NHS
National Patient Safety Agency
National Research Ethics Service

Ethics in Medical Research - with particular reference to people who may lack mental capacity

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with acknowledgements to NRES

- any errors I have made in adapting their material are my own responsibility

Why do we have research ethics?

Because bad things can happen if you don't

e.g. atrocious experiments by WW II Nazis which led to first codifications of research ethics

i.e. Nuremberg Code 1947

Declaration of Helsinki 1964

- (see Wikipedia articles)

Why do we have research ethics?

But bad(ish) things can still happen if you don't have a system for enforcing ethics

e.g. examples of ethically dubious research in US & UK collected by Dr Maurice Pappworth

In “Human Guinea Pigs” (1967)

(see Wikipedia article)

How do we have research ethics?

Now research in NHS facilities (& in some cases non-NHS) must have prior approval from an ethics committee, with a mix of expert and lay members.

Benefits of research (e.g. improved care or treatment) must be balanced against risks to participants in health, discomfort or privacy.

Issue of informed consent

Usually research participants must give "informed consent", indicating that they understand what the research means for them (including any risk of harm or discomfort), and that they agree voluntarily without any coercion.

People are usually given a Participant (or Patient) Information Leaflet, explaining the above in clear language, are given the opportunity to ask questions, and if they agree, sign a Consent Form

Issue of informed consent /2

But what if you have participants who lack capacity to give informed consent because they have e.g. dementia, mental illness or significant learning disabilities?

Does that mean you can't do research into such conditions, even though it would lead to benefits of improved treatment or care?

You may be able to do the research if you satisfy the safeguards of the Mental Capacity Act (or another set of regulations which relate specifically to drug trials)

Mental Capacity Act 2005

Applies in England & Wales

Law in Scotland & Northern Ireland

Is different

What is the MCA about?

The MCA is about people over the age of 16 who **cannot make decisions for themselves** because of an impairment or disturbance in the functioning of the mind or the brain (i.e. they lack capacity).

It provides a framework for making decisions in their **best interests** and ensure **protection from harm**.

Types of decision

- **Health care**
- **Personal welfare** including day-to-day care, accommodation, social activities, leisure, education, contacts with others (“social care”)
- **Property / financial affairs** including buying and selling, property upkeep, insurance, bank accounts, benefits, tax, mortgage, expenses, savings, gifts etc
- **Participation in research** – specific provisions in MCA

People who may lack capacity to consent

- Dementia
- Mental illnesses
- Significant learning disabilities
- Physical conditions affecting both physical and mental faculties, e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium
- Drug overdose / withdrawal

- BUT the Act is careful not to single out any particular group

- **Capacity is decision-specific**

Temporary loss of capacity

- The Act applies to temporary loss of capacity, e.g. in emergency medicine, as well as long-term conditions
- Some people may have conditions where their capacity fluctuates
- **Capacity is time-specific**

Loss of capacity in future

The Act also applies to making preparations for losing capacity in future. In particular, a person with capacity can:

- Create powers of attorney
- Make an advance decision to refuse treatment
- Make an advance statement about participation in research (does not constitute consent or a binding decision)

The 5 core principles (section 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 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 (1)

A person is unable to make a decision for himself if he has an impairment of, or disturbance to, the mind or the brain and as a result is unable to:

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

Assessing capacity (2)

- People with a duty of care must assess capacity to make a particular decision at the particular time
- Similarly, researchers must be able to assess capacity when recruiting participants --- or seek expert advice/input from other professionals where necessary

Helping people make decisions

- Best time of day
- Best location
- Right amount of detail
- Pacing the information
- Simple language
- Check understanding
- Repeat if necessary
- One decision at a time

- Non-verbal communication, e.g. DVD, signing, pictures
- Recognise language and cultural differences
- Involve others
- Involve an advocate
- Delay until capacity recovered?
- Address underlying difficulties, e.g. hearing

Deciding on best interests (s.4)

- Encourage participation, try to find out their wishes and feelings (including any written statements)
- Consider their beliefs and values
- Identify all relevant circumstances
- Avoid discrimination
- Assess whether the person might regain capacity
- Decisions about life-saving treatment must never be influenced by desire to bring about death
- Consult others

Best interests - consulting others

- Anyone the person has named
- Anyone involved in caring for them
- Anyone else who is interested in their welfare
- Anyone appointed under a Lasting Power of Attorney under the Act (or an Enduring Power of Attorney before the Act came into force)
- Any deputy appointed by the Court of Protection

MCA - Scope of research provisions

- England and Wales only
- Any "intrusive research" wherever it takes place (i.e. both NHS and non-NHS)
- **Drug trials** (CTIMPs) are specifically excluded – subject to separate regulations.

Possible research settings

- NHS Trusts (including special hospitals)
- Private hospitals
- Private residential care homes / nursing homes
- Local authority social services accommodation
- Drug and alcohol treatment units
- Social research (e.g. major censuses and surveys)
- Prisons and police cells

Section 30 of M C Act

- "Intrusive research" involving a person who lacks capacity is unlawful unless it is approved by an appropriate body ("Section 30 approval")

- "Appropriate bodies" include NHS Research Ethics Committees and Social Care REC (but not university RECs)

What is “intrusive research”?

- Research is “intrusive” if it would normally be unlawful to do it without consent
- Not limited to interventional studies
- For example, any research involving access to personal data, questionnaires/interviews or observations which infringe the right to privacy requires consent and is “intrusive”

Is consent legally required?

- Not always!
- Consent is not a legal requirement and therefore MCA does not apply where research is limited to use of:
  - Non-identifiable data
  - Identifiable patient data with approval of National Information Governance Board (NIGB) to set aside common law duty of confidentiality
  - Non-identifiable tissue from the living

Is it research?

- Section 30 approval is not required for projects which are not “research”
- It is ultimately for the researcher and their employer/sponsor to determine whether or not it is research (NRES exclude service audits & evaluations from their definition of research – see NRES guidance leaflet)

Section 31 – approval criteria

1. Research must be connected with an impairing condition affecting P (participant) or its treatment.

2. Research of equal effectiveness cannot be carried out if confined to participants with capacity.

3. (a) Research must have the potential to benefit P without imposing a disproportionate burden, *or*

   (b) Provide knowledge of the causes or treatment of others with same condition, *and* involve negligible risk to P, not interfere significantly with freedom of action or privacy, or be unduly invasive or restrictive.

4. Arrangements are in place to comply with s.32 and 33.

Section 32 – consulting carers

- Researcher must seek advice from a carer or another person ("consultee") on whether P should take part and what P's wishes and feelings would be
- **The consultee gives advice not consent**
- Under the MCA there is no "consent" representing the presumed will of the participant in law

Identifying a consultee

- Researcher must take reasonable steps to identify a **personal consultee**
- A “personal consultee” means a person who is (a) engaged in caring for P (not professionally or for payment) or is interested in his/her welfare, and (b) is prepared to be consulted
- If no personal consultee can be found, the researcher may consult a **nominated consultee**, i.e. a person independent of the project appointed in accordance with DH guidance

Possible consultees

Personal consultees:

- Usual carer
- Other close relative/ friend
- Person with Lasting Power of Attorney
- Court-appointed deputy

Nominated consultees:

- Independent Mental Capacity Advocate
- Participant's usual doctor or other paid carer (if not connected with research)
- Solicitor
- Other nominated person

Respecting the consultee's advice

- Researcher must not recruit P against the advice of the consultee
- Consultee should be kept informed during the study and may advise at any time that P should be withdrawn, unless this would significantly harm his/her health
- Good practice for consultee to attend during research procedures

Section 33 – additional safeguards during the research

1. Nothing must be done to which P appears to object unless it is to protect him from harm, or reduce or prevent pain or discomfort.

2. If P indicates he/she wishes to be withdrawn, this must be done without delay unless there would be a significant risk to health.

3. Nothing must be done contrary to an advance decision to refuse treatment or any other advance statement.

4. Interests of P must be assumed to outweigh those of science and society.

Loss of capacity during research

- **Key principle**: consent does not generally endure loss of capacity in common law
- Therefore, **intrusive research** following loss of capacity requires section 30 MCA approval from REC

Loss of capacity - options

1. Withdraw participant, **destroy or anonymise** data/tissue – *no further implications*

2. Withdraw participant, **retain identifiable data/tissue** already collected – *requires specific advance consent anticipating loss of capacity*

3. Participant remains in study, undergoes **further intrusive research** – *requires section 30 approval, consultee procedures etc*

Section 30 approval anticipating loss of capacity

- Where participants can consent but some are likely to lose capacity and it would be important to continue to include them in the research, researchers may apply for Section 30 approval from REC at the outset
- E.g. long-term health cohort or dementia study
- Research must still meet all Section 31-33 criteria

Section 30 application procedures

- Section 30 application may be submitted:
  - to recruit Adults Lacking Capacity from the outset
  - to continue intrusive research with adults who consent initially but lose capacity during the research
- If Section 30 approval is not sought in the initial application to the REC, it may be requested later as a "substantial amendment"
- Part B Section 6 of application form in IRAS must be completed for any Section 30 application at any stage

Trevor's tips for getting ethical approval – (my advice, not necessarily official)

- Make sure info for lay readers (information leaflets, consent forms) is easily readable – any *unavoidable* jargon must be explained
- Make sure any ethical issues (eg risk of distress to participants) are adequately addressed – see A6-2, A22 & A23 on IRAS form
- Not obligatory but very advisable for applicant(s) to attend REC meeting, to answer any questions
- For student research, usually advisable for academic supervisor to attend REC with student, unless student is well prepared and confident to attend alone

Sources of guidance – Code of Practice for MCA

Key chapters in the Code of Practice:

Chapter 2	Core principles
Chapter 3	Helping people make decisions
Chapter 4	Assessing capacity
Chapter 11	Research

http://www.justice.gov.uk/dowloads/protecting-the-vulnerable/mca/mca-code-practice-0509.pdf