OPTIMISE

Recommendations for Designing Inclusive Consent in Trials

OPTIMISE recommendations for designing inclusive consent processes in trials

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About the OPTIMISE recommendations

Clinical trials should reflect the population they are meant to serve. However, **people with communication and/or decision-making needs are often excluded from trials** because processes such as informed consent are not designed with accessibility in mind. Without a more inclusive approach, trials will continue to exclude this group, leading to poorer quality trials and widening disparities in health.

Improving accessibility could maximise people's ability to provide their own consent or express their wishes about taking part, ensure better compliance with legal and ethical requirements, and help meet funders' expectations for inclusive research. This could be achieved through **incorporating a range of strategies known to effectively support** people with communication and/or decision-making needs. Researchers have called for **clear, practical guidance** about which strategies can be incorporated into clinical trials to ensure they are more inclusive, starting with consent processes as this acts as the 'gatekeeper' to research. Similar considerations will also be needed for other aspects of a study, such as data collection and withdrawal processes.

As part of the CONSULT research programme, the OPTIMISE project developed a set of recommendations to help researchers **design more inclusive consent processes in clinical trials**. They were developed through combining evidence and key stakeholder consultation with experts in inclusive research, trials methodology and ethics, and with clinicians and public contributors. The recommendations will also be useful when **reviewing and supporting research**, such as by research ethics committees and funding panels.

The OPTIMISE recommendations are intended to be generic and high level, recognising that **accessibility and support needs vary** between populations and individuals, and the exact consent processes will depend on the **study design and context**. Intersectionality (additional characteristics/factors that may also affect inclusion) also needs to be carefully considered, including cultural factors, and there can be **resource and time implications**. However, even relatively modest adjustments can make a difference.

Further reading

HRA Design and Review Principles https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/

CONSULT designing inclusive studies: https://www.capacityconsentresearch.com/designing-inclusive-studies

Clinical Trials Toolkit consent: https://www.ct-toolkit.ac.uk/routemap/informed-consent

See also relevant mental capacity legislation and clinical trial regulations (amendment to come into force April 2026) and accompanying guidance: https://www.capacityconsentresearch.com/legal-frameworks

About this document

This document forms part of a toolkit to help researchers and others put the OPTIMISE recommendations into practice. The document has five parts:

Part 1 – Getting started with the OPTIMISE recommendations

Part 2 – Guiding principles for inclusive consent

Part 3 – OPTIMISE domains of inclusive consent

Part 4 - Supporting uptake of OPTIMISE recommendations

Part 5 – Accessing the toolkit

Part 1: Getting started with the OPTIMISE recommendations

When should the OPTIMISE recommendations be considered?

Inclusive consent should be considered throughout the lifecycle of a study, starting when **initially developing** a research idea (e.g when discussing the study population) so that adequate time and resources (e.g additional research support, community outreach, inclusive design) can be included in the **funding application** (e.g costing in provision for accessible materials such as easy read versions, translations), and to help **identify and build relationships** with key stakeholders and, importantly, for early involvement of public involvement contributors.

When **developing the protocol**, the consent process should be designed with accessibility in mind (e.g incorporating flexible approaches to consent, use of decision-support tools), including when: **developing participant information materials** (including piloting the materials and seeking feedback), drafting the **ethics application**, and **identifying research sites** (e.g translation needs).

When **identifying and recruiting participants** there needs to be an **assessment** of the individual's communication needs, appropriate **tailoring** of information using a range of communication strategies (which may include using staged approaches to consent) and supported decision-making, with **adaptations** as required and assessment of capacity to consent **if** there are concerns. Consent must also be **revisited** throughout the study, particularly if there are concerns about changes in capacity, or re-consent is required.

How should the OPTIMISE recommendations be used?

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

Part 2: Guiding principles for inclusive consent

Collaboration

Work together 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 have a role in facilitating inclusive consent.

Further reading

CONSULT page on participatory involvement: https://www.capacityconsentresearch.com/participatory-involvement

Example - No Research About Us Without Us co-produced terms of reference: https://www.learningdisabilityengland.org.uk/wp-

content/uploads/2025/07/No-Research-About-Us-Without-Us-Working-Together-Fairly-easy-read-final.pdf

Example - No Research About Us Without Us ‘Matrix of support’: https://doi.org/10.48785/100/393

Ethics

Embed **ethical practices and principles**, such as building and maintaining trust between researchers and communities and individuals, being respectful, and promoting autonomy. Reflexively engage with **ethical review** processes which can act as a barrier or facilitator to inclusive consent practices.

Further reading

CONSULT research ethics page: https://www.capacityconsentresearch.com/research-ethics

CONSULT top tips applying for ethics: https://www.capacityconsentresearch.com/uploads/1/3/5/9/135960405/consult_infographic_rec_tips.pdf

Dementia Enquirers DEEP Ethical Research standards: https://www.dementiavoices.org.uk/wp-content/uploads/2020/07/The-DEEP-Ethics-Gold-Standards-for-Dementia-Research.pdf

Reflection

Review whether consent processes are **effectively meeting** peoples' needs or if additional support is needed, whether collaborations are working (for everyone involved), and if there is an **appropriate balance** between burden and benefit for participants and any carers, consultees/legal representatives.

Think about how you can **start somewhere** – small achievable adaptations in one area could meaningfully improve accessibility. For example, by providing accessible or easy read versions of documents, offering information in video or audio format, or allowing more time for consent discussions.

Further reading

INCLUDE Impaired Capacity to Consent Framework: https://www.capacityconsentresearch.com/include-impaired-capacity-to-consent-framework

Consent Support Tool: https://www.jr-press.co.uk/product/consent-support-tool/

Part 3: OPTIMISE domains of inclusive consent

Consent processes can be made more accessible through considering seven OPTIMISE domains, which may require specific actions taken across one, more, or all of the domains as appropriate.

Content

Participants (and consultees/legal representatives where needed) 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 for any questions or more information. Attention should be paid to how **key concepts** (e.g randomisation, data protection) are introduced and explained, and the **order** in which they are presented, to ensure the information is understandable ('cognitively accessible').

Further reading

HRA Consent and Participant Information Guidance https://www.hra-decisiontools.org.uk/consent/

ICH E6 (R3) https://www.ct-toolkit.ac.uk/news/summary-key-changes-ich-e6-r3-guidelines

Producing accessible participant information sheets (MAPLE guidance and templates): https://maple.bristol.ac.uk/accessible-pil/

Practical Guide to Inclusive Research: https://medium.com/inclusive-research/preparing-for-inclusive-research-with-people-with-disabilities-228ce2f8cb2e

Language

Plain and accessible language should be used (e.g avoiding complex words, using shorter sentences with a simplified sentence structure) with careful consideration about the **literacy level** of the information and how it corresponds with that 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 those can be met throughout the study.

Further reading

CONSULT communication and capacity page: https://www.capacityconsentresearch.com/communication-and-capacity

Accessible information guidelines for people with aphasia: https://www.stroke.org.uk/sites/default/files/accessible_information_guidelines.pdf1_.pdf

Guidance on research involving interpreters and translators: https://arc-nenc.nihr.ac.uk/wp-content/uploads/2022/12/Guide-Part-Two-How-to-conduct-research-involving-interpreters-and-translators.pdf

Format

Consider the best choice of format for participant information materials. This may depend on the study design (e.g decentralised trial), setting (e.g primary or emergency care), 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 electronic/digital (e.g website, animation), with **routes** to delivery such as in person or remotely. Consider having **multiple options** available for both providing information and seeking/recording consent, and ensure the format, mode and route can be **tailored** to meet individuals' communication and decision-making needs.

Further reading

Accessible communication formats guidance: https://www.gov.uk/government/publications/inclusive-communication/accessible-communication-formats

Example - easy read participant information sheet CLOTBUST-L: https://indd.adobe.com/view/6d1ec727-c8dc-45f5-b46b-311eb32db54a

Design

Accessible design principles should be used to design informational materials, and the **layout** should be kept simple. Use of **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 (e.g with alt text).

Further reading

Preparing accessible and understandable clinical research participant information leaflets and consent forms: https://doi.org/10.1186/s40900-021-00265-2

Cognitive accessibility guidelines: https://accessibility.education.gov.uk/guidelines/coga

Accessibility By Design toolkit for inclusion of people with disabilities: https://mrctcenter.org/diversity-in-clinical-research/tools/abd_toolkit/

Support

Communication and decision-making can be supported through **layering** of participant information (e.g brief summary of information alongside more detailed versions), use of **communication strategies** (e.g keywords/cards, memory aids), **technology** (e.g hyperlinks to more detail or explanation), including **assistive technology** (e.g screen reader), and use of **tools** to support communication and/or decision-making (e.g Talking Mats, Consent Support Tool). Those involved in caring for or supporting the person (e.g family members, support workers) can help **facilitate communication**. **Multiple communication options** should be available and **tailored** to meet individuals' communication and decision-making preferences and needs.

As **communication behaviour** has a key role, consider **who** will be involved and whether they have the appropriate **skills and training** to communicate effectively and assess capacity if needed. For participants who lack capacity to consent, **consultees/legal representatives** should be provided with their own information and should be involved in exploring the person's preferences, potentially prior to any loss of capacity.

Further reading

CONSULT research conduct: https://www.capacityconsentresearch.com/research-conduct

Supporting people with communication disabilities to communicate and make decisions: e-learning resource

Example - Talking Mats: https://www.talkingmats.com/

Template for layered consent and supplementary information (Australia): https://www.informedpicf.com.au/

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 (e.g in emergency situations, during fluctuations in capacity, prior to any loss of capacity). It includes the **time taken to deliver** information such as staging of information (e.g providing information at multiple timepoints), support to **retain information** (e.g use of memory aids), and **revisiting consent**. It also includes ensuring there is **sufficient time** for discussions with public contributors when designing a study and to develop and tailor information and approaches.

Further reading

Applying a proportionate approach to the process of seeking consent: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Proportionate_approach_to_seeking_consent_HRA_Guidance.pdf

Guidance on consent in critical care studies: https://www.liverpool.ac.uk/media/livacuk/iphs/1healthservicesresearch/Perspectives_guidance_Version,1.0,02.04.2020.pdf

Example – video information for participants who recovered capacity: https://comited.blogs.bristol.ac.uk/for-patients-who-have-recovered-capacity/

Environment

Consider the environment (including digital environment) in which participants are approached and consent is being sought. This includes whether the environment is **accessible** and **safe**, it is somewhere the person feels **comfortable** (e.g a familiar place), is a place that they **trust**, and where there are appropriate levels of **sound, lighting** and other **sensory stimuli**.

Further reading

Guidance and tools for digital accessibility: https://www.gov.uk/guidance/guidance-and-tools-for-digital-accessibility

Dementia friendly environment checklist: https://www.alzheimers.org.uk/sites/default/files/2024-09/dementia-friendly-environments-checklist.pdf

Accessible environment resource: https://www.autism.org.uk/what-we-do/autism-know-how/autism-accreditation/autism-friendly-award/guides-and-resources/accessible-environments

Part 4: Supporting uptake of the OPTIMISE recommendations

Raise awareness – help spread the word about the importance of inclusive consent and OPTIMISE https://www.capacityconsentresearch.com/optimise

Consider training and skills needs – for example, CONSULT e-learning on legal, ethical and methodological issues in research with adults with impaired capacity to consent https://www.capacityconsentresearch.com/training

Build confidence – access collated resources on CONSULT website https://www.capacityconsentresearch.com, share examples of best practice

Consider how best to meet policy requirements – including funders, research governance, reasonable adjustments, and supporting people to make their own decisions where possible (e.g Mental Capacity Act 2005)

Create an inclusive research culture – research inclusion requires a system-wide approach, more work is needed to change attitudes as well as taking practical steps

Part 5: Accessing OPTIMISE toolkit

Access the toolkit via the OPTIMISE website:
https://www.capacityconsentresearch.com/optimise

For more information, please contact:
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