

# Improving inclusion in clinical trials through ensuring consent is 'accessible by design'

## Policy brief

**Overview:** The OPTIMISE recommendations, developed by a team led by Cardiff University, are a way to support organisations and researchers 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.



# Key Points

**20% of the UK population will experience communication difficulties at some point in their lives.**

(Royal College of Speech and Language Therapists, 2025)

**Communication difficulties can be associated with conditions such as dementia, disabilities (including learning disability), or an acute or critical illness.**

**People with communication difficulties are frequently excluded from clinical trials either explicitly (e.g due to concerns about their ability to provide informed consent) or because information about the study is not accessible to them.**

**As research is intended to improve health and care, routinely excluding populations from research means that the healthcare delivery that follows from it, is not designed for them.**

**This builds in inequity and can result in treatments that are less effective for the very people who most need support, leading to poorer outcomes.**



# Key Points

**Studies that are not accessible may also struggle to recruit participants, and to meet their statutory equality and accessibility requirements.**

**Improving inclusivity and diversity in research, including clinical trials, is a priority for research funders, regulatory bodies, and research organisations.**

**However, researchers often lack the knowledge and resources to ensure that their studies are designed to be accessible, including for people with communication difficulties.**

**The OPTIMISE project has developed a set of clear, practical, evidence-informed recommendations to help researchers design more accessible and inclusive consent processes for clinical trials and other research studies.**



OPTIMISE recommendations and toolkit of resources are available via the OPTIMISE website:  
**[www.capacityconsentresearch.com/optimise](http://www.capacityconsentresearch.com/optimise)**



# Policy context

Health and care research plays a fundamental role in helping to reduce the disparities that exist in health outcomes caused by factors such as age, socioeconomic disadvantage, ethnicity and disability.<sup>1</sup> However, these same factors can lead to groups being excluded from taking part in research, including clinical trials, which further exacerbates these inequalities.<sup>2</sup>

A lack of inclusivity and diversity can also affect scientific value, as trial results may be less generalisable to groups who would potentially benefit from the findings, despite them often being groups with the highest burden from a particular disease or condition.<sup>3</sup>

In 2025, the UK government outlined their vision for transforming clinical research to ensure it aligns with their health and growth missions, including to reduce inequalities through research inclusion towards a fairer Britain.<sup>4</sup>

The UKCRC Clinical Trials Unit Network shares a similar commitment<sup>5</sup>, as does the pharmaceutical industry through the ABPI.<sup>6</sup>

There is also a legislative impetus to improve inclusivity and diversity, with the incoming Clinical Trials Regulations being intended to bring the benefits of clinical trials to everyone.<sup>7</sup>

This regulatory focus on ensuring that the whole population can benefit from research is reflected in the HRA and MHRA's combined work in this area.<sup>8</sup>

Research funders such as Wellcome<sup>9</sup> and UKRI<sup>10</sup> have also strengthened their policy commitment to embedding equity, diversity and inclusion in the research they fund. The NIHR have gone further - now requiring inclusive research design as a condition of funding.<sup>11</sup>





# Policy context

A number of groups are recognised as being under-served by research, and the NIHR list some examples in their INCLUDE initiative.<sup>12</sup> This includes people with cognitive impairment and other disabilities and conditions that can result in communication and/or decision-making needs.

It is estimated that 20% of the UK population will experience communication disabilities at some point in their lives.<sup>13</sup> With a global ageing population, more people are living with conditions associated with communication disabilities such as dementia and stroke.



In 2025, the major UK research funders made a joint commitment to greater inclusion of older adults in health and care research and ensuring that research is designed with equity in mind.<sup>14</sup>

The importance of inclusive research design, particularly in informed consent processes, in order to receive ethical approval is highlighted by the HRA's Design and Review Principles.<sup>15</sup>

However, these principles are intended to be higher level and more generic and may not take account of those with additional communication and/or decision-making needs who are often excluded from research. They also focus on information provision, rather than the wider aspects of communication and decision-making.

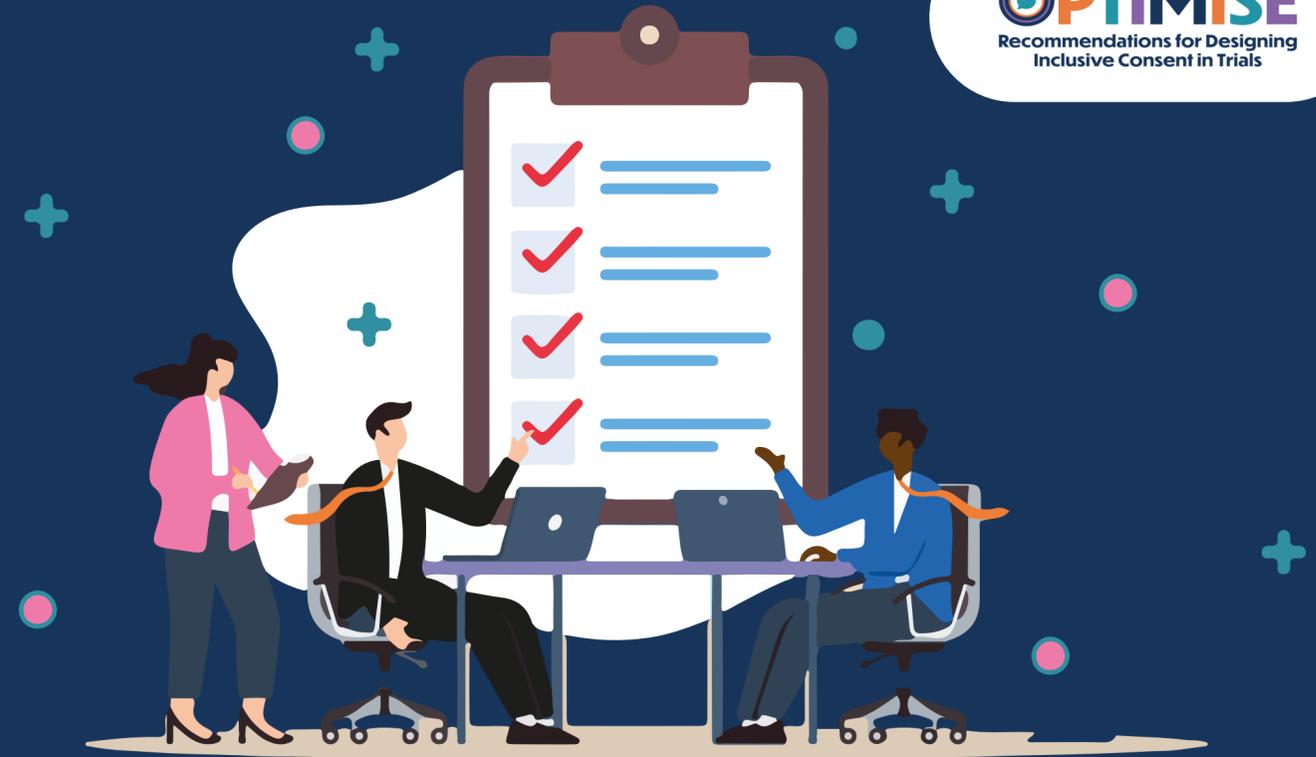
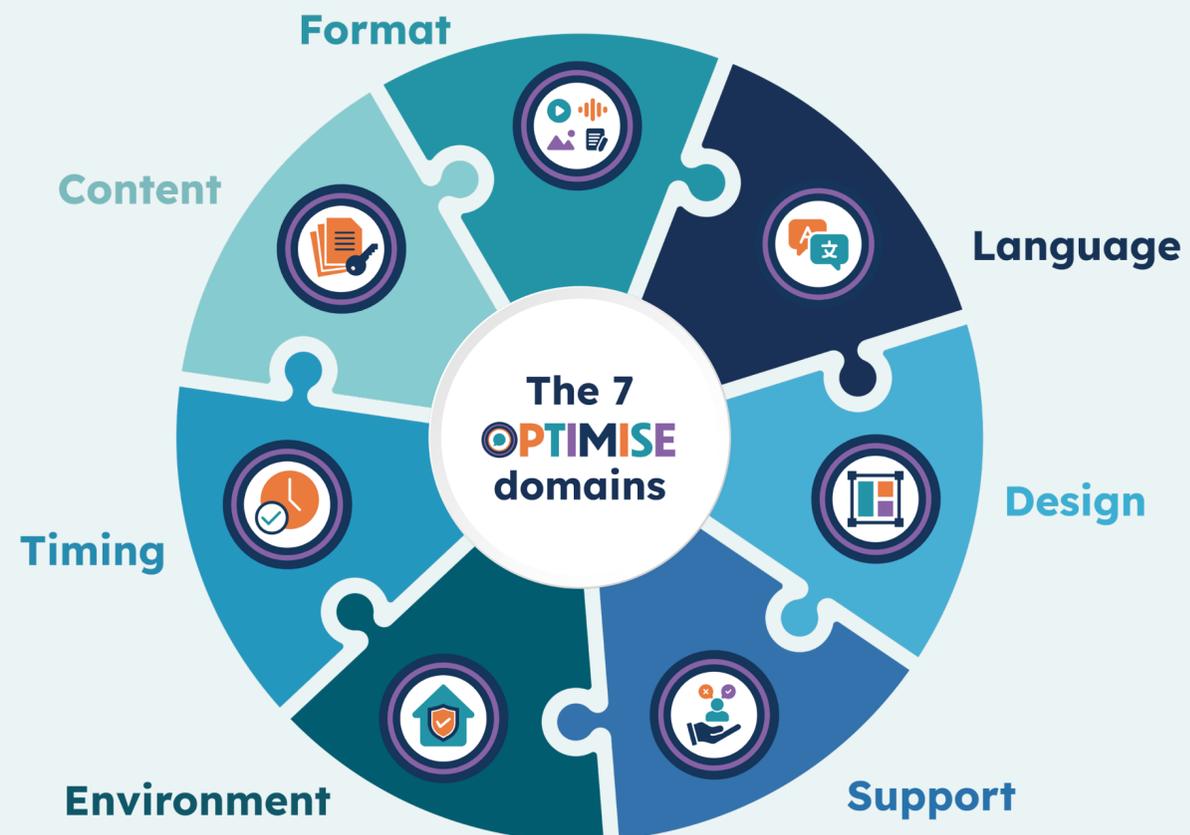
Previous research found that researchers often lack the knowledge and skills to ensure that research studies are designed to be accessible, and so more inclusive of people with communication difficulties.<sup>16</sup> They called for clear and practical guidance.



# OPTIMISE project

Through combining evidence with consultations with experts in inclusive research and members of the public, the OPTIMISE project at Cardiff University has developed a set of recommendations to help researchers design more inclusive consent processes in clinical trials.

Building on the HRA Design and Review Principles, OPTIMISE identified three guiding principles that underpin inclusive consent and the seven domains across which consent processes can be made more accessible if appropriate action is taken.



We then linked the recommendations to resources from our wide research programme, CONSULT ([capacityconsentresearch.com](http://capacityconsentresearch.com)) to equip researchers with the practical tools and examples they need.

There is also a toolkit to help research teams use the OPTIMISE recommendations in practice, including easy read versions of the recommendations which can help support inclusive public involvement.

As well as researchers, the OPTIMISE recommendations will also be useful for anyone reviewing or supporting research, such as members of research ethics committees and funding panels, to understand how (or if) researchers have considered accessibility in their application.



# Recommendations



## Recommendations for **research funders**

**Pre-application stage:** signpost applicants to OPTIMISE to ensure they consider accessibility requirements throughout their study and can ensure the necessary resources are costed into the funding application (e.g., developing accessible participant information sheets).

**Review stage:** consider whether the applicants have demonstrated that they have considered accessibility requirements and appropriately (co-)designed inclusive consent processes and other aspects of the study, with sufficient budget to enable them to do so.

## Recommendations for **regulatory organisations**

When reviewing studies, particularly those seeking to specifically include people who may have communication and/or decision making needs, consider whether the applicants have appropriately (co-)designed inclusive consent processes and other aspects of the study.

## Recommendations for **research organisations**

Signpost applicants to OPTIMISE to ensure they 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.



# More information

## About the author

Dr Victoria Shepherd is a Principal Research Fellow at the Centre for Trials Research, Cardiff University. She is an expert in informed consent and leads a research programme exploring the ethical, legal, and methodological barriers to inclusion in research for adults with impaired capacity to consent.



Email: [ShepherdVL1@cardiff.ac.uk](mailto:ShepherdVL1@cardiff.ac.uk)

## OPTIMISE

The OPTIMISE project was funded by a UKRI Impact Accelerator Award and forms part of the CONSULT research programme funded by Health and Care Research Wales.

The OPTIMISE Project team (Victoria Shepherd, Martina Svobodova) would like to acknowledge the Researcher Advisory Group, Lay Advisory Group and the Thinklusive Advisory Group for their support and to those who contributed to the stakeholder workshop.



## The OPTIMISE recommendations

The OPTIMISE recommendations and toolkit of resources are freely available via the OPTIMISE website:



[www.capacityconsentresearch.com/optimise](http://www.capacityconsentresearch.com/optimise)





# References

[1] [NIHR Best Research for Best Health: The Next Chapter, 2021](https://www.nihr.ac.uk/best-research-best-health-next-chapter)

<https://www.nihr.ac.uk/best-research-best-health-next-chapter>

[2] [NIHR Research Inclusion Strategy 2022-2027](https://www.nihr.ac.uk/about-us/who-weare/research-inclusion/strategy-2022-27)

<https://www.nihr.ac.uk/about-us/who-weare/research-inclusion/strategy-2022-27>

[3] [WHO Guidance for best practice in clinical trials, 2024](https://www.who.int/publications/i/item/9789240097711)

<https://www.who.int/publications/i/item/9789240097711>

[4] [DHSE Policy paper: Transforming the UK clinical research system: August 2025 update](https://www.gov.uk/government/publications/transforming-the-uk-clinical-research-system-august-2025-update/transforming-the-uk-clinical-research-system-august-2025-update)

<https://www.gov.uk/government/publications/transforming-the-uk-clinical-research-system-august-2025-update/transforming-the-uk-clinical-research-system-august-2025-update>

[5] [UK CRC Clinical Trials Network Strategy 2025-2030](https://ukcrc-ctu.org.uk/)

<https://ukcrc-ctu.org.uk/>

[6] [ABPI Industry Equality, Diversity and Inclusion Strategy, 2021](https://www.abpi.org.uk/media/o0sfmlhy/abpi-equality-diversity-inclusion-strategy-2021.pdf)

<https://www.abpi.org.uk/media/o0sfmlhy/abpi-equality-diversity-inclusion-strategy-2021.pdf>

[7] [UK Parliament Statement on Clinical Trials Regulations](https://questions-statements.parliament.uk/written-statements/detail/2024-12-12/hlws306)

<https://questions-statements.parliament.uk/written-statements/detail/2024-12-12/hlws306>

[8] [HRA Increasing the diversity of people taking part in research](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/increasing-diversity-people-taking-part-research/)

<https://www.hra.nhs.uk/planning-and-improving-research/best-practice/increasing-diversity-people-taking-part-research/>



# References

[9] [Wellcome Equity, diversity and inclusion policy, 2025](https://wellcome.org/research-funding/guidance/policies-grant-conditions/equity-diversity-inclusion-policy)

<https://wellcome.org/research-funding/guidance/policies-grant-conditions/equity-diversity-inclusion-policy>

[10] [UKRI Equality, diversity and inclusion strategy, 2023](https://www.ukri.org/wp-content/uploads/2023/03/UKRI-220323-UKRIEDIStrategyConceptsCorporateRT.pdf)

<https://www.ukri.org/wp-content/uploads/2023/03/UKRI-220323-UKRIEDIStrategyConceptsCorporateRT.pdf>

[11] [NIHR Inclusive research funding application guidance, 2024](https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/funding-application-guidance)

<https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/funding-application-guidance>

[12] [NIHR INCLUDE](https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/improving-inclusion-under-served-groups-clinical-research-guidance-include-project)

<https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/improving-inclusion-under-served-groups-clinical-research-guidance-include-project>

[13] [Royal College of Speech & Language Therapists](https://www.rcslt.org/policy-andinfluencing/communication-access-uk/)

<https://www.rcslt.org/policy-andinfluencing/communication-access-uk/>

[14] [NIHR and research funders' joint commitment for better inclusion of older adults in research and health studies, 2025](https://www.nihr.ac.uk/news/nihr-and-research-funders-joint-commitment-better-inclusion-older-adults-research-and-health-studies)

<https://www.nihr.ac.uk/news/nihr-and-research-funders-joint-commitment-better-inclusion-older-adults-research-and-health-studies>

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

<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/>

[16] [Shepherd et al, 2022 Unpacking the 'black box of horrendousness': a qualitative exploration of the barriers and facilitators to conducting trials involving adults lacking capacity to consent](https://doi.org/10.1186/s13063-022-06422-6)

<https://doi.org/10.1186/s13063-022-06422-6>