Recommendations for applying for ethical review for a trial involving adults who lack capacity to consent

01. Review

Review the information in Modules 2 and 3, alongside the REC requirements and processes outlined on the HRA website

02. Check

Check the questions on the HRA website to understand what details will be needed by the HRA REC and others involved in the approvals process

03. Develop

Use this to start developing the study protocol, other documents and IRAS form to apply for HRA REC approval for research involving adults lacking capacity to consent

04. Time

Allow additional time for regulatory approvals, and you may require ethical approval in more than one jurisdiction (e.g a dual application to Scotland)

05. Organisation

As the study may involve more documents to manage than other types of studies, setting up an efficient process for managing documents will be especially helpful

06. Terminology

Ensure that terminology is correct across all of the documentation and that they contain the essential information for consultees/ representatives

07. Justification

Be clear in IRAS and in the protocol why the trial could not *only be carried out* with participants who have capacity to consent (e.g using prevalence data)

08. Connection

Clearly state in IRAS and the protocol how the research is *connected with* an impairing condition, or with the treatment of the condition

09. Risk/benefit

Clearly state in IRAS and the protocol how the research meets the *risk/benefit requirements* outlined in the MCA Code of Practice

10. Safeguards

Clearly state in IRAS and the protocol how the requirements for *additional safeguards* to be in place will be met during the trial (see Module 2)

11. Assessment

Clearly state how and when *capacity will be assessed* if there are concerns that a potential participant might not have capacity to consent

12. Changes

Clearly state what steps would be taken if a participant *loses capacity* during the study, including study activities and the use of data

13. Consultation

Clearly state the arrangements for *consulting with others*, which will differ depending on the type of study and where it is being conducted (see Module 3)

More information on CONSULT e-learning on designing and conducting trials involving adults with impaired capacity to consent: https://www.capacityconsentresearch.com/training