11 How does the Act affect research projects involving a person who lacks capacity?

It is important that research involving people who lack capacity can be carried out, and that is carried out properly. Without it, we would not improve our knowledge of what causes a person to lack or lose capacity, and the diagnosis, treatment, care and needs of people who lack capacity.

This chapter gives guidance on involving people who lack capacity to consent to take part in research. It sets out:

- what the Act means by 'research'
- the requirements that people must meet if their research project involves somebody who lacks capacity
- the specific responsibilities of researchers, and
- how the Act applies to research that started before the Act came into force.

This chapter only deals with research in relation to adults. Further guidance will be provided on how the Act applies in relation to research involving those under the age of 18.

In this chapter, as throughout the Code, a person's capacity (or lack of capacity) refers specifically to their capacity to make a particular decision at the time it needs to be made.

Quick summary

The Act's rules for research that includes people who lack capacity to consent to their involvement cover:

- when research can be carried out
- the ethical approval process
- respecting the wishes and feelings of people who lack capacity
- other safeguards to protect people who lack capacity
- how to engage with a person who lacks capacity
- how to engage with carers and other relevant people.

This chapter also explains:

- the specific rules that apply to research involving human tissue and

- what to do if research projects have already been given the go-ahead.

The Act applies to all research that is intrusive. 'Intrusive' means research that would be unlawful if it involved a person who had capacity but had not consented to take part. The Act does not apply to research involving clinical trials (testing new drugs).

Why does the Act cover research?

11.1 Because the Act is intended to assist and support people who may lack capacity, the Act protects people who take part in research projects but lack capacity to make decisions about their involvement. It makes sure that researchers respect their wishes and feelings. The Act does not apply to research that involves clinical trials of medicines – because these are covered by other rules.[45]

How can research involving people who lack capacity help?

A high percentage of patients with Down's syndrome lack capacity to agree or refuse to take part in research. Research involving patients with Down's syndrome has shown that they are more likely than other people to get pre-senile dementia. Research has also shown that when this happens the pathological changes that occur in a person with Down's syndrome (changes affecting their body and brain) are similar to those that occur in someone with Alzheimer's disease. This means that we now know that treatment similar to that used for memory disorders in patients with Alzheimer's is appropriate to treat dementia in those with Down's syndrome.

What is 'research'?

11.2 The Act does not have a specific definition for 'research'. The Department of Health and National Assembly for Wales publications *Research governance framework for health and social care* both state:

'research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.'[46]

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45 The Medicines for Human Use (Clinical Trials) Regulations 2004.

46 www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4008777&chk=dMRd/5 and www.word.wales.gov.uk/content/governance/governance-e.htm

Research may:

- provide information that can be applied generally to an illness, disorder or condition
- demonstrate how effective and safe a new treatment is
- add to evidence that one form of treatment works better than another
- add to evidence that one form of treatment is safer than another, or
- examine wider issues (for example, the factors that affect someone's capacity to make a decision).

11.3 Researchers must state clearly if an activity is part of someone's care and not part of the research. Sometimes experimental medicine or treatment may be performed for the person's benefit and be the best option for their care. But in these cases, it may be difficult to decide whether treatment is research or care. Where there is doubt, the researcher should seek legal advice.

What assumptions can a researcher make about capacity?

11.4 Researchers should assume that a person has capacity, unless there is proof that they lack capacity to make a specific decision (see chapter 3). The person must also receive support to try to help them make their own decision (see chapter 2). The person whose capacity is in question has the right to make decisions that others might not agree with, and they have the right not to take part in research.

What research does the Act cover?

11.5 It is expected that most of the researchers who ask for their research to be approved under the Act will be medical or social care researchers. However, the Act can cover more than just medical and social care research. Intrusive research which does not meet the requirements of the Act cannot be carried out lawfully in relation to people who lack capacity.

11.6 The Act applies to research that:

- is 'intrusive' (if a person taking part had capacity, the researcher would need to get their consent to involve them)
- involves people who have an impairment of, or a disturbance in the functioning of, their mind or brain which makes them unable to decide whether or not to agree to take part in the research (i.e. they lack capacity to consent), and
- is not a clinical trial covered under the Medicines for Human Use (Clinical Trials) Regulations 2004.

11.7 There are circumstances where no consent is needed to lawfully involve a person in research. These apply to all persons, whether they have capacity or not:

- Sometimes research only involves data that has been anonymised (it cannot be traced back to individuals). Confidentiality and data protection laws do not apply in this case.
- Under the Human Tissue Act 2004, research that deals only with human tissue that has been anonymised does not require consent (see paragraphs 11.37–11.40). This applies to both those who have capacity and those who do not. But the research must have ethical approval, and the tissue must come from a living person.[47]
- If researchers collected human tissue samples before 31 August 2006, they do not need a person's consent to work on them. But they will normally have to get ethical approval.
- Regulations[48] made under section 251 of the NHS Act 2006 (formerly known as section 60 of the Health and Social Care Act 2001[49]) allow people to use confidential patient information without breaking the law on confidentiality by applying to the Patient Information Advisory Group for approval on behalf of the Secretary of State.[50]

Who is responsible for making sure research meets the Act's requirements?

11.8 Responsibility for meeting the Act's requirements lies with:

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47 Human Tissue Act 2004 section 1(9).

48 Health Service (Control of Patient Information) Regulations 2002 Section I. 2002/1438.

49 Section 60 of the Health and Social Care Act 2001 was included in the NHS Act 2006 which consolidated all the previous health legislation still in force.

50 The Patient Information Advisory Group considers applications on behalf of the Secretary of State to allow the common law duty of confidentiality to be aside. It was established under section 61of the Health and Social Care Act 2006 (now known as section 252 of the NHS Act 2006). Further information can be found at www.advisorybodies.doh.gov.uk/PIAG.

- the 'appropriate body', as defined in regulations made by the Secretary of State (for regulations applying in England) or the National Assembly for Wales (for regulations applying in Wales) (see paragraph 11.10), and
- the researchers carrying out the research (see paragraphs 11.20–11.40).

How can research get approval?

11.9 Research covered by the Act cannot include people who lack capacity to consent to the research unless:

- it has the approval of 'the appropriate body', and
- it follows other requirements in the Act to:
  - consider the views of carers and other relevant people
  - treat the person's interests as more important than those of science and society, and
  - respect any objections a person who lacks capacity makes during research.

11.10 An 'appropriate body' is an organisation that can approve research projects. In England, the 'appropriate body' must be a research ethics committee recognised by the Secretary of State.[51] In Wales, the 'appropriate body' must be a research ethics committee recognised by the Welsh Assembly Government.

11.11 The appropriate body can only approve a research project if the research is linked to:

- an impairing condition that affects the person who lacks capacity, or
- the treatment of that condition (see paragraph 11.17)

and:

- there are reasonable grounds for believing that the research would be less effective if only people with capacity are involved, and
- the research project has made arrangements to consult carers and to follow the other requirements of the Act.

[51] Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006

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11.12 Research must also meet one of two requirements:

1. The research must have some chance of benefiting the person who lacks capacity, as set out in paragraph 11.14 below. The benefit must be in proportion to any burden caused by taking part, or

2. The aim of the research must be to provide knowledge about the cause of, or treatment or care of people with, the same impairing condition – or a similar condition.

If researchers are relying on the second requirement, the Act sets out further requirements that must be met:

- the risk to the person who lacks capacity must be negligible
- there must be no significant interference with the freedom of action or privacy of the person who lacks capacity, and
- nothing must be done to or in relation to the person who lacks capacity which is unduly invasive or restrictive (see paragraphs 11.16–11.19 below).

11.13 An impairing condition:

- is caused by (or may be caused by) an impairment of, or disturbance in the functioning of, the person's mind or brain
- causes (or may cause) an impairment or disturbance of the mind or brain, or
- contributes to (or may contribute to) an impairment or disturbance of the mind or brain.

Balancing the benefit and burden of research

11.14 Potential benefits of research for a person who lacks capacity could include:

- developing more effective ways of treating a person or managing their condition
- improving the quality of healthcare, social care or other services that they have access to
- discovering the cause of their condition, if they would benefit from that knowledge, or
- reducing the risk of the person being harmed, excluded or disadvantaged.

11.15 Benefits may be direct or indirect (for example, the person might benefit at a later date if policies or care packages affecting them are changed because of the research). It might be that participation in the research itself will be of benefit to the person in particular circumstances. For example, if the research involves interviews and the person has the opportunity to express their views, this could be considered of real benefit to a particular individual.

Providing knowledge about causes, treatment or care of people with the same impairing condition or a similar condition

11.16 It is possible for research to be carried out which doesn't actually benefit the person taking part, as long as it aims to provide knowledge about the causes, treatment or care of people with the same impairing condition, or a similar condition. *'Care'* and *'treatment'* are not limited to medical care and treatment. For example, research could examine how day-to-day life in prison affects prisoners with mental health conditions.

11.17 It is the person's actual condition that must be the same or similar in research, not the underlying cause. A *'similar condition'* may therefore have a different cause to that suffered by the participant. For example, research into ways of supporting people with learning disabilities to live more independently might involve a person with a learning disability caused by a head trauma. But its findings might help people with similar learning disabilities that have different causes.

Scenario: Research that helps find a cause or treatment

Mr Neal has Down's syndrome. For many years he has lived in supported housing and worked in a local supermarket. But several months ago, he became aggressive, forgetful and he started to make mistakes at work. His consultant believes that this may indicate the start of Alzheimer's disease.

Mr Neal's condition is now so bad that he does not have capacity to consent to treatment or make other decisions about his care. A research team is researching the cause of dementia in people with Down's syndrome. They would like to involve Mr Neal. The research satisfies the Act's requirement that it is intended to provide knowledge of the causes or treatment of that condition, even though it may not directly benefit Mr Neal. So the approving body might give permission – if the research meets other requirements.

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11.18 Any risk to people involved in this category of research must be 'negligible' (minimal). This means that a person should suffer no harm or distress by taking part. Researchers must consider risks to psychological wellbeing as well as physical wellbeing. This is particularly relevant for research related to observations or interviews.

11.19 Research in this category also must not affect a person's freedom of action or privacy in a significant way, and it should not be unduly invasive or restrictive. What will be considered as unduly invasive will be different for different people and different types of research. For example, in psychological research some people may think a specific question is intrusive, but others would not. Actions will not usually be classed as unduly invasive if they do not go beyond the experience of daily life, a routine medical examination or a psychological examination.

Scenario: Assessing the risk to research participants

A research project is studying:

- how well people with a learning disability make financial decisions, and
- communication techniques that may improve their decision-making capacity.

Some of the participants lack capacity to agree to take part. The Research Ethics Committee is satisfied that some of these participants may benefit from the study because their capacity to make financial decisions may be improved. For those who will not gain any personal benefit, the Committee is satisfied that:

- the research meets the other conditions of the Act
- the research methods (psychological testing and different communication techniques) involve no risk to participants, and
- the research could not have been carried out as effectively with people who have capacity.

What responsibilities do researchers have?

11.20 Before starting the research, the research team must make arrangements to:

- obtain approval for the research from the 'appropriate body'
- get the views of any carers and other relevant people before involving a person who lacks capacity in research (see paragraphs 11.22–11.28). There is an exception to this consultation requirement in situations where urgent treatment needs to be given or is about to be given
- respect the objections, wishes and feelings of the person, and
- place more importance on the person's interests than on those of science and society.

11.21 The research proposal must give enough information about what the team will do if a person who lacks capacity needs urgent treatment during research and it is not possible to speak to the person's carer or someone else who acts or makes decisions on behalf of the person (see paragraphs 11.32–11.36).

Consulting carers

11.22 Once it has been established that a person lacks capacity to agree to participate, then before they are included in research the researcher must consult with specified people in accordance with section 32 of the Act to determine whether the person should be included in the research.

Who can researchers consult?

11.23 The researcher should as a matter of good practice take reasonable steps to identify someone to consult. That person (the consultee) must be involved in the person's care, interested in their welfare and must be willing to help. They must not be a professional or paid care worker. They will probably be a family member, but could be another person.

11.24 The researcher must take into account previous wishes and feelings that the person might have expressed about who they would, or would not, like involved in future decisions.

11.25 A person is not prevented from being consulted if they are an attorney authorised under a registered Lasting Power of Attorney or are a deputy appointed by the Court of Protection. But that person must not be acting in a professional or paid capacity (for example, person's solicitor).

11.26 Where there is no-one who meets the conditions mentioned at paragraphs 11.23 and 11.25, the researcher must nominate a person to be the consulted. In this situation, they must follow guidance from the Secretary of State for Health in England or the National Assembly for Wales (the guidance will be available from mid-2007). The person who is nominated must have no connection with the research project.

11.27 The researcher must provide the consultee with information about the research project and ask them:

- for advice about whether the person who lacks capacity should take part in the project, and
- what they think the person's feelings and wishes would be, if they had capacity to decide whether to take part.

11.28 Sometimes the consultee will say that the person 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 they should withdraw them from it. But if the project has started, and the person is getting treatment as part of the research, the researcher may decide that the person should not be withdrawn if the researcher reasonably believes that this would cause a significant risk to the person's health. The researcher may decide that the person should continue with the research while the risk exists. But they should stop any parts of the study that are not related to the risk to the person's health.

What other safeguards does the Act require?

11.29 Even when a consultee agrees that a person can take part in research, the researcher must still consider the person's wishes and feelings.

11.30 Researchers must not do anything the person who lacks capacity objects to. They must not do anything to go against any advance decision to refuse treatment or other statement the person has previously made expressing preferences about their care or treatment. They must assume that the person's interests in this matter are more important than those of science and society.

11.31 A researcher must withdraw someone from a project if:

- they indicate in any way that they want to be withdrawn from the project (for example, if they become upset or distressed), or
- any of the Act's requirements are no longer met.

What happens if urgent decisions are required during the research project?

11.32 Anyone responsible for caring for a person must give them urgent treatment if they need it. In some circumstances, it may not be possible to separate the research from the urgent treatment.

11.33 A research proposal should explain to the appropriate body how researchers will deal with urgent decisions which may occur during the project, when there may not be time to carry out the consultations required under the Act. For example, after a patient has arrived in intensive care, the doctor may want to chart the course of an injury by taking samples or measurements immediately and then taking further samples after some type of treatment to compare with the first set.

11.34 Special rules apply where a person who lacks capacity is getting, or about to get, urgent treatment and researchers want to include them in a research project. If in these circumstances a researcher thinks that it is necessary to take urgent action for the purposes of the research, and they think it is not practical to consult someone about it, the researcher can take that action if:

- they get agreement from a registered medical practitioner not involved with the research, or
- they follow a procedure that the appropriate body agreed to at approval stage.

11.35 The medical practitioner may have a connection to the person who lacks capacity (for example, they might be their doctor). But they must not be involved in the research project in any way. This is to avoid conflicts of interest.

11.36 This exception to the duty to consult only applies:

- for as long as the person needs urgent treatment, and
- when the researcher needs to take action urgently for research to be valid.

It is likely to be limited to research into procedures or treatments used in emergencies. It does not apply where the researcher simply wants to act quickly.

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What happens for research involving human tissue?

11.37 A person with capacity has to give their permission for someone to remove tissue from their body (for example, taking a biopsy (a sample) for diagnosis or removal of tissue in surgery). The Act allows the removal of tissue from the body of a person who lacks capacity, if it is in their best interests (see chapter 5).

11.38 People with capacity must also give permission for the storage or use of tissue for certain purposes, set out in the Human Tissue Act 2004, (for example, transplants and research). But there are situations in which permission is not required by law:

- research where the samples are anonymised and the research has ethical approval[52]
- clinical audit
- education or training relating to human health
- performance assessment
- public health monitoring, and
- quality assurance.

11.39 If an adult lacks capacity to consent, the Human Tissue Act 2004 says that tissue can be stored or used without seeking permission if the storage or use is:

- to get information relevant to the health of another individual (for example, before conducting a transplant), as long as the researcher or healthcare professional storing or using the human tissue believes they are doing it in the best interests of the person who lacks capacity to consent
- for a clinical trial approved and carried out under the Medicines for Human Use (Clinical Trials) Regulations 2004, or
- for intrusive research:
  - after the Mental Capacity Act comes into force
  - that meets the Act's requirements, and
  - that has ethical approval.

[52] Section 1(9) of the Human Tissue Act 2004

11.40 Tissue samples that were obtained before 31 August 2006 are existing holdings under the Human Tissue Act. Researchers can work with these tissues without seeking permission. But they will still need to get ethical approval. Guidance is available in the Human Tissue Authority Code of Practice on consent.[53]

What should happen to research that started before the Act came into force?

What if a person has capacity when research starts but loses capacity?

11.41 Some people with capacity will agree to take part in research but may then lose capacity before the end of the project. In this situation, researchers will be able to continue research as long as they comply with the conditions set out in the Mental Capacity Act 2005 (Loss of Capacity During Research Project) (England) Regulations 2007 or equivalent Welsh regulations.

The regulations only apply to tissue and data collected before the loss of capacity from a person who gave consent before 31 March 2008 to join a project that starts before 1 October 2007.

11.42 The regulations do not cover research involving direct intervention (for example, taking of further blood pressure readings) or the taking of further tissue after loss of capacity. Such research must comply with sections 30 to 33 of the Act to be lawful.

11.43 Where the regulations do apply, research can only continue if the project already has procedures to deal with people who lose capacity during the project. An appropriate body must have approved the procedures. The researcher must follow the procedures that have been approved.

11.44 The researcher must also:

- seek out the views of someone involved in the person's care or interested in their welfare and if a carer can't be found they must nominate a consultee (see paragraphs 11.22–11.28)
- respect advance decisions and expressed preferences, wishes or objections that the person has made in the past, and
- treat the person's interests as more important than those of science and society.

[53] www.hta.gov.uk

The appropriate body must be satisfied that the research project has reasonable arrangements to meet these requirements.

11.45 If at any time the researcher believes that procedures are no longer in place or the appropriate body no longer approves the research, they must stop research on the person immediately.

11.46 Where regulations do apply, research does not have to:

- be linked to an impairing condition of the person
- have the potential to benefit that person, or
- aim to provide knowledge relevant to others with the same or a similar condition.

What happens to existing projects that a person never had capacity to agree to?

11.47 There are no regulations for projects that:

- started before the Act comes into force, and
- a person never had the capacity to agree to.

Projects that already have ethical approval will need to obtain approval from an appropriate body under sections 30 and 31 of the Mental Capacity Act and to comply with the requirements of sections 32 and 33 of that Act by 1 October 2008. Research that does not have ethical approval must get approval from an appropriate body by 1 October 2007 to continue lawfully. This is the case in England and it is expected that similar arrangements will apply in Wales.