1. What is the Mental Capacity Act?

1.1 The Mental Capacity Act 2005 (MCA) provides a statutory framework for people who may not be able to make their own decisions, for example because of learning difficulties, brain injury or mental health problems. It sets out who can take decisions, in which situations, and how they should go about this. The Act applies to England and Wales only.

1.2 The MCA enshrines in statute current best practice and common law principles concerning people who lack mental capacity and those who take decisions on their behalf. Sections 30 to 34 apply these principles to research that seeks to involve people without the capacity to provide informed consent to their participation. Their aim is to balance the importance of properly conducted research with the need to protect the interests and respect the current or previously expressed wishes of those involved.

1.3 To undertake research with those who lack capacity, the MCA requires a researcher to obtain approval from an ‘appropriate body’. This Body must be satisfied that the research project meets certain requirements set out in the MCA and that arrangements are in place to consult a family member, friend or unpaid carer about the participant’s previous attitudes and beliefs relevant to taking part in research of this type.

1.4 Anyone carrying out research to which the requirements of the MCA apply must act in accordance with the provisions of the Act in order for the research to be lawful.

2. What kinds of research does it cover?

2.1 The MCA applies to research that is defined as ‘intrusive’, that is, any study that would normally require the consent of a person with capacity in order to be lawful.

2.2 The definition of ‘intrusive’ research (see section 30(2) of the MCA) is wide ranging and covers all primary data collection, apart from that which involves the collection of anonymised, or effectively pseudonymised, data where there is no breach of the Data Protection Act (DPA) or the common law duty of confidence. It is not limited to medical or biomedical research that is physically invasive (e.g. the collection of tissue samples).

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1 The MCA Code of Practice can be found at: http://www.dca.gov.uk/menincap/legis.htm#codeofpractice.

2 In England this is a research ethics committee (REC) recognised by the Secretary of State; in Wales, this recognition is by the Welsh Assembly Government. Mental Capacity Act 2005 (Appropriate Body) regulations 2006. Currently only RECs operating under the National Research Ethics Service (NRES) are so recognised, including the new Social Care REC.

3 It does not apply to clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).
2.3 However, only research which intends to include people without the capacity to consent is covered by the legislation. The purpose of the MCA is to enable the involvement of such participants, where it is appropriate to do so. While no group should be unreasonably excluded from a research study, the legislation also aims to ensure that people without capacity have the right to be free from unnecessary interference in the name of research.

2.4 It is thus for the research team to decide if it wishes to include people without the capacity to consent in their study. In making this decision, the team needs to address the following questions:

a) is the research related to the ‘impairing condition’ that causes the lack of capacity, or to the treatment of those with that condition?\(^4\);

If the answer to this question is ‘no’ then the study should proceed without involving those who do not have the capacity to consent to participation. If the answer is ‘yes’ the researchers need to answer a second question:

b) could the research be undertaken as effectively with people who do have the capacity to consent to participate?

If the answer to this question is ‘yes’ then the study should exclude those without the capacity to consent to participation. If the answer is ‘no’ then the inclusion of people without capacity in the study can be justified. The research team will still need to decide however - as it would have done prior to the legislation - if it has the time, resources and expertise to ensure the meaningful involvement of people without capacity.

2.5 If, having considered the questions above, the research team decides it is scientifically meaningful and methodologically viable to include people without the capacity to consent, it will need to seek approval for the study from an ‘appropriate body’\(^5\). To secure approval the research team will need to demonstrate that the study will meet one of the following central requirements:

i) that it will be likely to be of benefit to the person lacking capacity, either directly (i.e. by improving her/his personal circumstances) or indirectly (by improving the quality of treatment or care more generally), and that this benefit is in proportion to any burden on that person caused by taking part;

OR

ii) that the research will serve to increase knowledge of the cause, treatment or care of people with the same or similar condition and that the risks to participants will be negligible, with no significant interference with their privacy or freedom of action.

\(^4\) An ‘impairing condition’ is defined as being caused by, causing or contributing to an impairment of, or disturbance in, the functioning of the mind or brain. ‘Treatment’ is not used here in the medical sense and includes the way that people are cared for, or provided with a service, more generally. S31 (5)b of the MCA refers to providing knowledge on the care of people affected by an impairing condition.

\(^5\) Currently only Research Ethics Committees (RECs) operating under the National Research Ethics Service – including the Social Care REC – have been recognised as ‘appropriate bodies’ for this purpose.
Only if one of these two conditions can be effectively established is it likely that the study will be able to proceed under the MCA. The following two case studies illustrate the ways in which these conditions could play out in particular research studies:

**Case 1:**

A national charity is promoting a scheme in which local schoolchildren visit elderly residents living in the community to help with shopping or other tasks. It has contracted a research team to evaluate the impact of the scheme, from the perspectives of the young adults and the older people involved. The team is worried that some of the older people involved in the scheme could have capacity problems.

The research is not related to the condition causing the incapacity of these individuals, nor to the treatment of those with that condition. Moreover, it would be difficult for the research team to demonstrate that the study could not be as effectively conducted only with those who had the capacity to consent. Given this, the research team would find it difficult to justify including people without capacity to consent in the study.

**Outcome:**

The study team establishes clearly from the outset that it does not intend to include people without the capacity to consent to participation.

**Case 2:**

A research team is proposing to investigate the use of physical restraint on older residents of care homes. The researchers consider that the experience of people with dementia is crucial to this work, as they are disproportionately likely to be subject to restraint. For this reason, the team feels that the study could not be as effectively conducted if people with dementia were excluded. The team recognises that many, if not most, of the residents with dementia will lack the capacity to participate actively in the research and have selected non-participant observation as the main method of data collection.

Although observation is not physically invasive, the proposed research is intrusive under the definition given in the MCA and will need approval by an appropriate body. The research team is confident that the research will be enabled under the Act as it is directly relevant to the ‘impairing condition’ (dementia), and the team is proposing to identify personal or nominated consultee to ascertain the wishes of those without capacity to consent for themselves. It is able to demonstrate that the findings of the study will to be of indirect, if not direct, benefit to the older people involved and that any research ‘burden’ on participants would be minimal.

**Outcome:**

An application for approval of a study on this basis is made to a Research Ethics Committee within the National Research Ethics Service that has been recognised for the purposes of the Mental Capacity Act.
3. Obtaining Consent

3.1 The issue of consent is central to the implementation of the MCA. The requirement for consent is defined in terms of common law or statute. For social scientific research this involves the provisions of the Data Protection Act and the common law of confidentiality. As such, the MCA does not introduce any new requirements in respect of consent that do not already apply to the collection and processing of personal data.

3.2 The research sections of the MCA focus on situations where it is not possible to secure informed consent from the research participant, due to a lack of capacity on his or her part. They aim to provide a means for such research to proceed, under carefully controlled conditions.

3.3 A core principle of the MCA is that capacity should be assumed, unless established otherwise. In research, capacity is normally implied by the act of consenting to participate in a study. However, it is important to avoid the possibility that compliance is wrongly taken to imply consent. Demonstrable steps should be taken to ensure that the respondent is able fully to comprehend or retain information about a research study.

3.4 Where it is clear that informed consent cannot be provided by potential participants, the Act sets out the particular conditions under which it the study can still proceed, if eligible (see 2.4 – 2.5 above). In the first instance, this requires the researcher to take ‘reasonable steps’ to identify someone close to the person concerned (not acting in a paid capacity) to advise on whether s/he would want to be involved. This person is a ‘personal consultee’.

3.5 Where a ‘personal consultee’ cannot be identified, because the person who lacks capacity has no family or friends willing and able to fulfil this role, the Act requires the researcher to nominate someone else who will be able to act in this capacity – a ‘nominated consultee’. Guidance has been produced on the principles underpinning this role and the ways in which it can be discharged in different research settings.

3.6 The use of opt-out consent is common in social research but is problematic under the MCA. It should not be used if the study is planning to involve people without capacity, as consent is being assumed by default, rather than actively established. Moreover, even if it is not the aim to include people without capacity, the use of the opt-out approach increases the possibility that people without capacity will be inadvertently included in a study population.

3.7 If the team is clear that it does not wish to involve people without capacity, then it should take reasonable steps to prevent their inadvertent

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6 Unless approval is obtained from the National Information Governance Board (formerly the Patient Information Advisory Group) to set aside the duty of confidentiality in respect of patient data (under s251 of the NHS Act, 2006).

7 Guidance for Nominating a Consultee for Research Involving Adults who Lack the Capacity to Consent. DH 2008.
inclusion. Approach materials (e.g. survey contact letters) should clearly indicate that the study is not approved under the MCA and that no one should participate on another’s behalf. Data collected inadvertently on those without capacity should be destroyed. If a team decides subsequently that it does wish to involve people without capacity, it will need to submit an amended proposal for approval by an ‘appropriate body’.

3.8 Researchers are rightly concerned about the possibility that people who are able to consent at the outset of a study may lose, or experience fluctuations in, this capacity over the course of the research. The MCA makes provisions for such a situation, using a personal or nominated consultee, as set out above. Even where an individual originally gave consent, the research team must take account of any subsequent advice from a consultee that continued involvement would be contrary to his/her wishes or best interests.

3.9 Regardless of the views of a particular consultee, any person lacking capacity to consent who at any time does not appear to consent to the research procedures, or actively expresses discomfort or distress, should immediately be withdrawn from the study.

Case 3:

A government department wants to undertake a postal survey of the experiences and needs of adults with physical disabilities. The research team contracted proposes a random sample of households using an ‘opt out’ consent approach. The research commissioner is concerned that this approach will unintentionally capture people without the capacity to consent in the sample and that the research team will as a result be acting illegally under the MCA.

The team feels that the research could not be conducted as effectively by excluding people without capacity, as this group is likely to have a distinctive perspective. However, it recognises that it does not have the time or resources necessary to develop robust ways to obtain the views of such participants and reluctantly decides it is not able to include them. This decision is clearly stated in the research proposal which does not have to be submitted to an appropriate body under the MCA.

However, the team is still worried that the use of an ‘opt out’ consent mechanism could leave it in a difficult situation under the legislation if replies are received on behalf of those without capacity. It is also concerned that the experience of people without capacity will be excluded from the study.

Outcome:
The team marks all approach materials clearly with the statement that the study has not been approved under the MCA for people without capacity to consent for themselves. Any replies received on behalf of someone without capacity will be are excluded from the research study. However the scope of the study is expanded to include the views of carers or relatives about their own experiences.

What the MCA means for Social Scientists – Frequently Asked Questions

Q: Does the Act apply only to research ‘in or with’ the NHS?

A: 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 health, social care, criminal justice and many other settings. It is not limited to research undertaken within NHS organisations or other public bodies.

Q: Do projects that are not classified as research require approval under the Mental Capacity Act?

A: No. The provisions of Sections 30-34 of the Act apply only to studies that are designed and presented as research. It is the responsibility of the researchers’ employers or sponsors/funders to determine whether a project should be presented as research.

Q: To what extent is it acceptable to assume capacity on the part of participants and should researchers monitor this over the course of a study?

A: A core principle of the Act is that capacity should be assumed unless established otherwise. Section 3 of the Act discusses how a person may be unable to make decisions for him/herself, including possible reasons why s/he may not be able to comprehend or retain information about a research study.

If a participant has properly consented to take part, it may generally be assumed that capacity remains in place, although you should be alert to any changes suggesting that capacity has been lost. There is no need for the researcher to monitor capacity proactively. Where the research involves the administration of postal questionnaires, consent is usually considered to be implied by return of the questionnaire. However, you will need to check that the questionnaire has not been completed by someone other than the selected participant.

Q: What happens if, during the course of the study, some of my participants lose capacity?

A: Unless you have prepared for this eventuality, and have secured approval from an appropriate body to do so, the research will have to proceed without any further involvement of those losing capacity and any data collected from them so far will need to be anonymised or destroyed. If the study has approval from an appropriate body under the Act it may be able to proceed using personal or nominated consultees.
Q: I plan to withdraw any participants who lose capacity during the study. Does the study require approval under the Mental Capacity Act?

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

Q: Is it illegal to involve people without capacity in the research – even unintentionally – if the research has not been reviewed by an approved committee?

A: You will not be committing a criminal offence, but the research will be unlawful and you could expose yourself and your employer to complaint or the risk of litigation. This risk will be reduced if you take clear and appropriate steps to exclude such people from your study.

Q: What happens if I am undertaking a survey of, say, local households and someone without the capacity to consent is included in the sample unintentionally?

A: You will need to have taken a decision at the outset of the study whether you will seek to include those without the capacity to consent. If so, not only will the study have to approved by an appropriate body under the Act, and arrangements for consulting the likely wishes of this group be devised, but you will have to invest time and resources in developing appropriate methods to involve people who will probably also lack the capacity to respond to standard data collection techniques.

Q: What steps do I need to take to ensure that I don’t include people without capacity in my research study unintentionally?

A: You will need to state clearly in your research proposal and on approach materials that you are not able to include those without capacity. Where possible, use opt-in consent procedures and always ensure you have robust mechanisms for ensuring informed consent. If someone offers to respond on behalf of another who lacks capacity, explain that you are unable to accept their offer. If you find someone has submitted a response on behalf of someone else without capacity, this response should be excluded from your study.

Q: Does the MCA mean that I can’t have fully representative samples?

A: There is concern that excluding people without capacity may make samples less representative, in so far as the experiences of this group may differ in important ways from those with capacity. Provided that the research
topic meets the criteria for justifying the inclusion of people without capacity, and the research team has the time and resources to include them there is no reason to exclude such people. However, if people with limited capacity are not included in an effective way, it is likely that the data collected would not be meaningful enough to increase the representativeness of the study in any case.

Q: Isn’t the Act going to make it less likely that researchers will include people with cognitive problems in the research, even where their particular experience could be very relevant?

A: This could be a risk and would be an unintended and unwelcome consequence of the MCA. However, involving people with limited cognitive capacity has always been challenging, and the Act has the virtue of clarifying grey areas for researchers, such as the involvement of ‘proxy’ respondents. As before, if the experience of people without the capacity to consent is scientifically justifiable, and the team has the necessary expertise and resources to make their inclusion meaningful, every step should be taken to ensure they are included in the study. In such cases, the MCA provides a statutory framework to enable the research to proceed.