Ethics review and MCA research

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Introduction

- Ethics and governance approval processes
- Mental Capacity Act (MCA) and MCA research
- Justifying inclusion of people who lack capacity to consent
- Assessing capacity for consent to research
- Seeking advice about participation in research (consultees)
- Providing information
- Involving people who cannot consent to taking part in research
- Adapting methods
- Summary – completing the IRAS form

Ethics and governance approval processes

- Health Research Authority (HRA) Ethics Committees/Social Care Research Ethics Committee
- University Ethics Committees
- Local Research Governance
- HRA Approval, for research involving NHS organisations
- Association of Directors of Adult Social Services (for studies involving more than three local authority sites)

HRA review of social care research ethics

- Social Care Research Ethics Committees & two other ‘flagged’ RECs
- HRA research ethics review is needed for:
  - Most social care studies involving people who use services or carers
  - All social care research that involves people lacking capacity in England and Wales
- Other kinds of studies involving people using services or carers can be reviewed by HRA RECs:
  - Research undertaken by local councils, where the chief investigator and/or sponsor feels there are substantial ethical issues
  - Studies of integrated services (health and social care)
  - Studies taking place in NHS settings with patients or staff where the approach to data collection uses social science methods
  - Intergenerational studies in social care where both adults and children, or families, are research participants

Process

- Does research requires HRA REC review (HRA Decision Tool)
- Register on the Integrated Research Application System (IRAS)
- Produce all research materials (or include plan for developing documents and tools)
- Complete IRAS form, upload documents (including ‘protocol) and book REC meeting
- Attend REC meeting (Students: attend with supervisors if at all possible)
- Possible outcomes: ‘Favourable’, ‘Favourable with (minor) conditions’, ‘Provisional’, ‘Unfavourable’
- Submit Amendments as required (including for new research tools, information sheets etc)
- Submit progress and final report

Mental Capacity Act 2005

What is the MCA?

- The Act applies to any research involving people who are unable to give their consent within England and Wales
- Conditions for research Sections 31,32 * 33
  - s.30 – Intrusive research
  - s.31 – Requirements for approval
  - s.32 – Consulting carers etc.
  - s.33 – Additional safeguards

Five principles of the MCA

- Presume capacity
- Support individual
- Unwise decisions
- Best interests (Does not apply for research!)
- Least restrictive option

What is capacity?

- Capacity is the ability to understand, retain and use information to make a decision, and to communicate any decision made.
- Capacity is time and decision specific, which means that every decision needs to be considered separately at the time the decision is required. Some people have capacity for some decisions but not for others, this can change over time and is never diagnosis specific.
- People's capacity can fluctuate and can be impaired by many things, including various mental and physical health conditions, emotional distress, pain and substances such as alcohol, prescribed and non-prescribed drugs.
- People with capacity can consent to take part in research.
- The Mental Capacity Act makes special provisions to allow people with impaired capacity to participate in research.

Source: Health and Care Research, Wales and National Mental Capacity Forum (https://www.healthandcareresearch.gov.wales/uploads/News/research_and_impaired_mental_capacity_in_adults-guidance_for_researchers.pdf)

Assessing capacity

- Stage 1: is there a Is there a impairment of, or disturbance to, the functioning of the mind or brain? (Can be permanent or temporary)
- Stage 2: is the impairment or disturbance sufficient that the person is unable to make that particular decision? – four questions help assess this:
    a. Can the person understand the information relevant to the decision?
    b. Can the person retain that information?
    c. Can the person use or weigh that information as part of the process of making the decision?
    d. Can the person communicate their decision by any means?

Source: Welsh Government, Health and Care Research Wales, National Mental Capacity Forum (2018) *Research and Impaired Mental Capacity in Adults Guidance for Researchers*

Why include people who don't have capacity to consent in research?

Source: Welsh Government, Health and Care Research Wales, National Mental Capacity Forum (2018) *Research and Impaired Mental Capacity in Adults Guidance for Researchers*

Justification for including people who lack capacity to consent.

‘…we understand little about the experiences of people with these impairments in acute hospital settings. The evidence to date suggests that they are most vulnerable to not experiencing compassionate care. It is vital that we use this study to help understand how to develop compassionate care for this group…’

Decisions about participation in MCA research

- Decisions to take part in research are often confused with Best Interests decision making, which operates for clinical and other decisions
- The interests of the individual outweigh those of society
- Researcher has the final responsibility
- Decisions needs revisiting
  - Withdraw participant from research if they appear distressed at any point about taking part (and do not try to include them subsequently)
  - Sensitivity to verbal and nonverbal cues about willingness to continue participating to ensure nothing is done against participants' wishes

Assessing capacity

- How much to rely on opinions of carers or care/clinical staff?
- When is the assessment to be made and repeated?
- Skills, experience and training of researchers
- What happens if capacity to consent is regained?
- What happens if capacity to consent is lost during the study?
  - Legally, consent is not presumed to continue after loss of capacity

Seeking advice from consultees?

- Consultees:
  - ***Do not give proxy consent***, nor should they consider their own feelings about research
  - Give an opinion on the presumed wishes of the person, and any knowledge of past and present feelings about research (Researchers must respect their opinion)
  - Are given an information sheet, mirrors participant information sheets + explains their role
  - Sign a ***Declaration form*** confirming their opinion
- Personal: someone who knows the person well, but is not a paid care worker/professional
- Nominated (if no personal): can be a paid care worker or professional who is not involved in the study
- Respect advance decisions in respect of consent or choice of consultee.
- What if there is no time to consult a consultee? (mainly for emergency health research)

Providing information

- Participants
  - Produce Easy-Read materials to enable the potential participant to be involved in the decision to take part as much as possible
  - Use appropriate language and formats, including audio
  - Time to provide information
  - Support from family/carers and care workers in explaining the research
- Consultees
  - Explain reason for contacting consultees
  - Good information about the research (just as for a participant who is able to consent)
  - Make it clear whether participants can consent to different parts of the research (eg interview but not recording)
  - Importance of keeping in touch with consultees

Adapting methods for MCA research

- Simplified questions
- Minimum intrusion
- Kinds of interview
- Creative methods
- Observational studies
- Communication aids

- Proxy methods using family or carers as respondents, can be justified, ***but***:
  - Must be framed as asking for their opinion and referenced as such in the write-up
  - Must give due regard to confidentiality issues

Summary:
Key points for IRAS form (part B)

- Ensure clear connection to ‘impairing condition’ (B1)
- Consider justification for including people who lack capacity as participants (other than ethical and inclusivity arguments) (B2)
- Clear process for assessing capacity (including skills and training of researchers) (B3 & B11)
- Clear benefit (usually to improving care) and minimum risk (B4,B5, B6 & B13)
- Plan approach to consultees and consider their role (B7, B8 & B9, B14)
- Information for participants (B10)
- Withdrawing from the research (including response to distress, withdrawn by researcher) (B12 & B13)

Links to HRA Guidance

Informing participants and seeking consent

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/

HRA Consent 'Decision Tool', useful in its own right and has links to templates

http://www.hra-decisiontools.org.uk/consent/

Examples and Templates

http://www.hra-decisiontools.org.uk/consent/examples.html

NB Link to Information sheets and declaration forms for consultees is on the 'Adults not able to consent for themselves' section

Thanks for Listening!

Disclaimer

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