Research Department
Capacity & research -Guidance for researchers

This document is intended as an overview of the Mental Capacity Act [MCA] & the associated legislation, policy, & guidance. The MCA governs non-CTIMP research in England & Wales. CTIMPs are covered by the Clinical Trial Regulations.

If you are conducting research using incapacitated adults at KCH you should contact the Research Office for further help & guidance.

Capacity

Capacity is the ability to make an informed decision. It isn't absolute –individuals may have the capacity to make some decisions but not others. If they are able to make an informed decision (& to communicate it in any way whatever) they have capacity.

The MCA recognises that capacity can fluctuate. Since consent does not endure the loss of capacity, researchers must monitor capacity where they have any reason to think that it might change.

As such, capacity can relate to a number of conditions –for example, an unconscious patient in ITU or someone with severe learning disabilities.

Requirements for including participants

It is important to encourage incapacitated adults to participate as fully as they are able in any decision made on their behalf.

If you wish to include an incapacitated adult in your study you must also take 'reasonable steps' to identify & seek advice (not consent) from a Consultee. This advice must be fully informed and obtained in the same way that consent would have been –templates are available from NRES for documenting this process. The role of a Consultee is voluntary: individuals should not feel pressured into offering their advice.

A Personal Consultee should someone who knows the incapacitated adult well, either a friend or a family member. They are asked to set aside their personal feelings and advise the research team on what the incapacitated adult is likely to have decided had they retained capacity. Personal Consultees cannot be a professional engaged to care for the incapacitated adult.

Where a Personal Consultee cannot be identified, you may seek a Nominated Consultee; typically this will be a healthcare professional engaged in caring for the individual; Nominated Consultees cannot have any connection with the research project.

Exceptions. For emergency research, where patients need to be recruited quickly and the time taken to seek advice would make the study unfeasible, it is possible to temporarily suspend the requirements for seeking advice. This can only be done in line with a REC

approved protocol and advice from a Consultee must then be sought as soon as the situation allows it.

What if they regain capacity?

If a participant regains capacity during the active participation phase of a study, their consent should be sought to continue in the study & to retain study data. If they regain capacity during the follow-up period, consent should be sought to retain the data collected in relation to them. If they indicate that they do not wish these data to be kept, they should be destroyed.

Unless it is likely to pose a significant health-risk, participants, with or without capacity, should be withdrawn if they indicate in any way that this is what they want. This includes any signs of distress, discomfort, or anxiety.

What happens if the Consultee changes their mind?

If a Consultee indicates that they no longer believe that the participant would wish to participate in the study, the incapacitated adult should be withdrawn from the study if this does not constitute a hazard to the participant.

Ongoing considerations

Researchers should be aware that they may have to amend, suspend, or abandon their study if:

- If new evidence emerges which suggests that the trial could be conducted equally successfully on a population who could consent for themselves, or that the research is not related to the impairing condition.
- Where new risks or burdens became apparent, as the trial may then impose a disproportionate burden.

Researchers will have to seek further advice if they make substantial amendments which affect the participants.

More help

If you are thinking about conducting research using incapacitated adults at KCH you should contact your Research Office for further help & guidance.

More guidance is also available at http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/