MAKING DECISIONS FOR PEOPLE WHO LACK CAPACITY

Mental capacity Act 2005

RESEARCH

This is one of a series of resource materials for clinical ethics committees providing explanation and discussion of the sections of the Mental Capacity Act which are particularly relevant to their work.

Principles underlying the Act with regard to research

The provisions governing research aim to strike a balance between protecting and respecting the interests, wishes and feelings of those (aged 16 and over) who lack capacity with the need for appropriate research. Such research is considered essential if knowledge of what causes a person to lack or lose capacity, and the diagnosis, treatment, care and needs of people who lack capacity, is to be improved. The Act includes a range of safeguards, in particular the fundamental principle that the person’s interests must be assumed to outweigh those of science and society.

Change: Prior to the Act any intervention at common law without the consent of an adult was lawful only if it was in the person’s best interests. The legality of non-therapeutic research involving adults – although widely supported in national and international ethical guidelines – was therefore uncertain. The Act codifies, clarifies and supplements the common law in relation to research involving those over 16 who lack capacity. In so doing it distinguishes between therapeutic and non-therapeutic research (by introducing more stringent requirements for the latter) and imposes new legal responsibilities on researchers (e.g. to consult carers).

The Act is limited in its scope – it does not apply to the testing of new drugs. However, the combined effect of the Act, the Human Tissue Act 2004 and The Medicines for Human Use (Clinical Trials) Regulations 2004 is that there is now a comprehensive legislative framework regulating research involving those who lack capacity.

What research does the Act cover?

The Act applies to research that is ‘intrusive’ i.e. research normally requiring consent. The Act does not apply to research involving clinical trials (the testing of new drugs). Although no specific definition of research is given in the Act the Code of Practice provides guidance on the general meaning of the term.

2. Under the Human Tissue Act 2004 (which defines adults as 18 or over) research that only deals with human tissue (that has been anonymised) does not require consent. This applies to both adults who have capacity and those who do not. But the research must have ethical approval, and the tissue must come from a living person.

**What legal duties do researchers have?**

Section 30 lays down several conditions that must be complied with if it involves adults (i.e. those of 16 and over) who lack capacity. Failure to comply with them means that the research is **unlawful**. For clarity these will be divided into three sections, i.e. those that researchers must comply with before the research is started, those that apply before any decision is taken to involve a particular person in approved research and finally those that apply once the research has begun.

**Conditions to be complied with before the research is started**

*Obtain approval from the ‘appropriate body (s.30)*

The appropriate body will normally be a research ethics committee. For such approval to be granted all the following further 4 requirements must be met. *(section 31):*  
1) the research must:
   a) be linked to an impairing condition affecting the person who lacks capacity or
   b) its treatment, **and**

2) there must be reasonable grounds for believing that the research would be less effective if only people with capacity were involved (s.31(4)), **and**

3) there must be reasonable arrangements to consult carers and to follow the Act’s other requirements, **and**

the research must be either:
- have the potential to produce a **benefit to the person** that outweighs any risk or burden **or**

- be intended to provide knowledge about the cause of, or treatment or care of **people with, the same impairing condition** or a similar **condition** (note this does not cover research that is not related to a condition from which the person who lacks capacity suffers). **and** there must be reasonable grounds for believing:
  1) the risk to the person must be negligible, **and**
  2) there will be no significant interference with the freedom of action or privacy of the person who lacks capacity, **and**
  3) nothing will be done which is unduly invasive or restrictive, s.31(6)(a) & (b)
Conditions to be complied before any decision is taken to involve a particular person who lacks capacity in research (section 32).

Researchers must:

1) Decide who should be consulted (Box 1).

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**Box 1 Consultation**

Who should be consulted?

S. 32 states that the before a person who lacks capacity can be included in research the researcher must take reasonable steps to identify someone whom they can consult.

This person (the consultee) must be:
- engaged in caring for the person, or
- interested in his welfare, and
- willing to help

The consultee can be:
- an attorney appointed under a registered Lasting Power of Attorney, or
- a deputy appointed by the Court of Protection

The consultee cannot be:
- a person working in a professional capacity, or
- paid care worker

NB. If there is no-one who can fulfil the role of consultee the researcher must nominate a person (who must not have any connection with the research project).

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After identifying a consultee The researcher must then:

a) Provide information to the consultee about the research project (s.32(4))
Neither the Act nor the Code of Practice provide any further detail of what this information must consist of. The assumption must be, therefore, that researchers are expected to provide all the information they would normally disclose to a person with capacity in order to obtain their consent to participate in the research project.

b) Obtain advice from the consultee
The purpose of the consultation process is to make sure that the person acking capacity would want to join the research project. Note that those who are consulted do not have the right to consent to the research on the person’s behalf. Rather the Act gives them the legal right to be consulted.
The legal duty of consultation (in s.32(4)) means that researchers must ask the consultee:
1) whether the person should take part in the project, and
2) what they think the person’s wishes and feelings would be, if he had capacity to decide whether to take part.

*Note that this right of consultation is not absolute, i.e. it does not apply in urgent situations (Box 2)*

c) **Ensure** consultee’s advice is taken into account. Sometimes the consultee will say that in his opinion the person lacking capacity would probably not take part in the project or that they would ask to be withdrawn. In this situation, the researcher must not include the person in the project, or should withdraw him from it if the research is already under way (s.32(5)).

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**Box 2**  
‘Urgent’ situations

S.32 (8)&(9) sets out limited circumstances when the advice from a consultee need not be sought.

These circumstances apply where:
- treatment is being (or is about to be) to be provided for the person who lacks capacity as a matter of **urgency**, and
- having regard to the nature of the research, the researcher thinks it is **also necessary** to take urgent action for the purposes of the research, **but**
- it is not reasonably practical to consult anyone then that action can be taken.

To avoid consulting anyone, however, 2 further conditions must be satisfied. These are that the researcher must:

1. get the agreement of a doctor who is not connected to the project, **or**
2. follow a procedure agreed by the appropriate body (e.g. REC) at the time of approval.

Examples of urgent circumstances are typically those when it may not be possible to separate the research from the urgent treatment e.g. taking samples or measurements in the few minutes following a serious head injury or stroke and then taking further samples after some type of treatment to compare with the first set.

**NB.** This exception to the duty of consultation only applies:
- a) for as long as the person needs urgent treatment, and
- b) when the researcher needs to take action urgently for the research to be valid.
- c) the research proposal must give enough information about what is be done if a person lacking capacity needs urgent treatment during research and it is not possible to speak to the person’s carer or someone else.
Conditions to be complied with after the research has started

Most of the conditions (in section .33) that must be complied once the research has begun are designed to provide additional safeguards, in particular to ensure that incapacitated persons are only involved in research to which they assent (or clearly acquiesce in). A fundamental principle underpinning the section is that the interests of the person lacking capacity must always be assumed to outweigh those of science and society (s.33 (3)).

The specific responsibilities imposed on researchers are:

**a) To respect the person’s objections**

Section 33(2) makes it clear that nothing can be done to the person in the course of the research (or in relation to him) to which he appears to object. Researchers are ‘expected to be sensitive to the various ways in which a person may express his objections’. Thus although the section refers specifically to a person ‘showing signs of resistance, it also adds the words ‘or otherwise indicating that all types of ‘resistance’ should be respected, for example, they may become upset or distressed) .

Note however, that despite the person’s objections anything can be done which is intended to protect him from harm or to reduce pain or discomfort’ .

**b) To take into account any advance decision or other statement**

This related safeguard prohibits anything being done to the person (or in relation to him) in the course of research which is contrary to either an advance decision or any other form of statement which the person lacking capacity had previously made in which they had expressed their preferences about their care or treatment.

**c) To withdraw the person from the research without delay**

There are three types of situations which must result in the person being withdrawn from the project. These are:

1) if the person indicates (in any way) that he wishes to be withdrawn, or
2) if a consultee (under s.32(5)) whose advice has been sought (about the person’s wishes and feelings and whether he should take part in the research) advises the researcher that the person would want to be withdrawn from the research, or
3) if the researcher has ‘reasonable grounds’ for believing that that any of the Act’s requirements for approval (set out in s.31 (2) – (7)) are no longer met..

**NB.** In all of the above 3 situations the person can still receive any treatment he was receiving as part of the research project if withdrawing him from it would cause a significant risk to his health.
Conditions that must be followed if research started before the Act came into force?

Two types of situations are covered here:

Type 1: The person has capacity when the research starts but loses capacity

In this type of situation the person will have been able to give consent to participate in the research but subsequently loses the capacity to consent (i.e before the research project ends). Regulations covering this type of situation apply but only if the research involves tissue and data collected in certain circumstances (Box 3).

Box 3  Research involving those who lose capacity (before the end of the project).

The regulations apply to research (starting before 1.10.07) on tissue and data from a person who gave consent (before 31.03.08)

Research can only continue (on the tissue and date) if:

- the project already had procedures to deal with people who lose capacity
  an appropriate body must have approved the procedures (which the researcher must follow)
- the appropriate body is satisfied that the research project has reasonable arrangements to meet the following requirements imposed on researchers, namely to

Researchers must also:

- seek out the views of someone involved in the person’s care or interested in their welfare (if a carer cannot be found they must nominate a someone (see Box 1))
- respect advance decisions and expressed preferences, wishes or objections that the person has made in the past
- treat the person’s interests as more important than those of science and society

Researchers must withdraw the person from research if:

- the person indicates that he wishes the research in relation to him to be discontinued
- procedures are no longer in place or the appropriate body no longer approves the research

NB

1. These regulations do not cover research involving direct intervention (e.g. taking of further blood pressure readings or the taking of further tissue after loss of capacity).
2. Such research must comply fully with sections 30-33.
Type 2. The person participating in research never had the capacity to agree to it.

There are no regulations governing research projects that started before the Act came into force, and which involve a person who never had capacity.

The Code of Practice (11.7) advises that

a) projects that already have ethical approval will need to obtain approval from an appropriate body (under sections 30 & 31) and comply with sections 32 and 33 by 1 October 2008.

b) research that does not have ethical approval must get approval from an appropriate body by 1 October 2007 to continue lawfully.

Implications for health professionals

Health professionals caring for and treating adults who are involved in research might need to check the following

1. Is there evidence of research approval?

Guidance issued by the Department of Health (Core Training Set, 2007) suggests that it is good practice for healthcare staff to ask to see evidence that the research has received approval (i.e. from a REC).

2. Is the situation ‘urgent’?

One of the most important provisions (the duty of consultation) designed to safeguard the interests of participants who lack capacity and ensure that their wishes and feelings are respected, does not apply in ‘urgent’ situations. These are likely to be limited to research into procedures or treatments used in emergencies (i.e. not to those where the researcher simply wants to act quickly) when it is not possible to separate the research from the urgent treatment.

In this type of situation the legal duty to consult a person - who is caring for the person or interested in their welfare – is relaxed. This means that such a person need not be consulted before the action is taken. It is important to remember, however, that the urgent action cannot be taken unless either a doctor’s agreement has been obtained or a procedure (agreed at the approval stage) is followed.

3. Are the person’s objections or advance wishes being taken into account?

The Act makes it clear that nothing can be done to a person in the course of research (or in relation to him) to which he objects. Healthcare staff must therefore be alert to signs of ‘unhappiness’ or resistance which they can should immediately report to the appropriate person.

It must be remembered though that despite a person’s objections actions can still be taken to ‘protect the person from harm or reduce or prevent pain or discomfort’. Similarly healthcare staff may become aware that something is being done to a person which is contrary to an advance decision or another from of statement. In such cases the action should be stopped.
4. **Should the person be withdrawn from the research (without delay)?**
The Act states that the person must be withdrawn from the research in 3 situations, namely:

1) if he indicates (in any way) that he wishes to be withdrawn, or

2) the consultee’s advice is that the person would ask to be withdrawn, or

3) the researcher has reasonable grounds for believing that any of the Act’s requirements (in s.31) are no longer met (i.e. that the research must related to an impairing condition, have potential to benefit the person lacking capacity or be intended to provide knowledge about the same or similar condition).

**NB.**
In all the above 3 situations the person can still receive any treatment he was receiving as part of the research project if withdrawing him from it would cause a significant risk to his health.