

A simple guide to the Mental Capacity Act 2005 in relation to research

1 Summary

From 1 October 2007, research covered by the Act cannot include any people who lack capacity to consent to the research unless:

- The research has the approval of a research ethics committee recognised by either the Secretary of State or the Welsh Assembly Government, as appropriate
- The researcher considers the views of carers and other relevant people
- The research treats the person's interests as more important than those of science and society, and
- The researcher respects any advance decisions or expressed preferences of a person who lacks capacity and any objections the person makes during the research

1.1 Timetable

The provisions of sections 30-33 of the Act come into force on 1 October 2007. Any new research starting on or after 1 October 2007 must have section 30 approval from an NHS REC and comply fully with the provisions of sections 30-33 if it is "intrusive research" involving one or more adults unable to consent for themselves. Applications to a REC for section 30 approval for new research may be made from 1 July 2007 with a view to complying with sections 30-33 from 1 October 2007.

Research starting prior to 1 October 2007 is not required to comply with sections 30-33 until 1 October 2008, provided it has ethical approval. Where the research is still underway on 1 October 2008, it must have section 30 approval from an NHS REC by that date.

Applications for section 34 approval from an NHS REC may be made from 1 July 2007 with a view to complying with the Loss of Capacity Regulations from 1 October 2007.

2 Remit of the Act

The Mental Capacity Act is relevant to research involving adults over the age of 16 in England and Wales, except Clinical Trials of Investigational Medicinal Products (CTIMPs) - the Medicines for Human Use (Clinical Trials) Regulations 2004 make legal provision for participation in CTIMPs by adults lacking capacity to consent. In Scotland the Adults with Incapacity (Scotland) Act 2000 applies. There is no specific legislation in Northern Ireland. The parts of the Mental Capacity Act that are relevant to research come into force on 1 October 2007.

The Mental Capacity Act provides the legal arrangements to enable adults lacking capacity to consent to take part in research other than CTIMPs (including health and social care research) that would otherwise require the participant's consent. The Mental Capacity Act also enables adults with capacity to make arrangements or make their wishes known in advance, to deal with future situations where they lack capacity to consent to take part in research.

3 What is mental capacity?

Mental capacity is the ability to make a decision. Capacity can only be assessed in relation to a particular decision and a particular time – a person may have the capacity to make some decisions but not others, or the capacity may vary over time.

3.1 The two-stage test of capacity

- Is there an impairment of, or disturbance in, the functioning of the person's mind or brain?

If so:

- Is the impairment or disturbance sufficient to cause the person to be unable to make that particular decision at the relevant time?

Lack of capacity can be due to a range of causes, including unconsciousness, dementia, learning disabilities, stroke, head injuries or mental health problems.

Under the Mental Capacity Act, the following factors have to be considered when assessing if someone has capacity to make a decision:

- whether they are able to understand the information
- whether they are able to retain the information related to the decision to be made
- whether they are able to use or weigh that information as part of the process of making the decision
- whether they are able to communicate that decision – by any means, including blinking an eye or squeezing a hand.

3.2 The five core principles

- 1 A person must be assumed to have capacity unless it is established that they lack capacity.
- 2 A person is not to be treated as unable to make a decision unless all practicable (doable) steps to help them to do so have been taken without success.
- 3 A person is not to be treated as unable to make a decision merely because they make an unwise decision.
- 4 An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in their best interests.
- 5 Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

4 Mental Capacity and Research (Sections 30 – 34)

4.1 Ethical approval (Sections 30 - 31)

Any research involving, or in relation to, a person lacking capacity that would otherwise have required consent from participants may only be lawfully carried out if an NHS research ethics committee (REC) in England or Wales has given a favourable opinion. This requirement includes research that would otherwise fall outside the remit of an NHS REC. The REC can only approve the research if it meets the following criteria:

- the research must relate to the condition causing the mind or brain impairment, or to a condition resulting from or attributed to the mind or brain impairment;
- the research cannot be done as effectively using people who have mental capacity; and
- the research must produce results relevant to the condition (or a similar condition) affecting the person and have small risks or low adverse impact on the person, or it must have potential benefits to the person without disproportionate risk.

The researcher must stop the research if at any time they think that one of the above criteria is not met at any time during the research, unless withdrawal of any treatment as part of the research would impose a significant health risk.

Applications to RECs for research that will take place after 1 October 2007 may be made from 1 July 2007.

4.2 Identifying a consultee (Section 32 - 33)

Where an adult lacks capacity to consent to take part in research, a **consultee** should be consulted. A personal consultee may be a family member, carer, or attorney acting under a Legal Power of Attorney, as long as they are not paid to look after the person in question and their interest in the welfare of the person is not a professional one. If they say that the person who lacks capacity would not have wanted to take part, or to continue to take part, then this means that the research must not go ahead.

If there is no such personal consultee who can be consulted, the researcher must find someone who is not connected with the research who can fulfil this role instead – a nominated consultee. Where the research relates to serious medical treatment, the consultee could be an independent mental capacity advocate. Again, if the consultee says that the person would not have wanted to take part or continue to take part, the research must not go ahead.

The researcher must provide the consultee with information about the research, and ask for advice on whether the person should take part in the research, and what the person's wishes would be likely to be if they had capacity.

If the person shows any signs of resistance or indicates in any way that he or she does not wish to take part, the person must be withdrawn from the project immediately, unless withdrawal of any treatment as part of the research would impose a significant health risk.

In an emergency, if it is not possible to consult with a consultee in sufficient time, then the researcher must obtain agreement from an independent registered medical practitioner or comply with any other requirement of the REC.

Draft guidance on nominating a consultee for research involving adults who lack capacity to consent is open for consultation (see section 10). The sponsor or organisation providing care should have a local policy on the selection and training of the nominated consultees for research taking place within that organisation.

4.3 Loss of capacity during research (Section 34)

Where research started before the Act came into force (1 October 2007) and a person originally had capacity to consent and gave consent before 31 March 2008, research involving tissue or data collected from that person before a loss of capacity may continue if the participant later loses capacity before the end of the project. This research is permitted under the Loss of Capacity Regulations. Such research must have procedures for dealing with people who lose capacity during the project that have been approved by the research ethics committee. Approval for the procedures should be made by submitting a substantial amendment. However, the research does not need to meet the criteria in section 4.1. When a person loses capacity during a project, the researcher must seek the views of a consultee and act in the best interests of the person.

4.4 Research involving human tissue

The Mental Capacity Act permits the removal of tissue from a person lacking capacity, if it is in their best interests. The tissue can be stored or used for research if:

- The research is to get information relevant to the health of another individual, and in the best interests of the person who lacks capacity;
- The research is a clinical trial of an investigational medicinal product; or

- The research is carried out under the Mental Capacity Act, meets the Acts requirements and has ethical approval

4.5 Transitional arrangements for research started before 1 October 2007

Research that started before the Mental Capacity Act came into force and involving participants who did not have capacity to consent when they entered the study, must obtain approval from a relevant REC in order to continue under the Act after 1 October 2008. Application for approval should be made by 1 April 2008. Such research must meet the requirements of the Mental Capacity Act.

4.6 Research not covered by the Mental Capacity Act

Clinical trials of investigational medicinal products are not covered by the Mental Capacity Act because arrangements for participation of adults lacking in capacity are covered by separate legislation. Other research that does not require consent does not require specific arrangements for adults lacking capacity. This includes research involving only:

- anonymised data;
- anonymised human tissue obtained from the living;
- human tissue collected prior to 31 August 2006; or
- confidential patient information used under approval of the Secretary of State through the Patient Information Advisory Group (PIAG).

5 Best interests decisions and acts

The Mental Capacity Act requires any decision or act made on behalf of a person who lacks capacity to be made in that person's best interests. The interests of the person must be assumed to outweigh those of science and society. The Act does not define best interests but anyone making such a decision should take into account:

- The persons' past and present wishes and feelings, including any advance decisions
- The beliefs and values that would be likely to affect their decision if they had capacity
- Other factors that the person might have considered if they were able to do so.

6 Lasting Power of Attorney

Under a Lasting Power of Attorney (LPA) an individual can, while they still have capacity, appoint another person to make decisions on their behalf. They can give power to the attorney to make all decisions or they can choose which decisions they can make. When acting under an LPA, an attorney has the authority to make decisions on behalf of the person who made it if they can no longer make these decisions for themselves. In these cases, an attorney is not there simply to be consulted (although they should still be consulted if appropriate where other decisions are being made). Attorneys must act in accordance with the Code of Practice.

7 Advance decisions

An advance decision to refuse treatment enables an adult to make treatment decisions in the event of their losing their capacity at some time in the future.

8 Independent mental capacity advocates

The Mental Capacity Act introduces a duty on the NHS to involve an **independent mental capacity advocate (IMCA)** in decisions about serious medical treatment, when a person who lacks capacity to make a decision has no one who can speak for them. An IMCA is not a decision maker for the person who lacks capacity. They are there to support and represent that person

and to ensure that decision making for people who lack capacity is done appropriately and in accordance with the Act.

9 Children and young people

The Mental Capacity Act does not usually apply to children younger than 16 who do not have capacity. Generally, people with parental responsibility for such children can make decisions on their behalf under common law. For 16 or 17-year-olds who lacks capacity to consent, the person providing care or treatment must follow the Act's principles and act in a way that they reasonably believe to be in the young person's best interests. Parents, others with parental responsibility, or anyone else involved in the care of the young person should be consulted unless the young person does not want this or this would otherwise breach their right to confidentiality. Any known views of the young person should also be taken into account.

10 Further information

Mental Capacity Act 2005 <http://www.opsi.gov.uk/acts/acts2005/20050009.htm>

Mental Capacity Act 2005 Code of Practice, Chapter 11

<http://www.dca.gov.uk/menincap/legis.htm#codeofpractice>

Mental Capacity Act training materials

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074491

Guidance on nominating a consultee for research involving adults who lack capacity to consent (consultation document)

http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_076216

NRES Criteria for approving research under sections 30-33 of the Mental Capacity Act

http://www.nres.npsa.nhs.uk/docs/forms/Section30_approval_criteria.pdf

NRES Criteria for approving research under section 34 of the Mental Capacity Act

http://www.nres.npsa.nhs.uk/docs/forms/Section34_approval_criteria.pdf

NRES guidance for applicants - Research involving adults unable to consent for themselves

http://www.nres.npsa.nhs.uk/docs/guidance/AWI_Guidance.pdf

Adults with Incapacity (Scotland) Act 2000

<http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm>

Disclaimer: This document is for general information only. For detailed or specific guidance seek legal advice. For information on applying for ethical approval see the NRES website.