Research involving adults lacking the capacity to consent: The Mental Capacity Act 2005

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Issues in Research Ethics

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Introduction

- This presentation will:

  i. examine the regulatory context for research involving adults lacking the capacity to consent in England,

  iii. outline the main procedures that the Mental Capacity Act 2005 (MCA), and the Research Ethics Committee (REC), expects researchers to adhere to, and

  v. give guidance on applying for ethical review when seeking to undertake research involving adults lacking the capacity to consent, and outline some of the practical difficulties that researchers face when undertaking this form of research

1. Framing the issue

A. Clarifying the framework

i. England and Wales: the Mental Capacity Act, s. 30-34 (since October 2007)
   - excludes research involving clinical trials of investigative medical products (CTIMPS). These are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004

ii. Scotland: the Adults with Incapacity (Scotland) Act 2000, s. 51

iii. Northern Ireland: governed by common law

This presentation will only cover the regulation of research in England and Wales under the MCA.

For further information about undertaking clinical trials involving adults lacking capacity to consent see here:
http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=337

1. Framing the issue

B. Clarifying research

i. The MCA applies to all ‘intrusive’ research. This is any research that would otherwise require consent to be lawful

ii. Empirical research seeking to involve adults lacking capacity to consent as participants will extend across health, social care and criminal justice contexts, and be clinical and non-clinical in character

iii. If the purpose of the research is solely for the purposes of service development, it is defined as ‘audit’, and falls outside the remit of the MCA

iv. Note: in social care, a broader definition of research is preferred. Service audits are classed as research

1. Framing the issue

C. Clarifying relevant participants

i. The MCA applies to adults (16 and over) only
   - Research involving minors is governed by the common law. See: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430

ii. What does it mean to lack capacity to consent? The 'capacity test' under s. 2 and s.3 of the MCA

iii. Capacity cannot be presumed (MCA, s.1(2), but sometimes lack of capacity can be assumed (a patient in PVS or a coma)

iv. Sometimes capacity will be uncertain (in a person with a moderate learning disability)

v. Sometimes capacity will fluctuate (in a person with a drug dependency)

vi. Sometimes capacity will be a future concern (in longitudinal research involving people with dementia)

2. What does the MCA require?

To gain “section 30” approval to proceed, the MCA (and the REC) requires researchers to fulfil a number of requirements under three supplementary sections:

- s.31 (general requirements),
- s.32 (consultation requirements), and
- s.33 (supplementary requirements)

2. What does the MCA require?

A. Requirements under s.31

i. The research must be approved by an "appropriate body": This includes a small number MCA-flagged NHS RECs and the Social Care REC operating under the National Research Ethics Service (NRES)*

iii. The research must be connected to the impairing condition that means a participant is unable to give consent, or the care/treatment of that condition

iv. There must be reasonable grounds for believing that the research cannot be carried out without including those unable to consent

v. The research must have the potential to:

- benefit participants without imposing a burden disproportionate to this potential benefit OR
- benefit others with the same/similar impairing condition IF the risk to the participants is negligible AND the research will not be unduly invasive or interfere significantly with participants' freedom of action or privacy

* *University, service provider or internal R&D research ethics committees are NOT recognised as appropriate bodies under the MCA. All research must be channelled through NRES.*

2. What does the MCA require?

B. Requirements under s.32

i. The researcher must identify a "personal consultee" who is:

a) not connected to the research project, **and**
b) engaged in caring for the participant, or is interested in his/her welfare but not in a professional capacity or for remuneration, **and**
c) is willing to be consulted

The identified personal consultee should be provided with information about the project in order to advise on the what the proposed participant's wishes, feelings and values would be in relation to being involved in the project, if he/she had the capacity to consent. If the personal consultee's assessment of the person's wishes, feelings and values are aligned with that person's participation in the research, he/she should make a declaration that the research can proceed with the involvement of that person on these grounds.

Note: No-one can give consent/assent on behalf of any adult who lacks the capacity to consent.

2. What does the MCA require?

B. Requirements under s.32 (cont.)

ii. If a personal consultee cannot be identified, a "nominated consultee" should be identified. A nominated consultee must be:

a) a person who cares for the proposed participant, or is interested in his/her welfare, in a professional or paid capacity (e.g. key worker in a care home or a GP), **and**

b) unconnected to the research

The nominated consultee is expected to fulfil the same role as the personal consultee.

If a personal consultee refuses to make a declaration that the person can participate in the research, a nominated consultee cannot be approached. However, if the personal consultee refuses to fulfil this role, a nominated consultee can be approached.

2. What does the MCA require?

C. Requirements under s.33

i. Nothing can be done in the research that the person lacking capacity appears to object, **and**

ii. the person must be withdrawn immediately from the research if he/she gives any indication that he/she wishes to be withdrawn, or if the personal/nominated consultee indicates that the person should be withdrawn, **and**

iii. the interests of the person must always be assumed to outweigh those of science and society

The REC requires researchers to be able to demonstrate that reasonable arrangements are in place to meet the requirements under s.31, s.32 and s.33 of the MCA. For example do researchers have:

- the relevant skills and experience to assess capacity?
- good reasons for including adults lacking capacity in their research?
- a clear plan in their protocol for approaching, providing information to, and seeking the declaration of, personal consultees for individual participants?

3. Some practical considerations

There are some practical aspects of undertaking research involving adults lacking the capacity to consent to consider

A. Loss of capacity during the course of the research

i. Researchers no longer have valid consent if participants lose capacity. Researchers can continue if they comply with the MCA (Loss of Capacity During Research Project) (England) Regulations 2007

ii. Procedures must be in place to involve people lacking capacity, and these must have been approved by an appropriate REC

iii. These procedures must be in line with sections 30-33 of the MCA

iv. However, the research does NOT have to be linked to the person's impairing condition, have the potential to benefit that person, or aim to provide knowledge relevant to others with the same condition

3. Some practical considerations

B. Time and effort

i. Involving adults lacking capacity to consent is time consuming and requires more work on the behalf of the researchers. The capacity assessment and consultation process can take months to complete, and can be frustrating

iii. Extra information sheets and consultee declaration forms are required. The study protocol must clearly outline procedures for involving adults lacking the capacity to consent

v. The feasibility of student projects (e.g. dissertations by Masters students or PhD projects with a strict 3 year deadline) involving adults lacking the capacity to consent for student projects needs to be given careful thought

3. Some practical considerations

C. An emphasis on protection

i. The MCA treats research involving adults lacking capacity as a ‘special case’. Unlike providing care or treatment to adults lacking capacity, the ‘best interests’ concept does not apply, and the general principle is that people who lack capacity should be excluded from research whenever possible

ii. Researchers need to be prepared to give careful thought to justifying the need for their research to go ahead, and to provide a considered and extensive defence of their study

iii. The inconsistency between research and care/treatment is justified on the basis of the additional protections judged to be necessary in research ethics compared to clinical ethics

3. Some practical considerations

D. Inconsistencies in the REC system

i. Dixon-Woods and Angell (2009)* draw attention to inconsistencies in the knowledge and interpretation of the MCA's requirements in their analysis of REC decision letters

iii. Researchers need to consider the appropriateness of an appeal if they feel that they have designed a protocol that is consistent with the requirements of the MCA, but has been given an unfavourable opinion by an REC

Dixon-Woods, M. and Angell, E.L. (2009) 'Research involving adults who lack capacity: How have research ethics committees interpreted the guidance?', *Journal of Medical Ethics*, 35: 377-381.

Further information

Other guidance about involving adults lacking the capacity to consent in research is available

- The MCA and Code of Practice:
  - http://www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1
  - http://www.opsi.gov.uk/acts/en2005/ukpgaen_20050009_en_cop.pdf
- From NRES:
  - http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=321 (overview)
  - http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=4731 (s.30-33 requirements)
  - http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=48162 (Q&As)
- From the Department of Health:
  - http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_083133.pdf (nominating personal and nominated consultees)
  - http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@pg/documents/digitalasset/dh_106217.pdf (factsheet for social scientists)