policy and guidance documents. See Table 2 for details of policy and guidance documents.

Table 2
Policy and practice documents relevant to accessibility requirements for informed consent for UK research

Organisation	Title of policy or guidance	Details of policy or guidance
Health Research Authority (HRA)	Design and Review Principles	Guidance to support researchers and Research Ethics Committees (REC) to identify the important ethical considerations for participant information when planning or reviewing participant-facing documents https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/
	Participant Information Quality Standards	Guidance to support research ethics staff who check if the participant information is compliant when validating a research application for research ethics review https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/
	Ethics Review Form	Template to support Research Ethics Committee (REC) members to review applications and to help structure the discussion at the REC meeting, based on the Integrated Research Application System (IRAS) form submitted by researchers for research ethics review https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-members-area/guidance-and-policy-for-rec-members/ethics-review-form-lead-reviewerrec-member/
National Health Service (NHS)	NHS Accessible Information Standard	Guidance that sets out how providers of NHS services and adult social care services should ensure disabled people and people with impairments or sensory loss can access and understand information about NHS and adult social care services and receive the communication support they need to use those services https://www.england.nhs.uk/accessible-information-standard/
UK Government	Mental Capacity Act 2005	Law that sets out the principles and procedures for protecting and supporting people who lack capacity to make decisions in England and Wales, including statutory principles such as the need to support individuals to make their own decisions where possible https://www.legislation.gov.uk/ukpga/2005/9/contents

Organisation	Title of policy or guidance	Details of policy or guidance
World Health Organisation (WHO)	WHO Guidance for best practices for clinical trials (2024)	Guidance to support best practice in the design and conduct of clinical trials, including that good clinical trials respect the rights and well-being of participants https://www.who.int/publications/i/item/9789240097711
International Council for Harmonisation (ICH)	ICH E6(R3) Guideline	Good Clinical Practice (GCP) guidelines for the design and conduct of clinical trials which include standards for participant protection and data integrity https://www.ich.org/page/efficacy-guidelines#6-2

Coding of the articles and policy and guidance documents identified 13 candidate domains, including language, format, decision support, environmental support, and communication behaviour, alongside definitions of each domain. It also highlighted a number of challenges, including that these domains have considerable overlap and are not independent of each other. Following discussion with the Researcher Advisory Group and Lay Advisory Group, a set of candidate domains (n = 10) were drafted (see Table 3) in preparation for the stakeholder consultation workshop.

Table 3
Candidate domains of inclusive consent

Candidate domain*
Information content
Language/literacy level
Mode/format/route of delivery
Design
Assessment/tailoring
Communication support
Decision/preferences support
Communication behaviour/relationships
Environmental support
Timing
*Candidate domains were not numbered to avoid weighting any one domain as more important than another

Stage 2. Expert consultation to develop OPTIMISE recommendations

Following initial acceptance of the invitation to attend the workshop by 25 stakeholders, a total of 21 attended the workshop event. They were drawn from across England and Wales, with a range of disciplinary backgrounds including expertise in clinical trials in diverse populations who may have communication and decision-making needs (e.g. stroke, learning disabilities, obstetrics, palliative care, dementia), or mental capacity more broadly, and including people with lived experience.

When to consider designing more inclusive processes

In response to the question regarding when designing more inclusive processes should be considered, stakeholders were clear that inclusive consent is an important consideration right across the lifecycle of a study, with several key timepoints identified (see Fig. 2 for examples of responses to Q1).

Key domains to be considered in order to optimise accessibility

Building on the presentation which included the domains identified in the previous stage, stakeholders also identified additional domains of inclusive content processes. Through whole group discussion, they were then grouped into seven domains (although with some overlap), together with illustrative examples drawn from their experience (see Fig. 3 for examples of responses to Q2). They also identified three underpinning or guiding principles that they believed to be central to inclusive consent.

Supporting researchers to use OPTIMISE

Finally, turning to the issue of how to support researchers and other groups to use the OPTIMISE recommendations in practice, stakeholders proposed several strategies that they believed could support uptake by targeting a number of systems levels (see Fig. 4 for examples of responses to Q3). They recognised a need to go beyond raising awareness, although this was considered to be essential, and drew on behaviour change approaches to highlight the need to increase researchers' (and others') capability, opportunity, and motivation (e.g. [48]).

A post-workshop report summarising the discussions and the draft recommendations was circulated to workshops attendees for any amendments or comments.

Stage 3. Mapping practical tools and resources to the OPTIMISE recommendations

The recommendations were then mapped to existing resources. This included the policy and guidance documents shown in Table 2, content from 'CONSULT Training' e-learning modules which were previously developed by the same team [49], resources collated on the CONSULT website (www.capacityconsentresearch.com), and international examples such as a national co-designed participant information template from the Australian 'InFORMed' project (https://www.informedpicf.com.au/). It also included resources and examples from projects exploring the inclusion of specific populations who may have communication and decision-making needs, such as

the co-produced outputs from the NIHR-funded ‘No Research About Us, Without Us’ project exploring barriers to including people with a learning disability (https://sites.google.com/view/noresearch-about-us-without-us/work). The final version of the recommendations and linked resources were circulated to the two advisory groups who suggested minor changes to terminology, prior to being finalised.

Stage 4. Implementation of the OPTIMISE recommendations

The OPTIMISE recommendations can be accessed via the OPTIMISE webpage (www.capacityconsentresearch.com/optimise) and downloaded as a PDF with links to resources and examples. The recommendations are intended to help researchers design more inclusive consent processes, which spans from being initially informed about a study, through to consent discussions, and recording/evidencing consent. They will also be useful for those reviewing and supporting research, such as members of research ethics committees and funding panels, to understand how researchers have (or have not) considered accessibility. They are intended to be high level and applicable to people with a broad range of communication and decision-making needs, whilst recognising that accessibility and support needs vary between populations and individuals, and the exact consent processes will depend on the study design and context.

The recommendations consist of three guiding principles and seven domains of inclusive consent which are depicted in Fig. 5 and summarised below.

Guiding principles for inclusive consent

Three guiding principles for inclusive consent should be followed when designing inclusive consent processes in trials:

Collaboration

Researchers should work collaboratively with organisations (e.g. voluntary and third sector), multi-disciplinary teams (e.g. speech and language therapists, mental capacity teams), funders, research governance teams, patients, carers and members of the public who all play a role in facilitating inclusive consent.

Ethics

Researchers should embed ethical practices and principles throughout the design and conduct of the study. This includes building trust, being respectful, and promoting autonomy. Researchers should also reflexively engage with ethical review processes which can act as a barrier or facilitator to inclusive consent practices.

Reflection

Researchers should review whether the consent processes in place are effectively meeting people's needs or if additional support is needed, whether their collaborations are working (for everyone involved), and whether the balance between the burden and benefit for participants (and any carers and consultees/legal representatives involved) is appropriate.

Domains of inclusive consent

Consent processes can be made more accessible by acting across one, more, or all of these seven domains:

Content

Participants (and consultees/legal representatives where relevant) should be provided with clear and concise information about the purpose of the study, what is involved and what it might mean for them, how the findings will be shared, and contact details if they have any questions or more information. Attention should be paid to how key concepts such as randomisation and data protection measures are introduced and explained, and the order in which they are presented, to ensure the information is understandable and cognitively accessible.

Language

Plain and accessible language should be used, including avoiding complex words and using shorter sentences with a simplified sentence structure, with careful consideration about the readability of the information and how it corresponds with the literacy level of the population, as well as the tone of the language being used. Consideration should also be given to any translation and interpretation needs and how to ensure they can be met throughout the study.

Format

The best format for participant information materials should be carefully considered. This may depend on the study design, setting, recruitment pathways, and study population. Information could be provided in written, audio, pictorial, easy read or video formats, through various modes of delivery such as physical (e.g. paper, touch) or digital (e.g. website, animation) formats, with delivery routes including in person or remotely. Researchers should consider having multi-modal options (e.g. written and audio versions) available for both providing information and seeking/recording consent, and ensure that the format, mode and route can be tailored to meet individuals' communication and decision-making needs where possible.

Design

Universal accessible design principles should be used to design informational materials, and the layout should be kept simple. Images can be an important way of supporting the accompanying text, but care must be taken to decide which images help support understanding, are appropriate (e.g. culturally), and are accessible such as with accompanying 'alt' text.

Support

Communication and decision-making can be supported through layering of participant information such as using a brief summary information sheet followed by a more detailed version. It can also be supported using communication strategies (e.g. keywords/cards, memory aids) and use of tools to support communication and/or decision-making such as assistive technology. Researchers should also involve other people involved in caring for or supporting the person to help facilitate communication (rather than communicate for them), such as family members or support workers. As communication behaviour has a key role, researchers should also consider who will be involved in approaching participants and whether they have the appropriate skills and training to communicate effectively, and to assess capacity if needed. Where a participant who lacks capacity to consent is being included, their consultee/legal representative should be provided with their own information and should be involved in exploring the person's preferences, potentially prior to any loss of capacity.

Timing

Considerations around timing can help support inclusive consent processes. This includes identifying the best time to engage with the person that maximises their ability to make an informed decision such as when a person's capacity fluctuates or in an emergency situation, or prior to any loss of capacity. It also includes the time taken to deliver information or to provide information at multiple timepoints (e.g. staged consent) or the support that may be needed to ensure information is retained (e.g. use of memory aids) and how there is a need to revisit consent during a study as capacity and communication and decision-making needs may change over time.

Environment

Researchers should also consider the environment in which participants are approached and consent is being sought, which includes both physical and digital environments. Considerations should include whether the environment is accessible and safe, is somewhere familiar where the person feels comfortable, and ensuring there are appropriate levels of sound, lighting and other sensory stimuli.

Using the OPTIMISE recommendations

The recommendations may be useful for a number of different purposes during the design and conduct of trials, including:

- To help identify research team members and collaborators
- Inform (inclusive) public involvement approaches
- Identify (and enable requesting of) appropriate funding and resources
- Incorporate into the design of consent processes and consent materials
- Guide site selection and the development of consent training for recruiting staff

Inclusive consent should be considered throughout the lifecycle of a study, particularly at suggested key timepoints (see Fig. 6) and in terms of different ways the OPTIMISE recommendations may be useful (see Table 4).

Table 4
Suggested uses for the OPTIMISE recommendations at different timepoints

Developing a research idea	Designing the protocol	Approaching participants
• to plan adequate **time and resources** (e.g. community outreach, inclusive design) • identify **costs** to be included in the funding application (e.g. developing accessible materials such as easy read, translations) • identify and build **relationships** with key stakeholders and early involvement of public involvement contributors	• when designing the consent process to ensure **accessibility** (e.g. flexible approaches to consent, use of decision-support tools) • developing **participant information materials** (including piloting the materials and seeking feedback) • drafting an **ethics** application • identifying **research sites** (e.g. translation needs, research delivery staff time)	• to help inform assessment of the individual's communication **needs** • appropriate **tailoring** of information using communication strategies (e.g. staged approaches to consent) and **supported** decision-making, with adaptations as required • inform an **assessment of capacity** to consent should there be concerns that an assessment is needed. • **revisiting consent** during the study if concerns about changes in capacity

Implementation toolkit to support use of the OPTIMISE recommendations

In addition to the downloadable OPTIMISE recommendations, resources and examples, there is an interactive infographic that summarises the domains (see Fig. 7) to help raise awareness.

To ensure that information about the OPTIMISE recommendations (and how and why they could be used) is accessible, an easy read guide to the recommendations and an easy read summary were co-produced by experts in accessible design and with lived experience (Thinklusive Advisory Group). These resources are also intended to support help support inclusive public involvement when designing and conducting a trial, and act as exemplars of providing accessible information provided in easy read format see Fig. 8 for example pages).

A case study on developing materials to support trial accessibility was co-produced by Thinklusive to provide researchers with an example of how a participant information sheet and consent form for a liver transplant trial were co-produced in easy read format. The case study shows the process that was followed, the timescales and resources involved, and the evolution from the original study title and participant information sheet in a standard template through to the final streamlined and accessible version. To illustrate why accessible materials should be developed, the case study also contains a video in which a broad range of people describe why easy read is important to them.

A policy brief was also created to support organisations such as research funders, regulators, and research organisations to understand how the OPTIMISE recommendations can help them to meet policy requirements around improving inclusivity and accessibility. The policy brief contained several recommendations for these organisations (see Table 5) were co-produced in the stakeholder workshops.

Table 5
Recommendations to organisations on the use of OPTIMISE

Organisation type	Recommendations to organisations
Research funders	*Pre-application stage*: funders should **signpost applicants to the OPTIMISE recommendations and resources** to ensure they appropriately consider accessibility requirements throughout their study and can **ensure that the necessary resources are costed into the funding application** (e.g., developing accessible participant information sheets)
	Review stage: funding panels should use the OPTIMISE recommendations to **consider whether the applicants have demonstrated that they have appropriately considered accessibility requirements** and (co-)designed inclusive consent processes and other aspects of the study, with sufficient budget requested to enable them to do so
Regulatory organisations	When regulatory organisations such as research ethics committees (RECs) are reviewing studies, particularly those seeking to specifically include people who may have communication and/or decision-making needs, they should use the OPTIMISE recommendations to **consider whether the applicants have appropriately (co-)designed** inclusive consent processes and other aspects of the study
Research organisations	Organisations that are conducting research (including sponsor organisations) should signpost researchers to the OPTIMISE recommendations to **ensure they appropriately consider accessibility requirements** when: developing a research idea, drafting the funding application, designing the protocol and consent materials, applying for ethics approval, identifying research sites, approaching participants and beyond. This includes **ensuring that all communication with participants is accessible and inclusive**, and that those involved have the appropriate skills and training required

Launch webinar and initial feedback on the recommendations

The OPTIMISE recommendations and implementation toolkit were launched at a webinar in December 2025. There were 300 registered attendees from across England (56%), Wales (26%), Scotland (2%), Northern Ireland (1%) and beyond (18%), and a broad range of stakeholder groups including researchers (67%), health care professionals (34%), members of research ethics committees (11%), policymakers (2%), and members of the public (6%). Alongside a presentation about the OPTIMISE project and introducing the recommendations, the webinar included a presentation from a researcher with expertise in communication disabilities and the Thinklusive Advisory Group sharing their experiences of co-producing accessible participant information. There was also a Q&A with a panel of experts to explore the key challenges in designing inclusive consent processes and how can we address them. When registering, attendees were invited to submit questions to the expert panel and questions were also able

to be submitted during the webinar. There were 51 questions submitted ahead of the webinar, providing a rich source of potential future research questions. The webinar was recorded and can be accessed via the OPTIMISE webpage.

Attendees were asked to complete a post-webinar survey to provide feedback on the webinar and the OPTIMISE recommendations and a small number (n = 16) of participants did so. Their overall experience of the webinar was either very good (75%) or good (25%). When asked what they were planning to implement that is different, responses included commitments to implementing the OPTIMISE recommendations and changing practice such as:

Going forward, I will always prepare easy-read leaflets to accompany my information sheets

"*To link to OPTIMISE resources when engaging in discussions with ethics committees etc to justify approach taken*".

They also reported plans to share them more widely, including nationally and internationally:

I am involved in writing guidance about making clinical trials accessible for disabled people and I will be able to signpost to your work in our guidance

"*I run a course on Ethics and Research Integrity at [international] University and talk extensively about the Informed Consent process. I plan to inform my students (medical students and PhD students in Medicine and Surgery) about your initiatives and efforts*".

There was also a strong interest in future webinars or workshops, including on developing accessible participant information and on inclusive approaches to public involvement.

OPTIMSE workshop on developing accessible participant information

This led to a follow on OPTIMISE workshop which was held in March 2026 to give practical tips for researchers on how to develop accessible participant information. The online interactive workshop was co-produced and co-facilitated by Thinklusive with experts in accessible co-design and people with lived experience. The aim was for researchers (including trial managers and healthcare professionals) to learn the principles of accessible design with tips, techniques and best practice examples, and to gain practical hands-on experience with access to follow-on one-to-one support. The content consisted of a series of short presentations from the facilitators, with interactive polling and discussions (via Slido) throughout, and a breakout session where attendees were divided into three groups with each group being provided with an outline of a (hypothetical) trial and sections of a participant information sheet and of one of three 'characters' with a description of the person and their communication and decision-making needs and preferences. Each group was asked to revise the sections of the information sheet,

including the study title, to ensure they were more accessible for that person (and others). Workshop numbers were limited to facilitate interactive engagement.

Researchers who attended the workshop (n = 24) were asked to complete the pre- and post-workshop questionnaire. Of those who completed the pre-workshop questionnaire (n = 17), their experience of developing accessible study information ranged from none or little experience (35%) to reasonably experienced (18%), and 35% stated they were not very knowledgeable about how to do so with 65% rating themselves as somewhat or reasonably knowledgeable. When asked about their confidence in developing accessible information, 29% were not very confident and 71% were somewhat or very confident. In comparison, responses to the post-workshop questionnaire (n = 11) showed that all but one (91%) stated they were now either somewhat or reasonably knowledgeable and one reported they were now very knowledgeable, illustrated by responses such as:

Really interesting, informative, supportive, thoughtful. I know where to start now!

Confidence also increased, with all but one (91%) feeling somewhat or very confident and one reported feeling very confident. When asked what they were planning to implement that was different, attendees' responses included:

Using more diverse ways of presenting information with less jargon and look at more creative ways of engaging with participants

[I] feel more confident using contributors feedback (in terms of their words) to support why I have reduced/changed wording of documents when presented to an ethics committee

There was also strong support for further OPTIMISE workshops on topics such as assessing capacity to consent for research and inclusive approaches to public involvement. To support researchers to implement the learning form the workshop, a resource pack was shared with attendees following after the event and they were also offered follow-on one-to-one consultancy support from Thinklusive which could take the form of advice and guidance for a current project, or for an idea that is in the planning stage.

Discussion

People with communication and/or decision-making needs which may be due to lifelong or acquired health conditions such as learning disability, stroke, brain injury and dementia, or those with lower literacy or limited language ability, face many barriers to participation and inclusion, including in research [50]. This group experience worse health outcomes, including people with communication needs experiencing higher rates of depression and anxiety [50], and the inability to speak English being linked to worse health in the UK [51]. A lack of communication support and disabling environments, practices and policies contribute to their exclusion from research [50]. People may also experience other barriers to inclusion such as sensory impairment [52], language, cultural differences and a lack of cultural

competence [53]. Improving accessibility can support people to make informed decisions, promotes their autonomy, enables more people - and more diverse groups of people - to participate in research and therefore provides more equitable opportunities and ensures that research leads to better outcomes for all in society [52].

The OPTIMISE project developed a set of recommendations to help researchers design more inclusive consent processes in clinical trials, including three guiding principles (collaboration, ethics and reflection) that underpin inclusive consent and seven domains across which consent processes can be made more accessible if appropriate action is taken. Linking the recommendations to resources, including those from our wider research programme (CONSULT), helps equip researchers with the practical tools and examples they need. The accompanying toolkit is intended to help research teams to use the OPTIMISE recommendations in practice and support inclusive public involvement. While the recommendations focus on consent processes as this acts as the 'gatekeeper' to research, all components of a study should be designed to be inclusive [54].

In addition to researchers, the OPTIMISE recommendations will also be useful for anyone reviewing or supporting research (e.g. members of funding panels and RECs) to understand how (or if) researchers have considered accessibility in their application. Whilst RECs must balance the protection of 'vulnerable' populations with supporting inclusion of under-served groups [55], they are often viewed as perpetuating exclusion of people with communication and decision-making needs [41, 56, 57]. Recent updates to the HRA's guidance on applying a proportionate approach to seeking and evidencing informed consent in health and social care research, which cites OPTIMISE as having informed its development [58], may help strengthen the shared commitment from researchers and RECs to ensure consent processes are accessible and studies are designed to include people who could benefit from the findings.

A strength of the project is the inclusive involvement of people with lived experience, including co-producing accessible summaries, and the inclusion of stakeholders drawn from across disciplines and with experience of different populations with communication and decision-making needs. Inclusive co-production plays a key role in making clinical trials more disability-inclusive [59], and involving people with communication disabilities in methodological guidance is key to ensuring trial processes are designed to be inclusive [60]. The inclusion of diverse perspectives and resources across a broad range of policy and practice, together with the development of co-produced implementation materials, helps to maximise the relevance of the recommendations and accompanying resources and so support uptake by the wider research community. However, there are a number of limitations to acknowledge, including that the literature review was not conducted as a systematic or scoping review as the aim was to capture the range of potential domains of enhanced consent, rather than to provide a definitive answer or map all the available literature. While this approach was appropriate to the aim of this project, it may have led to relevant sources not being included. While the OPTIMISE recommendations are built on evidence-based strategies in a range of populations who experience communication and decision-making difficulties, the recommendations themselves have not yet been formally evaluated.

Further research is needed to explore whether the OPTIMISE recommendations do effectively support researchers to design more inclusive consent processes in trials, and whether those processes are more accessible to people with communication and decision-making needs. While the recommendations were developed in collaboration with researchers and experts with professional and lived experience, future research could also explore a range of implementation outcomes, such as the acceptability and scale of adoption of the recommendations. As new relevant resources are likely to be developed in the future, further revisions are planned at regular intervals to ensure the content and links remain current. This will form part of a follow-on project to address consent-based challenges to improve inclusion in research (ACCORD) [61].

Conclusion

People with communication and decision-making needs often encounter barriers to participating in trials. The OPTIMISE recommendations could help support research teams and organisations to achieve their commitments to ensuring research is more inclusive and better able to reduce health and research disparities by ensuring consent processes are accessible by design. The key takeaway message is that even small, achievable adaptations can meaningfully improve accessibility. The OPTIMISE recommendations and toolkit of resources are freely available via the OPTIMISE website: https://www.capacityconsentresearch.com/optimise. Future work should focus on evaluating whether the OPTIMISE recommendations are effective in improving accessibility and bridging the gap between policy and practice related to informed consent and accessibility requirements, and to explore the factors influencing their implementation in practice.

Abbreviations

HRA
Health Research Authority
NIHR
National Institute for Health and Care Research
REC
Research ethics committee
UKCRC CTU Network
UK Clinical Research Collaboration Clinical Trials Unit Network
UKTMN
UK Trial Management Network

Declarations

Ethics approval and consent to participate

This work included a literature review and public and stakeholder engagement activities and therefore did not require research ethics approvals or participant consent.

Consent for publication

Not applicable.

Availability of data and materials

The OPTIMISE recommendations are available online and can be accessed at: https://www.capacityconsentresearch.com/optimise

Competing interests

ST has acted as a paid consultant on trial diversity to the NIHR Oxford Health Biomedical Research Centre and the NIHR Cambridge Biomedical Research Centre. He received a fee to speak about pragmatic trials at the Cancer Drug Development Forum meeting in November 2025. The other authors all declare that they have no competing interests.

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Authors' contributions

VS conceived the project in collaboration with MS and the Researcher Advisory Group members (ST, AMR, AV, MJ, JW) and drafted the first version of the manuscript. All authors critically revised the manuscript and approved the final version.

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Figures

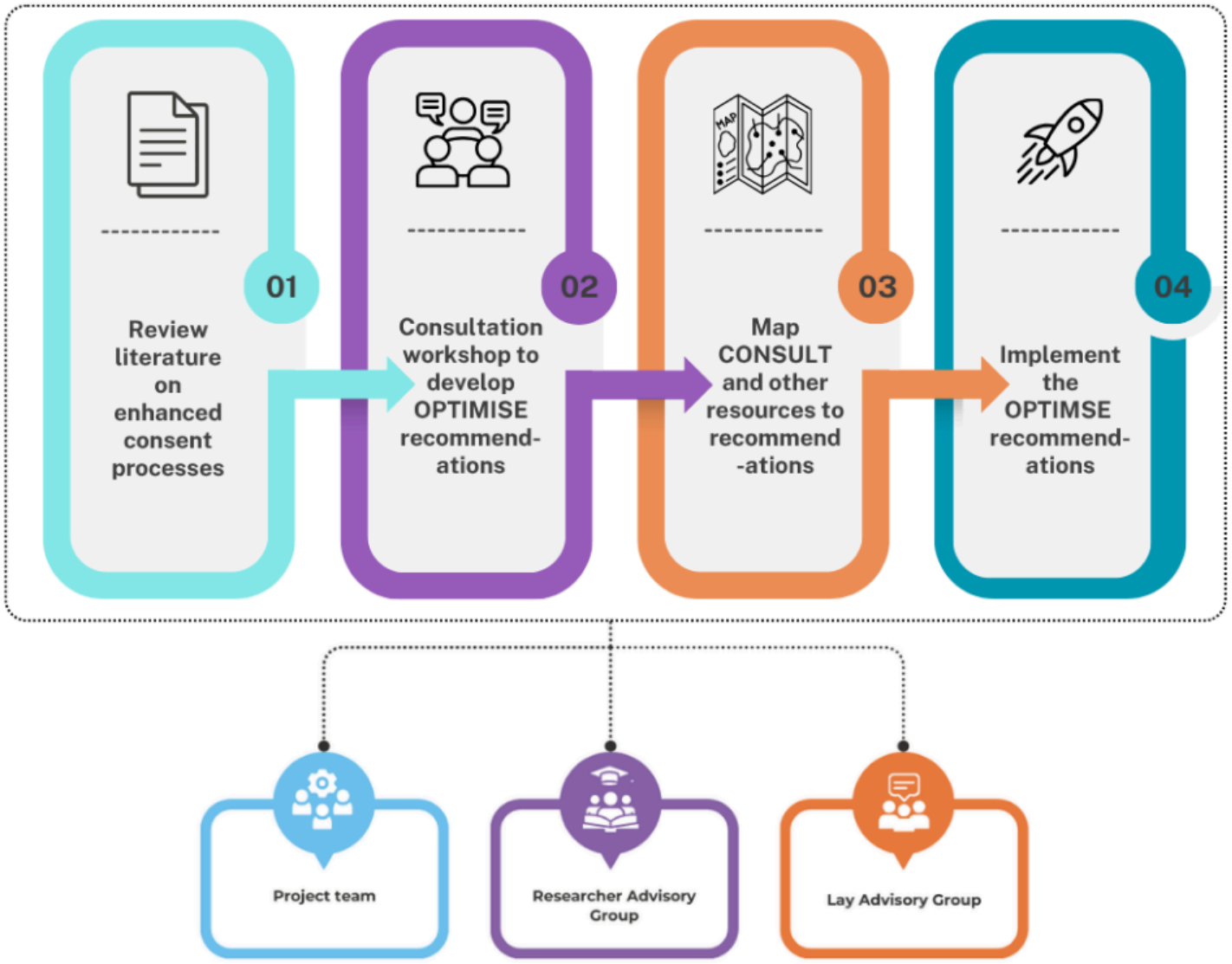


Figure 1

OPTIMISE project stages

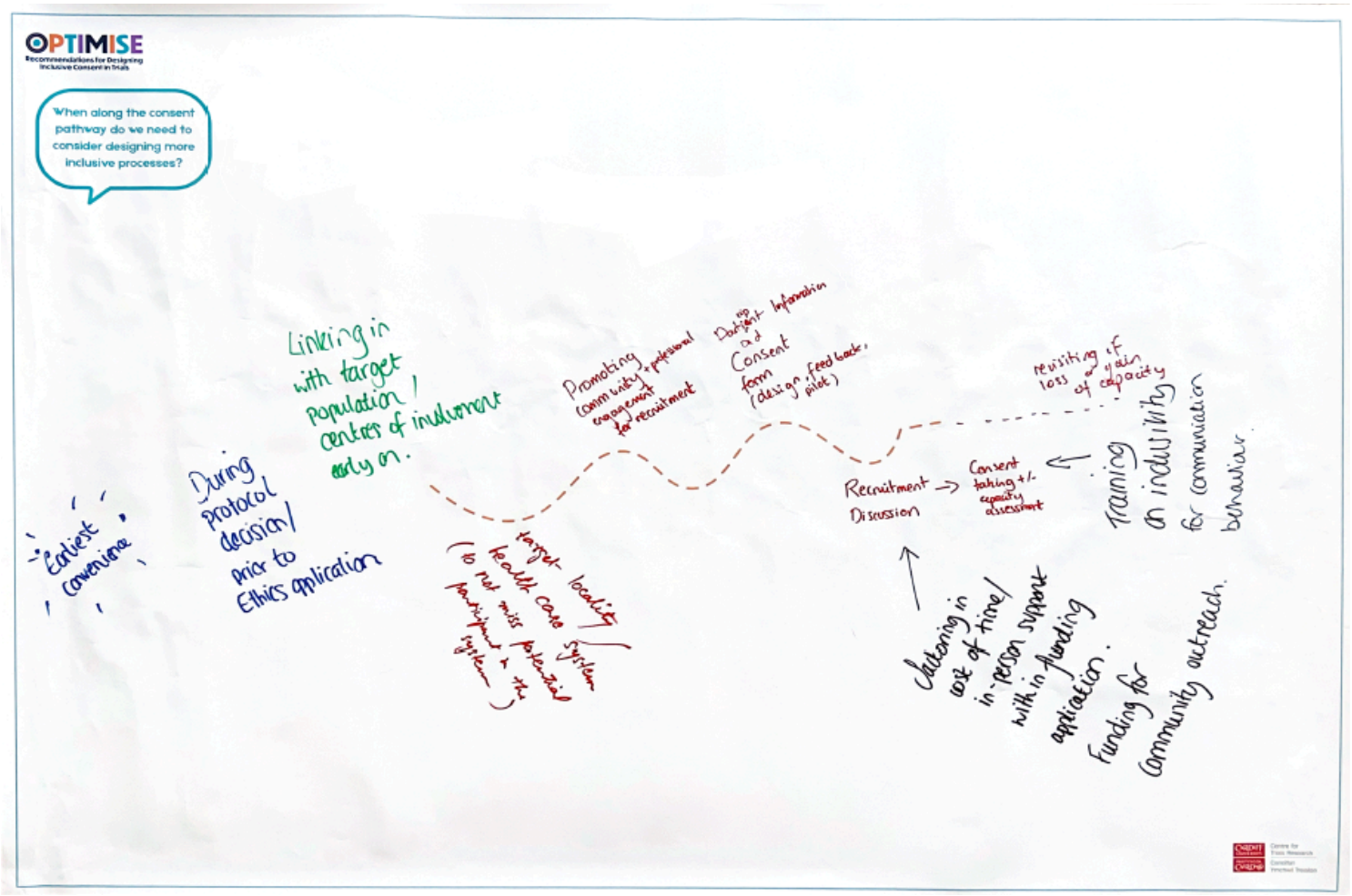


Figure 2

Example response to the question 'When along the consent pathway do we need to consider designing more inclusive processes?'

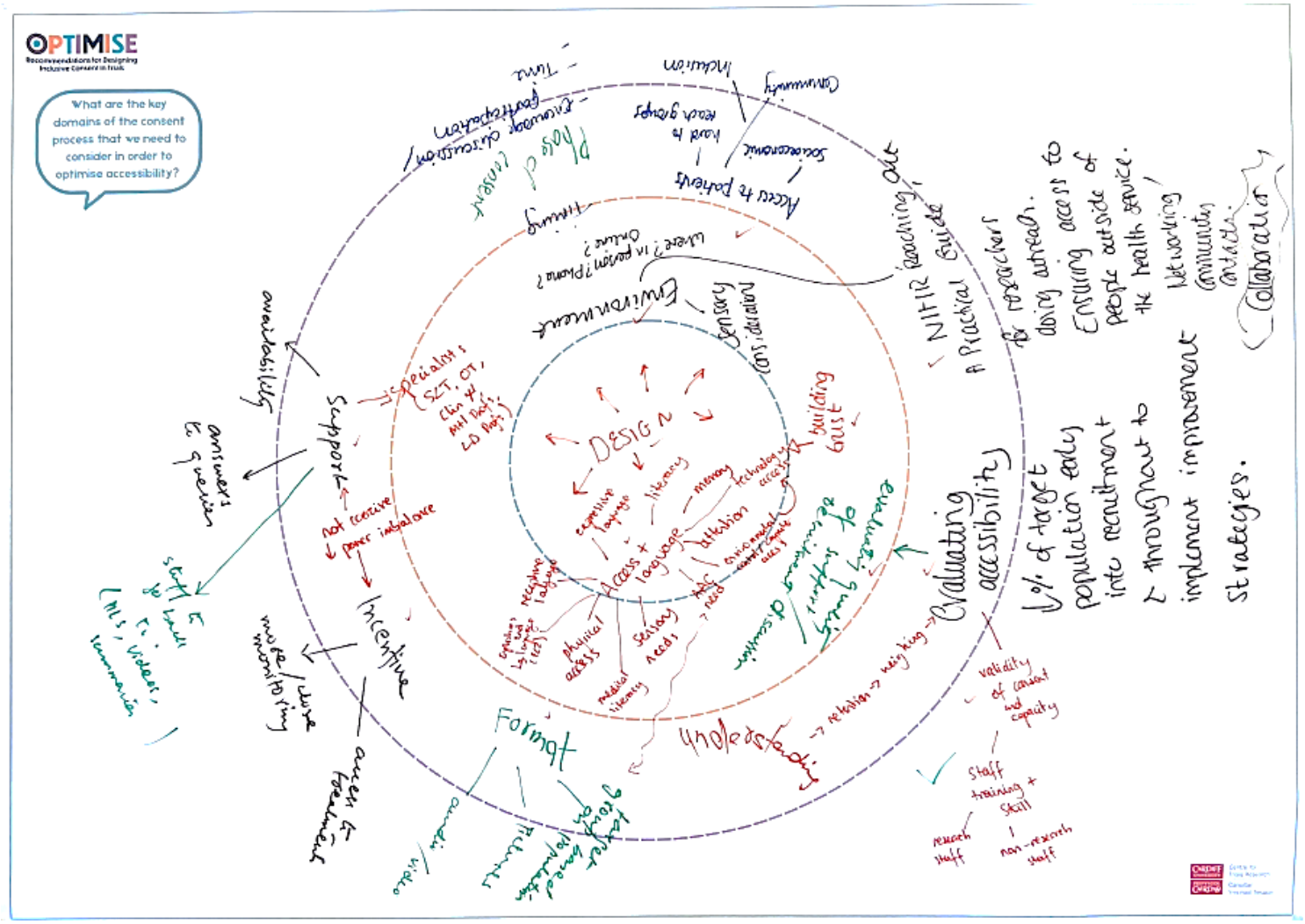


Figure 3

Example response to the question 'What are the key domains of the consent process that we need to consider in order to optimise accessibility?'



Figure 4

Example response to the question 'How can we support researchers to use OPTIMISE?'

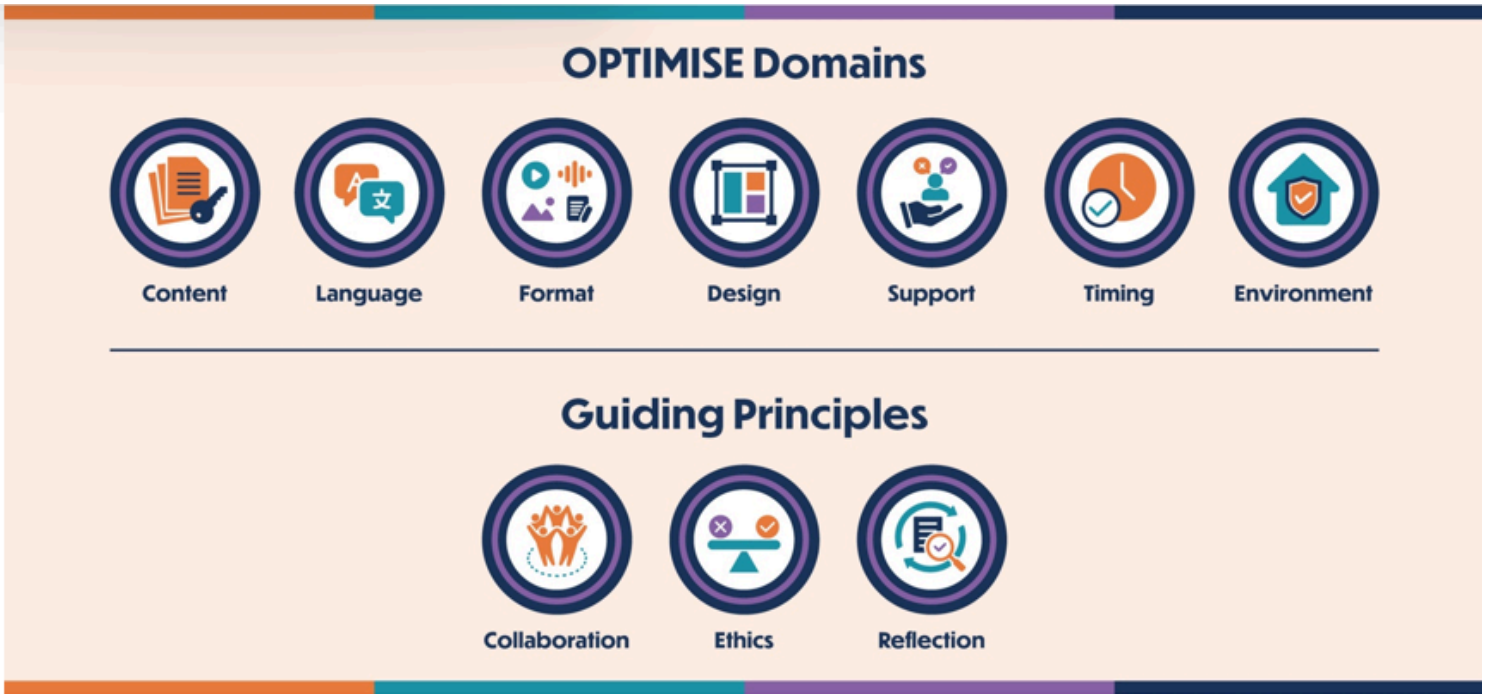


Figure 5

OPTIMISE guiding principles and domains of inclusive consent



Figure 6

Suggested timepoints to consider the OPTIMISE recommendations in a trial

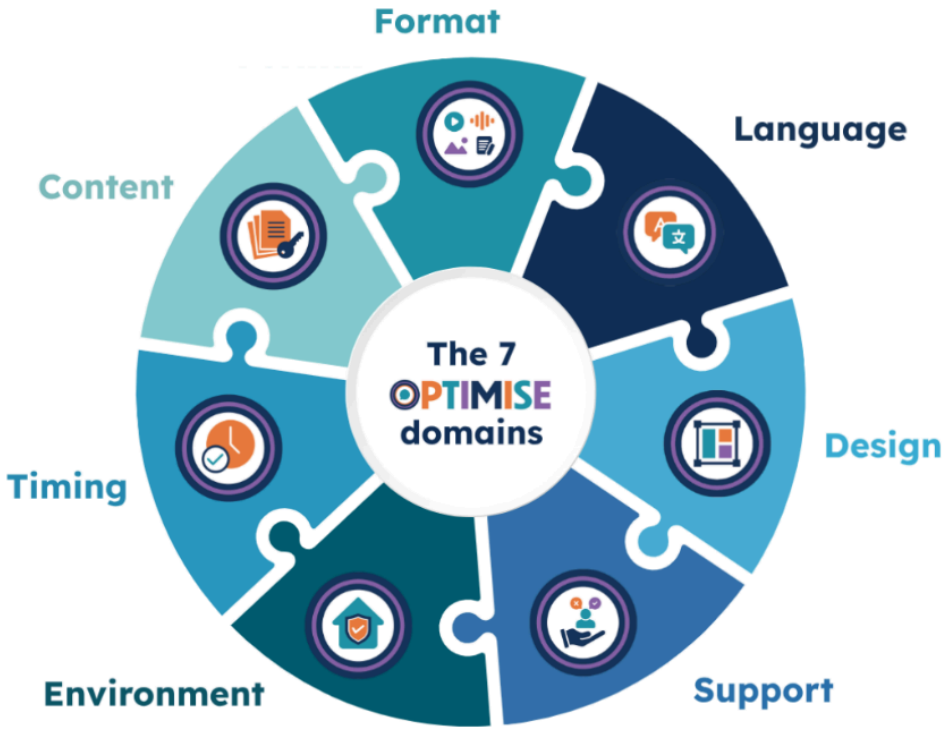


Figure 7

Image of OPTIMISE domains from the interactive infographic



Figure 8

Example pages from the easy read guide to the OPTIMISE recommendations

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryfilePostwebinarsurvey.docx
- SupplementaryfilePreandpostworkshopquestionnaire.docx
- SupplementaryFileSearchstrategy.docx