Research and the Mental Capacity Act 2005

The Act applies to England & Wales only

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With acknowledgments to:
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Core principles of ACT (sec 1)

1. People must be assumed to have capacity unless it is established that they lack capacity
2. Before treating people as unable to make a decision, all practicable steps to help them to do so must be tried
3. People should not be treated as unable to make a decision merely because they make an unwise decision
4. Acts or decisions on behalf of people who lack capacity must be in their best interests
5. Before any act or decision, the person responsible must consider whether the purpose could be achieved in a less restrictive way
Assessing capacity  (sec 3)

1. A person (P) lacks capacity in relation to a matter if *at the material time* P is unable to make a decision for themselves *in relation to the matter* because of an impairment of, or a disturbance in the functioning of, the mind or brain and as a result is unable to:
   1. Understand information relevant to a decision
   2. Retain the information
   3. Use or weigh the information
   4. Communicate their decision (by any means)

2. A lack of capacity cannot be established merely by reference to age, appearance, or a condition or an aspect of behaviour which might lead others to make unjustified assumptions about capacity
Capacity may depend on type of decision:

1. Capacity must be assessed for each particular decision – because P might lack capacity to make a complex decision it should not be assumed that they do not have the capacity to make a less complex one.

2. Researchers must be able to assess capacity when recruiting participants – or seek expert advice/input from other professionals where necessary.
The MCA & research provisions:

1. Background:

- Government agreed at Bill stage that there should be provision for strictly controlled research to avoid current legal uncertainty and inequity
- Clauses based on ethical norms
- Consistent with other statutes, human rights and international instruments
- Final provision aimed at balancing concerns to enable essential research whilst respecting and protecting vulnerable people
Scope of research provisions:

1. Any ‘intrusive’ research - definition of intrusive
2. Wherever it is conducted, including eg:
   1. Prisons & police cells
   2. Residential care homes & day centres
   3. Drug & alcohol treatment centres
   4. Universities
   5. Private & NHS treatment settings
   6. Armed services including battle zones
   7. Social research (including censuses & surveys)
3. People aged 16 and over
4. CTIMPs (clinical trials) are excluded
5. HTA
The research provisions:

- Sections 30-33 make it lawful to conduct intrusive research involving people who lack capacity
  - Section 30: intrusive research
  - Section 31: requirements for approval
  - Section 32: consulting carers
  - Section 33: additional safeguards

There is also transitional provision (s 34) relating project s approved before the law came into force.
Section 30:

1. Since 2007, under a statutory instrument for England, intrusive research involving a person who lacks capacity is unlawful unless it is approved by an ‘appropriate body’ (sometimes referred to as ‘section 30 approval’)

2. An appropriate body is in practice a research ethics committee recognised for these purposes under the Act by the secretary of state.

3. What are the appropriate bodies? In England - all NRES RECs including the national Social Care REC and NHS RECs. University RECs are not recognised as appropriate bodies
Intrusive research:

1. Research is intrusive if it would normally be unlawful to do it without consent

2. The requirement for consent is not limited to interventional studies and includes, for example any research involving access to personal data, questionnaires, interviews or observations which infringe the right to privacy

3. Consent is not a legal requirement and therefore the MCA would not apply where research is limited to the use of: non identifiable data; identifiable data approved for process without consent by NIGB (formerly PIAG); non identifiable tissue from the living

4. S 30 approval is not required for projects which are not ‘research’ (ultimately for research, employer, sponsor to determine)
Section 31 approval criteria

1. Research must be connected with an impairing condition
2. Research of equal effectiveness cannot be conducted if confined to people with capacity
3. Must have the potential to benefit the participant without imposing a disproportionate burden OR provide knowledge of treatment for others with same condition and involve negligible risk (& other safeguards)
4. Arrangements are in place to comply with sections 32 & 33
Section 32: consulting carers

1. Researcher must seek advice from a carer or another person (the ‘consultee’) on whether P should take part and what P’s wishes and feeling would be.

2. The consultee gives advice NOT consent.

3. Under the MCA there is no ‘consent’ representing the presumed will of the participant.
Section 32:
Identifying a consultee

1. Researcher must take reasonable steps to identify a *personal consultee*

2. A personal consultee means a person who is a. engaged in caring for P (not professionally or for payment) or is interested in P’s welfare and b. is prepared to be consulted

3. If no personal consultee can be found, the researcher may consult a *nominated consultee* ie a person independent of the project and appointed in accordance with DH guidance
Section 32:

1. The researcher must respect the advice of the consultee

2. The consultee should be kept informed during the study and may advise at any time the P should be withdrawn

3. It is good practice for the consultee to be provided with full information about the research and to attend during research procedures.
Section 33: additional safeguards

1. Nothing must be done to which P appears to object, unless it is in their best interests
2. If P indicates a wish to withdraw from the research this should be respected without delay
3. Any advance statement by P must be respected
4. P’s interests must be assumed to outweigh those of society
MCA Questions:

- Q1 A Local Authority wishes to get feedback and suggestions on the domiciliary services it provides to older people in the Borough with a view to extensive re-design and re-commissioning. It has contracted a private research organisation to evaluate the existing scheme and seek suggestions for future services. A semi-structured interview conducted in the recipient’s home has been designed. The team is worried that some of the older people contacted because they receive the service could have capacity problems.
MCA Questions:

- Q2. A study wanted to interview partners of adults lacking capacity about their experiences of living with the ALC, but to exclude the ALC as a participant. Would it nonetheless be necessary to involve a consultee on behalf of the ALC? The ALC is not a participant so arguably it would not be necessary in relation to the MCA. Is that a reasonable interpretation? An ethical issue may or may not remain.
MCA Questions:

Q3. If the ALC is a participant in the research, the best person to be (personal) consultee would be the partner. However the researcher might wish to include the partner in the study. The MCA research guidance says that a nominated consultee cannot be connected with the research, however it is silent on this matter regarding a personal consultee. It follows therefore that a personal consultee may be connected with the research – eg may also be a participant. Is that a reasonable interpretation?
DH advice (by extrapolation from MCA helpsheet) Q1

The research is not directly related to the condition causing the incapacity of these individuals, nor to the treatment of those with that condition, although it is related to their general care. It would however 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. It is also unlikely that people lacking capacity to consent would be able to respond directly to the interview questions.

The study team establishes clearly from the outset that it does not intend to include people without the capacity to consent to participation. It attempts to screen out people lacking capacity from the initial mailshot (an introductory letter, explaining the study). It relies on people who are interested to ‘opt-in’ (volunteer), and includes a note in the letter for recipients and carers to the effect that participation is entirely voluntary, and they need take no further action if they cannot or do not wish to take part. (A separate study of carers’ views is planned.)
This is a particularly tricky issue which is not addressed in the Code of Practice. The question is whether the research is intrusive in relation to the person lacking capacity ("P"). Although not a participant as such, would the research intrude into their privacy in a manner that would involve a breach of the Human Rights Act or the Data Protection Act if done without their consent? It may depend on the circumstances and the research procedures to some extent. If the research team will not be holding or analysing identifiable personal information about P, one might argue there is no breach of privacy or confidentiality. But the researchers may well become aware of P's identity in the course of the interview, and personal matters relating to P could be discussed. In replying recently to a similar query from a researcher planning to interview relatives about the care of adults subject to Deprivation of Liberty Safeguards, we advised erring on the side of caution and treating the research as intrusive and subject to sections 30-33 of the MCA. This advice was actually welcomed as the researcher had been uneasy about proceeding without the protection of section 30 approval! But it is a borderline judgement. Ultimately it is a matter for the researcher and their sponsor, and they are free to seek their own legal advice.
There is no *legal* obstacle to the consultee being connected with the research. The provision relating to nominated consultees is presumably designed to address the scenario where the consultee could have a vested interest in the research, e.g. as a collaborator or close colleague of the researcher. The Act does not appear to be concerned with personal consultees having their own interest in the research as participants. Whether this is an *ethical* problem is a matter for the REC. At training events we have discussed a case study involving interviews with both P and the nearest relative, who was also likely to be the personal consultee. Some delegates expressed concerns that the consultee could be unduly influenced by their own desire to take part, or their personal support for the research aims. However, the general view was that this was not a significant risk - most consultees could reasonably be expected to consider the interests of P as well as their own views. Also, a requirement to seek a separate consultee, e.g. another family member, would be artificial, onerous for the researcher and could lead to family tension. On balance, delegates considered it reasonable to allow the consultee to wear both hats, but the consultee information sheet should stress that this role requires them to put aside their own views and consider the wishes and feelings of P.
Additional information:

1. Applications for section 30 approval are made through the Integrated Research Application System (IRAS) advice is also available, at: [www.myresearchproject.org.uk/](http://www.myresearchproject.org.uk/)


3. A help sheet for social scientists, which is applicable to other disciplines too, and which provides helpful definitions of some of the Act’s terms, advice and case examples can be accessed at: [www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@pg/documents/digitalasset/dh_106217.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@pg/documents/digitalasset/dh_106217.pdf)