

Revising the Mental Capacity Act Code of Practice: Call for Evidence Consultation

Details of the consultation: <https://consult.justice.gov.uk/digital-communications/revising-the-mca-2005-code-of-practice/consultation/>

NHS R&D Forum Research Management Working Group Response

The NHS R&D Forum Research Management Working Group welcomed the opportunity to comment on how best to refine and improve the Code of Practice to reflect current needs. The Research Management Working Group is a group of members of the NHS R&D Forum with a wealth of experience and expertise in both managing and delivering research activity within NHS organisations. The group aims to bring together expertise and leadership from within existing NHS R&D professional management teams to support the planning, development, sharing and implementation of best practice in NHS Research Management; acting as a collective voice to represent the research management community to policy makers and stakeholders.

Following consultation with our working memberships we have specifically focused on chapter 11 – How does the Act affect research projects involving a person who lacks capacity. This response has been written in the spirit of collaborative working and as such we trust our comments will be taken in the constructive manner in which they are intended.

There was a general consensus of opinion that the chapter provides an up to date explanation about how the Act affects research projects involving a person who lacks capacity and that the scenarios in this chapter are both relevant and effective but could be expanded and improved. We would like the following points to be taken into consideration when refining and improving the Code of Practice:

- The Mental Capacity Act is embedded in clinical research practice. Researchers generally have understanding of issues around capacity in the context of research but good knowledge of the legislation can be varied. Some of the terminology used within the Code of Practice is ambiguous and could be simplified to facilitate understanding.
- Clarification is needed about the exception of the statutory principle of *'best interests'* to research involving a person who lacks capacity. A study in 2018¹ demonstrated that this is a common area of misunderstanding by health and care professionals and more examples around this area would be welcome.
- Clarity is also needed in the relationship between Power of Attorney and acting as a consultee (a study found there was a lack of understanding around whether a consultee is required to hold Power of Attorney in order to act – this was particularly the case from those from healthcare settings¹).
- The Code of Practice provides advice on good practice in assessing capacity but it does not identify a specific process to be used. As such the assessment of capacity has the potential

to be subjective and sometimes can present a conflict between legality and the principle of non-maleficence. More detailed guidance and examples would be welcomed and would mitigate a degree of uncertainty within the current Mental Capacity Act decision-making capacity provisions.

- The examples used need greater diversity to reflect the range of individuals who may experience impaired decision-making capacity, and the range of settings in which research involving adults who lack capacity is conducted. Research is now conducted across many settings, including for example in Ambulance services, non-traditional NHS organisations, through social media and out in the community.
- It would be beneficial to update the section regarding the continued participation of a participant who loses capacity during the research project (these currently relate only to research projects started before the commencement of the Act) and to reflect on some examples of good, ongoing/dynamic consent practice.
- Additional guidance is needed for health and social care professionals who act as nominated consultees (currently there is no guidance at all despite this being a relatively common occurrence) and examples of circumstances when this might occur in a range of settings would also be helpful.
- It would be helpful to have further guidance on good practice for documenting all decision making processes.

Use of Language

- The code is often written in the masculine with people who are incapacitated described as ‘him’ or ‘he’. This is something that could be amended in the new revision.
- On p202 of the code reference is made to ethical approval and should be amended to an ethical opinion and research approval. We advise you consult with the HRA around this specifically.
- P.203 second paragraph “The Act does not apply to research involving clinical trials (testing new drug) should be replaced with “The Act does not apply to Clinical Trials of Investigational Medicinal Products (CTIMPS)” A drug trial under the Clinical Trials Legislation may not just be testing a new drug.
- Update the references to Research Governance Framework to the UK Policy Framework for Health & Social Care Research.

References ¹ = Shepherd V, Griffith R, Sheehan M, *et al* Healthcare professionals’ understanding of the legislation governing research involving adults lacking mental capacity in England and Wales: a national survey *Journal of Medical Ethics* 2018;44:632-637