

National
Mental
Capacity
Forum



Ymchwil Iechyd
a Gofal **Cymru**
Health and Care
Research **Wales**



Llywodraeth Cymru
Welsh Government

Research and Impaired Mental Capacity in Adults Guidance for Researchers

TAKING PART
IN RESEARCH WAS
MY FIRST STEP...

TO ACCEPTING MY CONDITION



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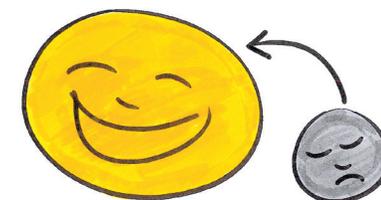
Research and Impaired Mental Capacity in Adults

Taking part in research is usually a positive personal experience and is good for the health and wellbeing of all of us. Everyone should have the opportunity to take part in health and social care research for the benefit of themselves and of others.

This guidance aims to answer key questions, to signpost helpful resources and, most importantly of all, to maximise inclusion of individuals with impaired capacity in high quality research, whilst ensuring that their rights are protected.

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.



MADE A POSITIVE
OUT OF A NEGATIVE
FOR ME

What is the Mental Capacity Act?

The Mental Capacity Act 2005 is a law (legislation) for England and Wales that is designed to protect and empower individuals who may lack capacity to make their own decisions. It facilitates the inclusion of individuals with impaired or fluctuating capacity in research.

The Act applies to any research involving people who are unable to give their consent within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products, which are covered by different legislation.

The Mental Capacity Act has five principles:

Presume capacity

All adults are presumed to have sufficient capacity to make decisions, unless there is definitive evidence this is not the case.

Support individual

Individuals must be helped to make their own decisions as far as practicable. It is important to be flexible and creative with communication and to give people time.

Unwise decisions

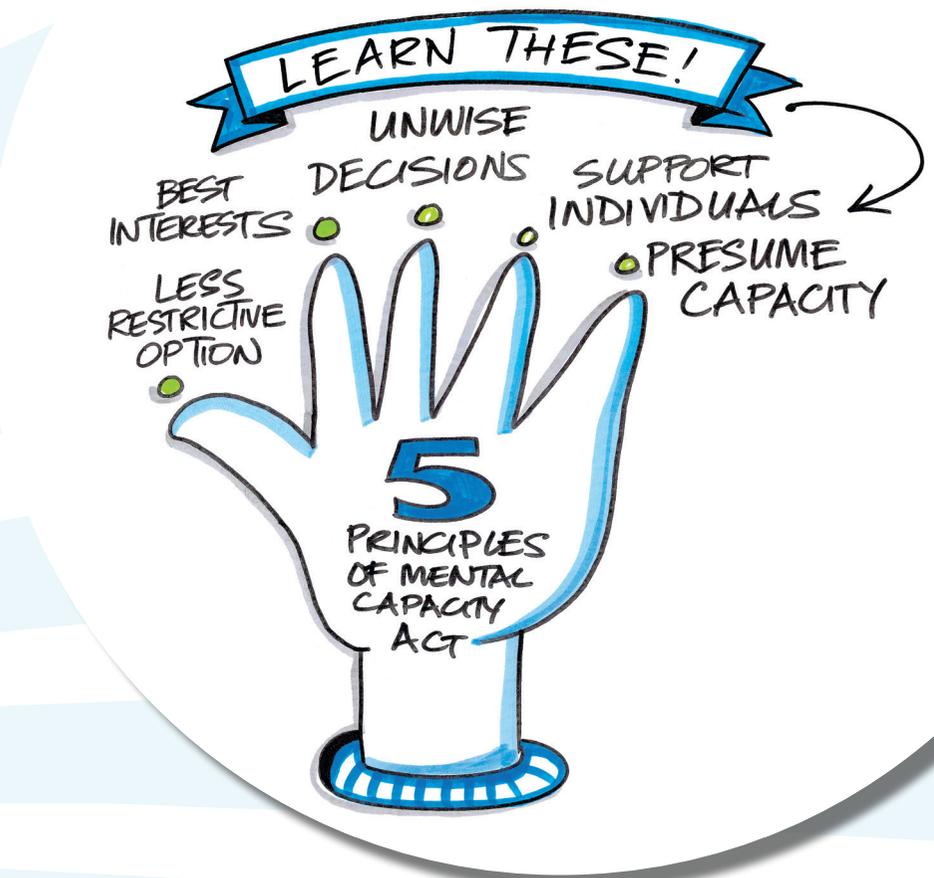
If someone makes a decision that other people would consider to be irrational, it does not mean they lack capacity, as long as they understand the reality of their situation.

Best interests

All decisions and actions must be taken in the best interests of the person lacking capacity.

Least restrictive option

All decisions and actions must be the least restrictive of the person's rights and freedom of action.



The five principles underpin everything we do but it is important to remember that additional safeguards are in place to protect adults lacking capacity when participating in research, such as review by a **Research Ethics Committee**. Decisions should be based on what the person's wishes and feelings would be about taking part rather than a determination about whether or not it is in the person's best interests. However, the person's interests must always be more important than those of the research project, and any objection a person who lacks capacity makes during research must be respected.

How is a person's capacity to consent assessed for research?

It is the responsibility of the researcher, with appropriate consultation, to decide whether someone has the capacity to consent for research. Capacity can change and it should be assessed at the time a decision is required. Assessment is usually undertaken by an appropriately qualified health professional or researcher. The Mental Capacity Act requires a two-stage test of capacity that must be properly documented.

Stage 1

Is there an impairment of, or disturbance to, the functioning of the mind or brain?

If so,

Stage 2

Is the impairment or disturbance sufficient that the person is unable to make that particular decision?

The second stage is determined by the answers to the following questions:

- Can the person understand the information relevant to the decision?
- Can the person retain that information?
- Can the person use or weigh that information as part of the process of making the decision?
- Can the person communicate their decision by any means?

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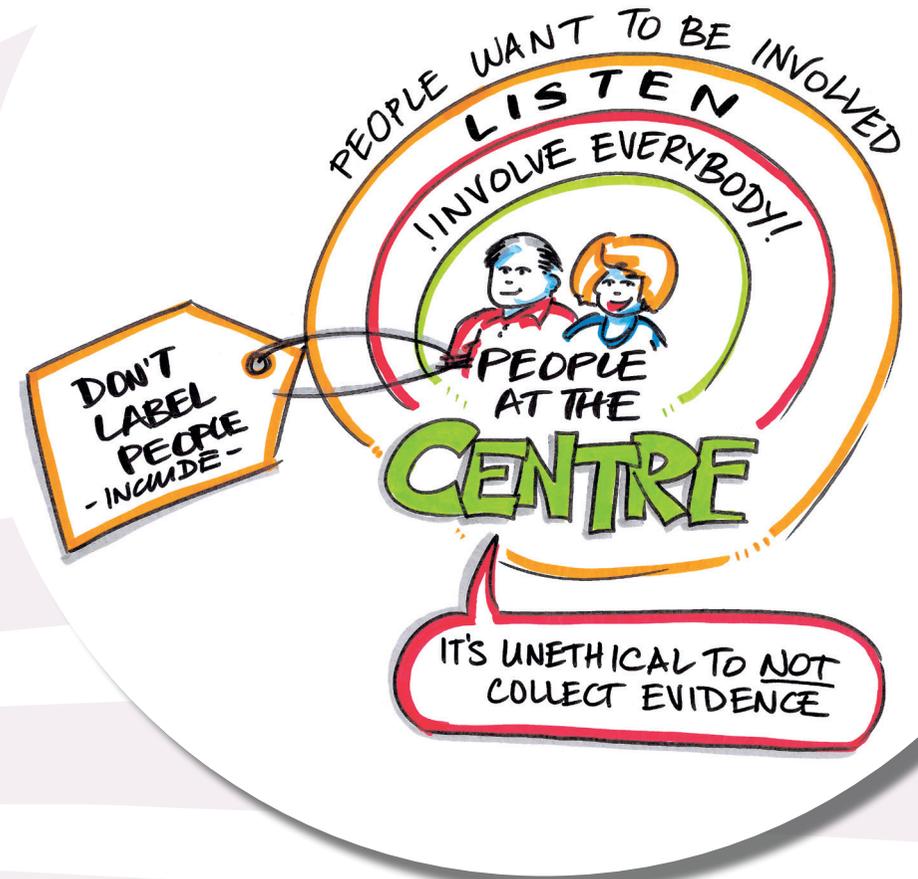


What happens if capacity to consent is present?

If capacity to consent is present, the researcher presents the information sheet and consent form as usual and the individual can consent (or not) to take part in the research being considered.

What happens if capacity to consent is absent?

- Responsibility to decide whether the person should be entered into the research lies with the researcher – no-one can give consent on behalf of a person lacking capacity (except for a clinical trial of an investigational medicinal product).
- The researcher is required to seek advice from a consultee (often a close family member) on whether the person should take part in the project, and what the wishes and feelings of the person might be if they had capacity to decide. If, at any time, the consultee advises that the person would decline to take part in the study (or to wish to withdraw from it) the advice must be respected. The consultee cannot give consent.
- The researcher should seek the views of any carers and other relevant people (such as a person appointed with Lasting Power of Attorney for Health and Welfare) before involving a person who lacks capacity in research.
- A consultee can be a “personal consultee” or a “nominated consultee”. A “personal consultee” is an unpaid person involved/interested in the care and welfare of someone and willing to be consulted, e.g. a close family member. A “nominated consultee” is a person with no connection with the research project who is appointed in the absence of a “personal consultee”.
- The researcher will need to carefully consider what is in an individual’s interests before making a decision. Key points include whether capacity could be regained and if it is possible to wait, and whether there are specific issues such as religious or moral beliefs or previously expressed views that need to be taken into account. Some individuals might have recorded their preferences in advance, which will be important to follow as closely as possible.



What happens if capacity to consent is regained?

The participant should be fully informed about the study and their consent sought to continue in it. If they do not wish to remain in the study, they must be withdrawn and any data and samples collected destroyed unless consent is given to retain and analyse them.

What happens if capacity to consent is lost during the study?

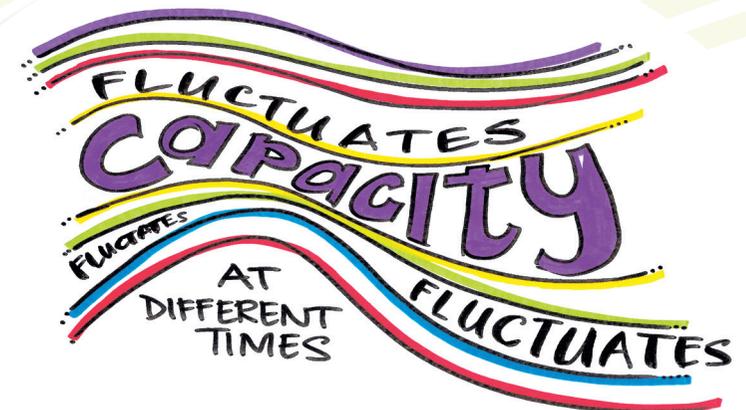
The participant can only remain in the study if it has been approved in accordance with the Mental Capacity Act (see below), a consultee has been consulted and advised that ongoing involvement is appropriate. If this is not the case, data and samples collected must be destroyed or anonymised unless consent was given to retain and analyse them following loss of capacity. There are separate requirements under the Mental Capacity Act for research that started before 1 October 2007, and for clinical trials under Medicines for Human Use (Clinical Trials) Regulations 2004 where consent does remain valid if capacity is lost.

What happens if the person shows signs of distress or unwillingness to take part?

The researcher must not do anything the person who lacks capacity objects to. If the person indicates in any way that they want to be withdrawn from the study (for example, if they become upset or distressed) they must be withdrawn without delay.

What if there is no time to consult a consultee?

Where urgent intervention is to be provided as part of a research study, a person lacking capacity may be entered into the study prior to a consultee being consulted, subject to strict conditions including ethical approval. As soon as is reasonable, the researcher must consult a consultee or seek the participant's consent (if capacity has been regained).



How is research involving adults lacking capacity approved?

The Mental Capacity Act requires a recognised Research Ethics Committee to approve research involving adults lacking capacity. The Committee will ensure the research is necessary and that appropriate safeguards to protect participants are in place. It will also ensure that the assessment is proportionate and not risk averse; it is both unethical to undertake unnecessary research and not to undertake necessary research.

A number of things need to be satisfied for approval:

- The research question must be connected with a condition affecting the participant that could not be answered if only participants with capacity were included.
- The research must either have the potential to benefit the participant and/or to improve knowledge without significant burden through participation.
- Appropriate arrangements must be in place for consulting close family members or friends, carers and, when applicable, consultees.
- Additional safeguards must be in place, including doing nothing if the participant appears to object to unless the decision is in their best interests and respecting any expressed wish to be withdrawn.

● IMPORTANT
Research
IS CONDUCTED
Properly



Helpful Resources

National Mental Capacity Forum

Joint Ministry of Justice and Department of Health initiative to work with stakeholders across sectors to improve implementation of the Mental Capacity Act

<http://www.scie.org.uk/mca-directory/forum/>

Health Research Authority

The Health Research Authority is responsible for the approval process for research studies taking place in the NHS in England. Other UK nations have compatible processes

<http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/>

Mental Capacity Act 2005

http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf

Mental Capacity Act 2005 Code of Practice

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

Medicines for Human Use (Clinical Trials) Regulations 2004

http://www.hra.nhs.uk/documents/2014/04/nres-guidance_informed-consent-ctimps_v3-1_2014-04-14.pdf

Online toolkit (University of Leicester and University of Bristol)

An on-line toolkit on research involving adults lacking capacity to consent for themselves, covering the provisions of the Mental Capacity Act 2005 and the Medicines for Human Use (Clinical Trials) Regulations 2004

<https://connect.le.ac.uk/alctoolkit/>

How the guidance was developed

This guidance was developed through **Mental Capacity: Action in Research**; a one day meeting that brought together UK research leaders working across a range of disciplines and other key stakeholders (including research participants) to develop a consensus about facilitating access to health and social care research for adults with impaired capacity to consent.

All images used in this document were created at the **Mental Capacity: Action in Research** one day event and were used as an aid to illustrate the day.