QUESTIONS and ANSWERS
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Core principles of the Act

What is the Mental Capacity Act about?
The Mental Capacity Act 2005 (MCA) provides a comprehensive framework for decision making on behalf of adults aged 16 and over who are unable to make decisions for themselves, i.e. they lack capacity. The Act applies in England and Wales only.

The Act applies to all decisions taken on behalf of people who permanently or temporarily lack capacity to make such decisions themselves, including decisions to include such people in research. All researchers working with research participants who lack, or may lack, capacity need to be aware of its underlying principles and the provisions relating to research.

The Act is accompanied by a statutory Code of Practice providing guidance on how it should be used. Researchers and others making decisions involving people lacking capacity have a legal duty to have regard to the guidance in the Code of Practice.

**What are the core principles of the Act?**

Section 1 of the Act sets out a number of core principles. These are rooted in the common law, ethical guidelines and best practice and are designed to be fully compliant with the relevant sections of the Human Rights Act. These principles are:

- A person must be assumed to have capacity unless established otherwise
- Individuals should be helped to make their own decisions as far as practicable
- A person is not to be treated as unable to make a decision merely because he makes an unwise decision
- All decisions and actions must be in the best interests of the person lacking capacity
- All decisions and actions must be the least restrictive of the person’s rights and freedom of action

**What is capacity?**

Capacity refers to the everyday ability that individuals possess to make decisions or to take actions that affect them, from simple decisions such as what to have for breakfast to far-reaching decisions about serious medical treatment or financial affairs. A person lacks capacity if he or she is unable to make or communicate a decision about a particular matter because of an impairment of, or a disturbance in, the mind or the brain.

This may be the result of a variety of conditions, including:

- Dementia
- Mental illness
- Learning disability
- Brain damage
- Intoxication
- Any other condition causing confusion, drowsiness or loss of consciousness (e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium)
**How is capacity assessed?**

The Act contains a two-stage test of capacity:

- Is there an impairment of, or disturbance to, the functioning of the mind or brain?

  *and if so*

- Is the impairment or disturbance sufficient that the person is unable to make that particular decision?

The Act says that a person is unable to make a decision if unable to:

- understand the information relevant to the decision
- retain the information
- use or weigh the information
- communicate his or her decision (by any means)

A person with a duty of care must assess capacity to make a particular decision at the time the decision needs to be made, and should not assume that a person cannot make any decision. A person’s loss of capacity may be temporary, and capacity may fluctuate. Some people may lack capacity to make a complex decision but retain the capacity to make other decisions.

The duty to assess capacity also applies to researchers when recruiting participants into, and conducting, intrusive research.


**Whose responsibility is it to decide whether a potential participant has the capacity to consent for themselves to research?**

This is the responsibility of the researcher, consulting as appropriate with other care professionals.

**Scope of the research provisions**

**Does the Mental Capacity Act apply to my research?**

The Act applies to any intrusive research within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products. This may include research in healthcare, social care, criminal justice and other settings. It is not limited to research undertaken within NHS organisations or other public bodies.

**Which parts of the Act apply to research?**
Sections 30-33 of the Act provide lawful authority for intrusive research to be carried out involving people without capacity provided that the research has been approved by an appropriate body.

Section 34 makes transitional provisions relating to the loss of capacity in research which started before 1 October 2007.

What is “intrusive research”?

Under Section 30 of the Act, research is intrusive if it is of a kind that would be unlawful if it was carried out “on or in relation to a person who had capacity to consent to it, but without this consent”. Therefore intrusive research means research that would legally require consent if it involved people with capacity.

Intrusive research is not limited to trials of clinical interventions. It includes non-interventional research where consent is legally required, for example involving the processing of personal data or the administration of questionnaires, interviews or observations.

Intrusive research involving a person who lacks capacity is unlawful unless it is approved by an appropriate body.

What research is not intrusive?

Consent is not a legal requirement, and therefore the research is not intrusive, if it is limited to one or more of the following:

- Processing of non-identifiable data;
- Processing of identifiable patient data with the approval of the National Information Governance Board under Section 251 of the NHS Act 2006 (or formerly by the Patient Information Advisory Group under Section 60 of the Health and Social Care Act 2001);
- Use of tissue samples (cellular material) held prior to the coming into force of the Human Tissue Act on 1 September 2006 (“existing holdings”);
- Use of tissue samples (cellular material) taken from a living person, provided that the person is not identifiable to the researcher and the research project has ethical approval;
- Use of the results of the analysis of DNA in material taken from a living person, provided that the person is not identifiable to the researcher and the research project has ethical approval.

Does the Mental Capacity Act apply to clinical trials of investigational medicinal products (CTIMPs)?

No. Under Section 30 of the MCA, CTIMPS are specifically excluded from the research provisions of the Act. This is because separate provision is made for including adults
lacking capacity in CTIMPs in Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004

Further information about these provisions is available in our information paper on informed consent in CTIMPs

Do the research provisions apply in Scotland and Northern Ireland?

No. The Mental Capacity Act only applies to England and Wales. In Scotland, the inclusion of adults lacking capacity in research is governed by the provisions of Section 51 of the Adults with Incapacity (Scotland) Act 2000. In Northern Ireland, it is currently governed by common law.

Do the research provisions apply to children?

In general the Act applies only to people aged 16 and over. There are a few exceptions, which are explained in Chapter 12 of the Code of Practice. http://www.opsi.gov.uk/ACTS/acts2005/related/ukpgacop_20050009_en.pdf

For projects involving children under the age of 16, researchers and research ethics committees are advised to follow existing guidance such as the booklet Medical research involving children issued by the Medical Research Council. http://www.mrc.ac.uk/Newspublications/Publications/Ethicsandguidance/index.htm

Do projects not classified as research require approval under the Mental Capacity Act?

No. The provisions of Sections 30-34 of the Act apply only to intrusive research. Further guidance from NRES on defining research and distinguishing between research, audit and service evaluation is available here. It is the responsibility of researchers’ employers or sponsors to determine whether a project should be treated as research. For research within the NHS advice may be sought from a NHS R&D office. For research outside the NHS advice can be obtained from a REC or from the NRES Queries Line. (E-mail queries@nres.npsa.nhs.uk)

Appropriate body

What is the role of the appropriate body?

The appropriate body is responsible for approving intrusive research involving adults lacking capacity. It must be satisfied that all the criteria in Section 31 of the Act are met, including that arrangements are in place to satisfy the requirements of Sections 32 and 33.

Who can act as the appropriate body?
An appropriate body is a Research Ethics Committee recognised by the Secretary of State or Welsh Ministers. All NHS RECs in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act.

In addition, there is a national Social Care REC (SCREC) established in 2009 under the aegis of the Social Care Institute of Excellence (SCIE). The SCREC will be recognised as an appropriate body under the Mental Capacity Act.

University ethics committees are not recognised by the Secretary of State or Welsh Ministers and are not appropriate bodies under the Act. Enquiries about recognition of committees under the Act should be directed to the Research and Development Directorate in the Department of Health.

Applications under the Mental Capacity Act relating to research outside the NHS will be accepted for review by NHS RECs. NRES has designated around 30 RECs (“flagged RECs”) to receive new applications under the Act, and concentrated initial training on members of these committees. The flagged RECs are aware of the scope of the Act and that they may receive non-NHS applications.

All applications should be booked with the NRES Central Allocation System for review by a flagged REC.

Applying for approval under the Act

Which REC should I apply to?

NRES has flagged a number of NHS RECs in England and Wales to review new applications for approval under the Mental Capacity Act. Members of these RECs have had additional training in issues relating to the MCA. Applications should be booked with the NRES Central Allocations System so they can be allocated to an appropriate REC.

To find a flagged REC for the MCA, click http://www.nres.npsa.nhs.uk/contacts/find-your-local-rec/

Are there any specific requirements for applications under the Act?

The application form, available via the Integrated Research Application System, incorporates specific questions about compliance with the Act in Part B Section 6 of the form.

The study protocol should describe the procedures for recruiting people lacking capacity, including arrangements for identifying and consulting consultees. If appropriate, procedures should be described for seeking consent from participants who may regain capacity during the study.
What happens where research is conducted in Scotland as well as England or Wales?

Research conducted in England/Wales and Scotland requires separate approvals under the Mental Capacity Act and the Adults with Incapacity (Scotland) Act 2000 respectively. Separate applications should be made to recognised RECs in each jurisdiction. In Scotland, the application must be made to the Scotland A REC and should include a consent form for the guardian, welfare attorney or adult’s nearest relative.

Guidance on documentation to be used in recruiting participants lacking capacity in Scotland is available in our guidance on information sheets and consent forms.

What happens where research is conducted in Northern Ireland as well as another UK nation?

If the research is taking place in England or Wales as well as Northern Ireland, only one application is needed. This should be made to a recognised REC in England and Wales. The REC will liaise with a committee in Northern Ireland in reviewing the documentation to be used in Northern Ireland. The usual practice is for an assent form to be used to seek agreement from relatives in Northern Ireland to recruit a person lacking capacity. Further guidance is available in our guidance on information sheets and consent forms.

What is the position for research that started before the Act came into force?

Any intrusive research involving adults lacking capacity, that started prior to 1 October 2007, required further approval from a recognised REC under Section 30 of the Act by 1 October 2008. If such approval has not been obtained, it is no longer lawful to undertake any intrusive research procedures on or in relation to adults lacking capacity.

Do I have to submit a SSI Form?

For NHS sites, you should submit the SSI Form to the responsible R&D office together with other documentation required for R&D review. There is no need to send SSI Forms for NHS sites to RECs.

For non-NHS sites, research involving adults unable to consent for themselves normally requires site-specific assessment (SSA) as part of the ethical review. The main REC for the study will confirm this on receipt of the main application. A SSI Form for each non-NHS site should then be submitted to a local REC.

Approval criteria
What are the requirements for approval?

The approval criteria are set out in Section 31 of the Act:

(i) The research must be connected with an impairing condition affecting the participant or its treatment.

(ii) Research of equal effectiveness could not be carried out if confined to participants with capacity.

(iii) The research must either:

   (a) have the potential to benefit the participant without imposing a disproportionate burden, or

   (b) provide knowledge of the causes of, or treatment or care of others with, the same or a similar condition – in this case the research must involve negligible risk to the participant, not interfere significantly with their freedom of action or privacy, or be unduly invasive or restrictive.

(iv) Arrangements must be in place to comply with section 32 (consulting carers) and section 33 (additional safeguards).

What arrangements need to be in place to comply with Section 32?

The researcher must have adequate arrangements in place for consulting consultees about whether a person lacking capacity should take part in the research.

Reasonable steps must be taken to identify a “personal consultee”. If no appropriate person can be identified who is willing to act as a personal consultee, the researcher may consult a “nominated consultee”, i.e. a person independent of the project appointed in accordance with the Department of Health’s Guidance on nominating a consultee for research involving adults who lack capacity to consent.

The consultee must be given information about the project and advise on what the participant's wishes and feelings would be about taking part. The consultee gives advice rather than consent.

The advice of the consultee must be respected. If the consultee so advises, the participant must not take part and, if already taking part, must be withdrawn unless withdrawal of treatment would involve significant risk to the participant’s health.

Where urgent treatment is to be provided, the Act allows exceptionally for a person lacking capacity to be entered into research prior to a consultee being consulted, subject to strict conditions.

What arrangements need to be in place to comply with Section 33?
Nothing must be done to which the participant appears to object unless it is to protect him/her from harm, or reduce or prevent pain or discomfort.

If the participant indicates he/she wishes to be withdrawn, this must be done without delay unless there would be a significant risk to his/her health.

Any advance statement by the participant must be respected.

In conducting the research, the interests of the participant must always be assumed to outweigh those of science and society.

Consultees

Who can act as a consultee?

A “personal consultee” means a person who is:

- engaged in caring for the participant (not professionally or for payment) or is interested in his/her welfare, **and**
- is prepared to be consulted.

If no appropriate person can be identified who is willing to act as a personal consultee, the researcher may consult a “nominated consultee”, i.e. a person independent of the project appointed in accordance with the Department of Health’s Guidance on nominating a consultee for research involving adults who lack capacity to consent.

What is the role of the consultee? How do I find more if I am approached to be a consultee?

The consultee advises the researcher on what the participant’s wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. The consultee does not give consent, only advice. The responsibility to decide whether the participant should be entered into the research lies ultimately with the researcher.

Further information is available in the Department of Health’s Guidance on nominating a consultee for research involving adults who lack capacity to consent.

Can a paid carer act as a personal consultee?

No. However, where no personal consultee can be identified, a paid carer could act as a nominated consultee provided they had no connection to the research project.

Is there a hierarchy of relatives the researcher should approach?
Q&A MCA

The Act does not specify a hierarchy. It is a matter of judgment for the researcher, in consultation with the participant’s care team, to identify the most appropriate person. This will normally be the participant’s usual carer or another person closely concerned with their welfare. This may or may not be the nearest relative.

What information should be provided to the consultee?

The application should include an information sheet for personal/nominated consultees, including the same level of information that the participant would receive if they had capacity. They should also be asked to sign a “record of consultation” form to confirm that they have received this information and had the opportunity to ask any questions and give advice.

If some participants may have capacity to give fully informed consent, or may regain capacity during the research, the application should also include an information sheet and consent form for them. For those lacking capacity but with some measure of understanding, consideration should be given to providing a simplified information sheet.

Further guidance and examples of these documents are available in our guidance on information sheets and consent forms.

Should the consultee continue to be involved during the study?

Yes. If the study involves a series of procedures, it is good practice for the researcher to keep the consultee fully informed, for example by attending any research procedures and providing support to the participant. If the consultee advises that the participant should be withdrawn, the researcher must withdraw them unless this would produce a significant risk to their health.

What should I do if the personal consultee becomes unavailable during the study, or is no longer willing to undertake the role?

The researcher should take steps to identify another personal consultee to take on the role. If no other appropriate person can be identified, a nominated consultee should be approached.

What if the treatment to be given as part of the research is urgent and there is no time to approach a consultee?

Section 32(8) of the Act allows exceptionally for a person lacking capacity to be entered into research prior to a consultee being consulted. There are strict conditions:

- urgent treatment is to be provided and it is not possible to separate this from inclusion in the research
- it is not practicable to identify and consult a consultee before providing the treatment.
This exception only applies during the emergency situation. As soon as time allows, the researcher must then consult a consultee or seek the participant’s consent (if capacity has been recovered) about their continued inclusion in the research and use of any samples or data already collected.

**Consent**

**Who do I seek consent from if a participant lacks capacity?**

Under the Mental Capacity Act, no-one gives consent on behalf of a person lacking capacity. Instead, the researcher is required to seek advice from a consultee on what the wishes and feelings of the person might be and whether or not they should take part. The consultee gives advice, not consent in law. Responsibility to decide whether the person should be entered into the research lies with ultimately with the researcher.

**Can researchers seek advance consent anticipating the loss of capacity, without needing approval under the Act?**

No. Consent does not survive the loss of capacity under common law.

A person with capacity may make an advance statement about their wishes to be included in research, or not to be included. Such statements should be taken into account by the researcher if relevant to a particular study. However, the statement does not amount to consent. If the person lacks capacity to give consent at the time they are to be recruited, the requirements of the Act must be followed.

**Loss of capacity during research**

I plan to withdraw any participants who lose capacity during the study. Does the study require approval under the Mental Capacity Act?

No. However, ethical approval may still be required under other regulations or the policy of the host institution(s) for the research.

**What is the approval criteria and process for loss of capacity in a participant in a study which was started before 1 October 2007?**

Section 34 makes transitional provisions for existing projects involving people with capacity who later lose it [Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006]
The Regulations apply where (a) The project started before 1 October 2007, and (b) the participant consents to take part in the project before 31 March 2008 but loses capacity before the end of the project.

Section 34 approval makes it lawful to continue to use tissue or data taken with consent before loss of capacity.

Protocol must be approved by a REC. Any researcher who has not sought approval for existing research by 1 October 2008 is breaking the law.

Researcher must seek advice from a consultee about participant’s presumed wishes and feelings. The participant’s tissue/data must be withdrawn if consultee so advises or if the participant indicates he wishes research to be discontinued.

You do not have to actively monitor capacity – it may be assumed (core principles).

Section 34 approval only allows for continued use of tissue/data already collected. Subsequent intrusive research would require section 30 approval.

You need to submit a Notice of Amendment to the main REC for the study with supplementary form MCA2, revised protocol and information sheet for consultee.

The process is subject to the 35 day clock. There is an additional statement in opinion letters.

**Should researchers monitor the capacity of participants during a study?**

A core principle of the Act is that capacity should be assumed unless established otherwise. If a participant has consented to take part, it may generally be assumed that capacity remains in place but the researcher should be alert to any changes suggesting that capacity has been lost.

Where the research involves administration of questionnaires by post, consent is usually considered to be implied by return of the questionnaire. There is no need for the researcher to monitor capacity proactively.

**What if a patient loses capacity after they have already consented to take part in a study?**

Under common law, consent is generally not valid following loss of capacity.

If you wish to keep the participant in the study and undertake further intrusive research, it must have approval under Section 30 of the MCA, and you will need to seek advice from a consultee on whether the participant should remain in the study.

If you withdraw the participant and either destroy or anonymise any samples or data already collected, Section 30 approval is not required and you will not need to seek advice from a consultee.
Where the participant gave specific consent to use samples and data following loss of capacity, these may be retained in identifiable form if this is necessary for the research.

Section 34 of the MCA makes specific provision relating to loss of capacity in research which started prior to 1 October 2007.

**When is Section 34 approval required?**

Section 34 and the Loss of Capacity Regulations make transitional provisions for existing projects involving people with capacity who later lose it.

The Regulations apply where (a) the project started before 1 October 2007, and (b) the participant consented to take part in the project before 31 March 2008 but loses capacity before the end of the project.

Section 34 approval makes it lawful to continue to use identifiable tissue or data taken with consent before loss of capacity. It does not authorise further intrusive research such as collection of further personal data. This would require Section 30 approval.

**How do I apply for Section 34 approval?**

To apply for Section 30 approval, you should submit a Notice of Substantial Amendment to the main REC for the study with supplementary form MCA2, a revised protocol, a consultee information sheet and a “record of consultation” form.

**What is the role of the consultee under the Loss of Capacity Regulations?**

The researcher must seek advice from a consultee about the participant’s presumed wishes and feelings. The participant’s samples and data must be withdrawn if the consultee so advises or if the participant indicates he/she wishes the research to be discontinued.

**Regaining capacity during research**

**What happens if a participant regains capacity during a study approved under the Act?**

The participant should be fully informed about the study and their consent sought to continue in it. If they do not wish to remain in the study, they must be withdrawn. Unless they give consent to retain and analyse any data and samples collected so far, these must be destroyed. Procedures for dealing with this situation should be included in the protocol. Further advice may be sought from the ethics committee if required.
Other questions

Can samples and data collected from participants lacking capacity in an approved study be used in a new study?

Where the samples or data have been anonymised or effectively pseudonymised so they are not identifiable to the researcher, they may be used in a further study without requiring Section 30 approval under the Act.

Where identifiable data is to be used in a new study, further approval should be sought under Section 30 of the Act.

Where the samples or data were originally collected from participants with capacity and broad consent was given for future research, this consent can still be considered valid.

Further guidance and resources

NRES procedures and guidance:

Standard Operating Procedures for Research Ethics Committees in the United Kingdom (SOPs) – Section 12

NRES guidance on research involving adults unable to consent for themselves (incorporating guidance on the Mental Capacity Act 2005)
http://www.nres.npsa.nhs.uk/rec-community/guidance/#PIS

Information sheets, consent forms and records of consultation
http://www.nres.npsa.nhs.uk/rec-community/guidance/#PIS

External links:

- Mental Capacity Act 2005
  http://www.opsi.gov.uk/ACTS/acts2005/ukpga_20050009_en_1

- Mental Capacity Act Code of Practice, see especially
  Chapter 2 What are the statutory principles and how should they be applied?
  Chapter 3 How should people be helped to make their own decisions?
  Chapter 4 How does the Act define a person’s capacity to make a decision and how should capacity be assessed?
  Chapter 11 How does the Act affect research projects involving a person who lacks capacity?
- Explanatory Notes to the Mental Capacity Act 2005

- Guidance issued by the Secretary of State for Health and Welsh Ministers on the appointment of consultees under Section 32 of the Mental Capacity Act

- Social Care Research Ethics Committee

- Resources commissioned by the Department of Health and the Social Care Institute of Excellence

- Guidance issued by the Medical Research Council on *Medical research involving adults who cannot consent*
  http://www.mrc.ac.uk/PolicyGuidance/EthicsandGovernance/InformedConsent/In
  dex.htm