

MRC ETHICS GUIDE 2007

Medical research involving adults who cannot consent

A person unable—

- (a) to **understand** the information relevant to the decision,
- (b) to **retain** that information,
- (c) to **use** or weigh that information, the process of making his or her decision,
- (d) to **communicate** (using signs or other means).

A person unable—

(a) to understand the information relevant to the decision,

(b) to retain that information,

(c) to use or weigh that information in the process of making a decision (whether or not the person is unable to understand the information, retain that information, or use or weigh that information in the process of making a decision).

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I. Introduction

Medical research involving adults who lack mental capacity to consent can lead to innovations in healthcare that can substantially improve their health and quality of life and that of others with similar conditions. It is therefore important that these adults are given the opportunity to participate in such research. To exclude them from any research would be discriminatory and would diminish their ability to participate as fully as possible in society. It would also prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the care and treatment of those who have such disorders. However, such research requires special safeguards to ensure that this vulnerable group are protected when they do participate in medical research.

The law relating to the conduct of research when the potential participants lack capacity to consent has developed considerably over the past years. These changes provide welcome clarification of the legal framework within which such research can be carried out. Specific legislation has been introduced in Scotland¹ and England and Wales² relating to adults with mental incapacity (or who may become incapacitated). In Northern Ireland the recommendations of a review of mental health legislation are currently being considered. Further guidance for this region will be issued once available. Other instruments, such as the Clinical Trials Regulations 2004, the Human Tissue Act 2004³ and the Data Protection Act 1998, are also of relevance to research in this area.

This guidance aims to set out the general principles for assessing whether individuals have the capacity to consent to participation in research. It will also discuss participation in research projects when such capacity is lacking. The guidance does not deal with determining capacity in children, which is discussed in a separate MRC publication⁴. The emphasis of this publication is on the legislation relating to mental capacity, including explanation of this legislation. The greater emphasis than in previous MRC guidance⁵ on the legal requirements for such research reflects the altered legal framework.

It is hoped that this guidance will help scientists to ensure that research involving people who lack mental capacity is conducted in a legally and ethically acceptable manner. It is also intended to give confidence to researchers that adults with incapacity can be included in their studies so that, when appropriate, they will make the opportunity available, in accordance with the required and recommended safeguards described here.

¹ *Adults with Incapacity Act 2000.*

² *Mental Capacity Act 2005.*

³ *Medicines for Human Use (Clinical Trials) Regulations 2004. SI 2004 1031 (as amended).*

⁴ *MRC Ethics Guide: Research involving children, 2004.*

⁵ *The Ethical Conduct of Research in the Mentally Incapacitated. MRC 1991.*

2. Ethical principles

2.1 General principles

As with any research, the need to respect the interests of an individual participant is more important than any potential benefits of the research to others^{6,7}.

All medical research studies, including those involving adults who lack mental capacity, should comply with accepted principles of good practice, including the Declaration of Helsinki and relevant European and UK legislation. In accordance with section 13 of the Declaration, the research protocol should be submitted to and approved by an independent research ethics committee (REC). Under UK legislation relating to research involving adults who lack the capacity to consent, this REC approval is a legal requirement⁸. Detailed guidance on applying for approval is available from the National Research Ethics Service⁹.

2.2 Specific principles

Individuals unable to consent to participation in a research project due to a lack of mental capacity are a particularly vulnerable group. Their interests must therefore be protected. They should be given the same opportunities to participate in ethically designed research projects as those who do not lack capacity but must not be put at unwarranted risk. Their participation needs to be agreed by someone who is independent of the study and who can assess the potential participant's interests in accordance with current legislation and guidance. This person may be a relative, a carer or an independent representative.

⁶Declaration of Helsinki, 2000: www.wma.net/e/policy/b3.htm.

⁷Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine Oviedo, 4.IV.1997 Chapter 1 article 2.

⁸Excluding, at present, Northern Ireland.

⁹National Research Ethics Service: www.nres.npsa.nhs.uk/applicants/help/guidance.htm#awi.

If possible, the proposed study should also be discussed or communicated with the person themselves in a way appropriate to their understanding. In an emergency setting, consultation with the representative or participant may not be immediately possible but should occur as soon as practical. (There is more information about emergency situations in section 4.3).

Someone who lacks the mental capacity to consent to take part in research should not take part in a study if he or she does not seem in agreement with any intervention or part of the study, even if agreement has been given by another person. If this happens, researchers are expected to inform the individual's independent representative that the individual will not be taking part despite the representative's agreement, and tell them the reasons for this decision.

The risks and benefits of participation in any research must always be weighed up so that potential direct benefits outweigh any risks. Any potential risks must be minimised through the study design. If no direct benefit is anticipated the risks must be negligible (see Table 1).

Table 1: Key principles when considering the participation of adults who lack capacity in research

- The interests of the individual must always outweigh those of science and society.
- The research must relate to a condition or impairment that affects the individual or the treatment of this condition¹⁰.
- It must not be possible to conduct equally effective research with adults who have the capacity to consent.
- The potential benefits of the project should outweigh the risks: the level of acceptable risk depends partly on the possible benefit to the individual.
- Views of those close to the participant should always be sought, unless this is not possible due to particular circumstances.
- A participant who lacks capacity should only be included in a study when there are no indications that he or she objects to this.

¹⁰Under the Mental Capacity Act and Adults with Incapacity (Scotland) Act, this condition or impairment must relate to the reason for incapacity. Under the Clinical Trials Regulations this is not specified.

2.3 Risks and benefits

Acceptable level of risk

The extent to which the likely benefit of a research project affects the acceptable level of risk has been widely discussed. This debate is reflected in changes to the wording of the statutes in relation to the acceptable level of risk:

- *Adults with Incapacity (Scotland) Act*: In relation to the level of acceptable risk, the Scottish Act does not differentiate between research that may potentially benefit participants and that which will not. Both must impose, at most, minimal foreseeable risk and minimal discomfort.
- *Mental Capacity Act*: If research has the potential to benefit participants, the burdens imposed should not be disproportionate to that benefit. If there is no potential benefit then the risks to the patient should be 'negligible'. The Code of Practice interprets 'negligible' as equivalent to 'minimal'.
- *Clinical Trials Regulations*: The trial should be expected to offer a benefit that outweighs the risks of participation or involve 'no risks at all'.

In summary, although these various instruments differ slightly in their interpretation of acceptable risks, it is clear that any risks involved in a research project should, at most, be proportionate to any expected direct benefit. If no benefits for participants are anticipated, risks should be at a minimal or negligible level.

Minimal risk has been defined by the Council of Europe¹¹ as a risk that "will result, at the most, in a very slight and temporary negative impact on the health of the person concerned". The Council defines minimal burden on participants as that where it is "to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned."¹²

Assessment of risk has been described in MRC guidance relating to medical research involving children¹³, which divides risk into minimal, low or high. Examples of minimal risk procedures include¹⁴:

- Observing and measuring, provided this is done in a sensitive way and with respect for the participant's autonomy and privacy.
- Obtaining samples in a non-invasive manner, for example, urine collection.

¹¹ Additional protocol to the convention on human rights and biomedicine, concerning biomedical research. Council of Europe at article 17 (2). <http://conventions.coe.int/Treaty/en/Treaties/Htm/195.htm>.

¹² Above article 17 (1).

¹³ MRC Ethics Guide: Medical research involving children 2004.

¹⁴ www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430.

¹⁴ MRC children guidance adapted from the Royal College of Paediatrics and Child Health. Guidelines for the ethical conduct of medical research involving children 2002.

Potential benefits of participation

The statutes discussed here distinguish between research projects which may directly benefit participants and those which will not. This reflects a previous division of research projects into 'therapeutic' and 'non-therapeutic' – a distinction which has been widely criticised¹⁵.

Estimating the potential for direct benefit is an important part of weighing up the risks and benefits of taking part in a research project. There may be occasions, however, when it is difficult to determine the potential for benefit to the individual. This may occur, for example, if clinicians are divided in their views of a particular therapy or are in equipoise – such as when a randomised controlled trial is considered appropriate.

It is up to a REC to decide whether the risks associated with a research project are acceptable in relation to the expected benefits. A careful assessment of this should therefore be provided by the researchers. (See Example A).

Example A: assessment of risks and benefits

The Blandfordshire REC was asked to review a proposal to study whether electronic tagging was beneficial to the care of older people with varying degrees of dementia who lived in residential homes. The hypothesis was that the tagging would allow the residents more freedom while minimising their risk of getting lost. There was some discussion about whether the tagging was an invasion of privacy when the individuals concerned were unable to provide informed consent. However, the results of an independent consultation, commissioned by the researchers, of relatives and carers suggested that the benefits to the residents were perceived to outweigh this concern. The tagging device was very small and not noticeable when worn. When the project was reviewed by the REC, it was questioned whether the radiofrequencies used constituted a health hazard in this age group. A decision on whether the study might go ahead was deferred until the researchers provided an updated analysis of the literature on this issue, in light of new scientific evidence. This analysis suggested that the radiofrequency risk was similar to that of mobile telephones. The REC decided that this was equivalent to a risk encountered in normal daily life and approved the study.

¹⁵Royal College of Psychiatrists: www.rcpsych.ac.uk/publications/cr/council/cr821.pdf 3.4.
British Medical Association: www.bma.org.uk/ap.nsf/Content/consenttk2~10.

3. Key concepts

3.1 Capacity/competence

A person is assumed to have the mental capacity to make a decision unless it is shown to be absent. This is a fundamental principle. Mental capacity is considered to be lacking if, in a specific circumstance, a person is unable to make a decision for him or herself because of an impairment or a disturbance in the functioning of their mind or brain¹⁶. In designing a study, researchers should consider whether it is likely that some or all participants could lack or could lose their capacity to consent to take part. In this case the information provided to potential participants should include options for their continued participation if they should lose capacity.

Table 2: Defining incapacity – from the adults with Incapacity (Scotland) Act

'Incapable' means unable to:

- act; or
- make decisions; or
- communicate decisions; or
- understand decisions; or
- retain the memory of decisions

by reason of mental disorder or of inability to communicate because of physical disability.

It should be noted that:

- Capacity is specific to the matter in question and so a person could have mental capacity in relation to some matters but not to others.
- Capacity can also vary in time, for example, in a patient who is temporarily unconscious or who has suffered a relapse in their psychiatric condition.
- Capacity is present if the person only has a difficulty with communication that can be overcome with human or mechanical assistance.

¹⁶Section 2 Mental Capacity Act 2005: "A person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of or a disturbance in the functioning of the mind or brain."

Assessment of mental capacity

The Mental Capacity Act (MCA) 2005 and its associated Code of Practice¹⁷ set out criteria for assessment of mental capacity. They build upon principles previously used in the courts¹⁸ and set out by bodies such as the General Medical Council¹⁹ and the British Medical Association²⁰. Assessment of mental capacity is described in the MCA as a two-stage process. First, the person must be shown to have an impairment or disturbance of brain functioning and, second, it must be shown that this renders them unable to make a particular decision.

In general, researchers must ask potential participants for consent to take part in a study²¹. In doing so they must consider whether the person approached has the capacity to make this judgement. In some cases the researcher may have the necessary expertise to make this decision, but often they will need to seek an opinion from the clinical team caring for the potential participant. There are several factors to be considered when deciding whether a person lacks the mental capacity to provide consent to participate in research. These are outlined in Table 3.

If a researcher or clinician is uncertain as to whether a person has the mental capacity to consent to participation in research or does not have the skills to assess this, an independent assessment should be carried out. If doubt remains or there are differences of opinion, for example, between clinical staff and relatives or carers, a court could make a ruling on this. However, it is unlikely that such steps would be taken: if such uncertainty exists it may be better not to include the patient in the study. On the other hand, when an adult does have the ability to make a decision or to indicate willingness to participate in a study for which they are eligible, this willingness should be respected as far as is practical in accordance with legal requirements. See Example B (page 12).

¹⁷ MCA Code of Practice issued on 23 April 2007: www.dh.gov.uk/mentalcapacityact.

¹⁸ *Re C adult: refusal of medical treatment* [1994] 1 All ER 819.

¹⁹ General Medical Council: Consent at www.gmc-uk.org/guidance/library/consent.asp.

²⁰ Assessment of mental capacity: BMA/Law Society Guidance. 2nd ed 2004.

²¹ MCA Code of Practice section 11.7 summarises these for England.

²² MRC Code of Practice at 11.4.

Table 3: How to decide whether an individual lacks the mental capacity to consent to research participation (based on MCA Code of Practice)

Researchers should assume capacity is present unless it is shown to be absent.²²

Capacity is absent if, at the time of decision making:

- The person in question has impaired functioning of their mind or brain.
- This impairment makes the person unable to decide whether to participate in this particular research.

A person is deemed unable to decide whether to take part in research if they cannot²³:

- **Understand** the information relevant to the decision (information should be given in a way that is appropriate to the particular person, this might include use of simplified information sheets, pictures or sign language).
- **Retain** that information for long enough to make the decision (this may be for a relatively short time, but still long enough to enable decision making to occur).
- **Use** or **weigh** that information as part of the process of making the decision (they need to understand the consequences of each option and of not making the decision).
- **Communicate** their decision (whether by talking, using sign language or any other means).

²²MCA Code of Practice at 11.4.

²³Section 3 MCA 2005.

Example B: assessment of capacity

Mr B had taken early retirement from his career as head teacher of a large school following the diagnosis of Pick's disease. His condition meant that he had problems with language. He often misunderstood what was said to him and he had trouble putting sentences together. This made him anxious and frustrated. However, his memory remained intact. The researchers wanted to track the progress of this form of disease to assess whether there were benefits from treatment with a new antidepressant. In their ethics application they had stated that they would *only include adults with capacity to consent* in this initial study. In seeking consent from Mr B, it was necessary to explain that the treatment might alleviate the anxiety he was feeling, but could not fundamentally alter the course of the disease.

However, when talking to Mr B the researchers found that while he readily *retained* the information presented to him, he did not seem to *understand* that he would be a participant in a research study or that the treatment would be for symptoms only. The consultant neurologist leading the study decided that it would be more appropriate for Mr B to be treated by his clinical team rather than taking part in a research study, pending the outcome of studies in participants with less advanced Pick's disease who did have the capacity to consent.

- The principal investigator decided that Mr B lacked capacity to make this decision.
- The protocol submitted to the research ethics committee (REC) was for inclusion of adults who had capacity to consent only.
- Mr B could be suitable for a different research study. As capacity is decision specific, his capacity to make a decision in relation to a future study would need to be reassessed.
- If he lacked capacity in relation to making a decision to participate in another study, his participation would be subject to the steps of the relevant legislation being followed.

3.2 Consent

When seeking consent, researchers should consider how to present the information about the study to each individual with respect to their lifestyle, interests, needs, religious beliefs and priorities²⁴. If someone is unable to provide consent for themselves due to a lack of mental capacity, the next step to consider is

²⁴General Medical Council guidance

whether the legal requirements and safeguards can be met if they are included without their own consent (for example, under section 30 of the MCA). Alternatively the researchers should consider not including the person in question in the research.

Example C: materials for consent

A team of researchers was carrying out a series of studies comparing the benefits of different types of physiotherapy for people with serious physical restrictions following a severe stroke. They began with the assumption that all potential recruits would have the capacity to consent. The first step was to talk with each person to establish their mental capacity, irrespective of physical disability, using picture cards to help show what the intervention involved. Among those they approached was Mrs C, who was only able to communicate by nodding her head slightly and through her facial expression. She seemed able to understand that the physiotherapy would benefit her and to indicate that she would like it. To check that she could retain the information they gave her, the researchers returned to discuss the project on a separate occasion and she responded in the same way. The researchers determined that she had capacity and discussed this with her GP who agreed. The reasons for believing she had capacity were documented in the study records.

Mrs C's daughter was her main carer. Using the same methods the researcher obtained Mrs C's agreement to discuss the study with her daughter.

3.2.1 Giving consent on behalf of an adult who lacks capacity

There are varying interpretations of the meaning of consent by others for an adult who cannot give their own consent to participate in a research study. The laws and regulations relating to medical research involving adults who lack capacity to consent do not use the 'best interests' test. Instead they set out the necessary criteria for the research to be legal and allow for varying degrees of consent by others. In relation to all clinical trials throughout the UK (and all types of medical research in Scotland), consent to the participation of an adult lacking capacity is given by the legal representative or relative of the participant (the hierarchy for this is described further below). The Clinical Trials (CT) Regulations described below specify that this consent by a legal representative represents the presumed will of the participant²⁵. For research outside Scotland not covered by the CT Regulations, the person consulted gives agreement rather than consent (see Table 4).

²⁵Medicines for Human Use (Clinical Trial) Regulations SI 2004 no. 103sch 3 part 5 (12).

Table 4

Type of study	Who should be asked	What should they be asked	What is given?
Clinical trial in England, Wales and Northern Ireland	Legal representative: <i>1. Relative or person independent of trial and providing care or 2. Doctor primarily responsible for adult's treatment, or another independent person nominated by healthcare provider</i>	Presumed will of participant	Informed consent
Clinical trial in Scotland	Legal representative: <i>1. Guardian or welfare attorney authorised to take decisions re research or 2. Nearest relative or 3. Doctor primarily responsible for adult's treatment, or another independent person nominated by healthcare provider</i>	Presumed will of participant	Informed consent
Research which is not a clinical trial (England and Wales)	Carer or consultee <i>1. Unpaid person with an interest in the welfare of the potential participant or 2. Person who is independent of project</i>	Opinion on views and feelings of participant	Advice as to whether participant would decline to take part if he or she had capacity
Research which is not a clinical trial (Scotland)	<i>1. Guardian or welfare attorney authorised to take decisions about the research or 2. Nearest relative</i>	Their consent	Consent

Note: Emergency recruitment to research projects has separate requirements which are summarised in section 4.3.

3.2.2 Loss of capacity during the course of the research

(See separate guidance for transitional arrangements for studies already underway in England and Wales on 1 October 2007.)

1. Clinical Trials Regulations:

In a clinical trial (as defined by the CT Regulations – see more details in section 4.1), consent from an adult to participate in a trial remains valid after loss of capacity, providing the trial is not significantly altered. It is good practice in such a case to consult with carers and take note of any signs of objection or distress from the participant. The investigator should consider withdrawing a participant if any objections are raised.

2. Mental Capacity Act:

1. Where it is known that a participant has lost capacity following agreement to take part in a study and further consent is required from all participants, for example for further blood sample collection, researchers should comply with the requirements of the MCA.

2. For participants who gave consent before 31 March 2008 to take part in a study that began before October 2007, there are specific regulations under the MCA detailing the steps to be taken if a participant is subsequently known to have lost capacity²⁶.

3. For participants and studies that do not fall under guidance for the above dates, the MCA does not specify what steps should be taken if capacity is lost following consent to participate in a study. If no further interventions are required in the study and researchers wish to keep using data or tissues, it is open to interpretation as to whether further consent is required. Current guidance from the Department of Health, England (DH) and the Welsh Assembly Government is that in this situation ‘properly informed and expressed consent’²⁷ given prior to loss of capacity can be relied upon. In the absence of such consent, DH and Welsh Assembly Government guidance says that the requirements of the MCA must be fulfilled. This includes obtaining agreement from a personal or professional consultee for continued use of data or tissues in the study, as well as obtaining REC approval for this.

²⁶Please see separate guidance from the MRC on these transitional arrangements.

²⁷Mental Capacity Act and consent for research, Department of Health (England) and Welsh Assembly Government 2007.

If an individual has made a decision to participate in research and subsequently loses capacity, it is expected that this consent would be respected in most circumstances and so use of samples or data could continue. Procedures should be in place in any study to ensure that, where necessary, participants can withdraw or be withdrawn from the study at any time. If the participant loses capacity, a request by a representative for withdrawal from a study should be considered carefully to ensure that it reflects the wishes of a participant before loss of capacity, their current situation and any potential benefits or harm that could arise from continued participation in the research study.

When designing studies, researchers should consider the risk of participants losing capacity during the course of a study and, where appropriate, should discuss this possibility with them. The consent form should include an option to consent to remain in the study in the event of incapacity. This consent would not be 'absolute', as continued participation will depend upon individual circumstances.

The participant may continue to receive a treatment received during the research if withdrawal would create a significant risk to their health.

3. Adults with Incapacity (Scotland) Act:

The Act does not refer to loss of capacity during a research study. It will be up to researchers and the REC to decide whether procedures need to be in place for such an eventuality. The MRC advises that the principles described above should be followed when considering existing consent and the potential for withdrawal from a study.

4. Human Tissue Act 2004:

The Act and its associated regulations²⁸ state that storage and use of human tissue for research must be done in accordance with the provisions of the MCA, unless the adult consented before losing capacity. In Northern Ireland approval is required from an REC to store and use tissue from adults who lack capacity to consent.

Example D illustrates some of the issues that may arise when a person loses capacity during the course of research.

²⁸Human Tissue Act 2004 (Persons who lack capacity to consent) Regulations 2006 at 3c and d and Human Tissue Act 2004 at s6.

Example D: consent for new samples in long-term study

Mr D had enrolled in a long-term, REC-approved, population study of people at risk of dementia 20 years previously. Aware of the devastating effects of the disease, he wanted to help find out more about it to help expand the options for future treatment and care. Mr D went on to develop Alzheimer's in his late 60s and was now in an advanced stage of dementia. When signing up for the study, he had given consent to re-assessment at yearly intervals throughout his life and indicated that he would wish this to continue in the event that he lost capacity. He also consented to continued use of his data in the study in the event that he lost capacity or was withdrawn from the study. This meant that the researchers were able to continue to monitor him.

For a long time, he had seemed perfectly happy with this arrangement and this was confirmed when the researchers checked annually with his carers. However when an important new test became available that would involve taking further blood samples from the entire study population it became necessary to ask each participant for their specific consent to the alteration in sampling practice. Although the researchers would have liked to keep Mr D in the study, he was no longer able to consent for himself and his prior wishes were unknown. Furthermore, his carers informed the researchers that he had recently been hospitalised with an infection and had subsequently developed a marked fear of needles.

The researchers agreed with the family that Mr D should not be included in the next round of sampling as the outcome of the research would not be of any direct benefit to his own health. In addition, his present condition meant that he may have found the taking of blood samples distressing: this was deemed an unacceptable risk.

However, the family agreed that the data and samples already collected could continue to be used in the study, in accordance with Mr D's previously expressed wishes.

4. Legal requirements for research

4.1 Legislation relevant to medical research

The law in the UK now makes a distinction between two types of research involving people. These are (i) clinical trials of medicinal products and (ii) other research involving people. In relation to capacity, these studies are governed by three separate pieces of legislation. Clinical trials of medicinal products are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004 (CT Regulations) while other research is governed by the Adults With Incapacity (Scotland) Act 2000 (AWIS) or the Mental Capacity Act 2005 (MCA). The CT Regulations implement a European Directive and apply to all of the UK. The AWIS applies only to Scotland and the MCA applies only to England and Wales.

To ensure that research is conducted lawfully researchers must first determine into which category their proposed research falls. It is important to note that the legal definition of a 'clinical trial' (i.e. a study which falls under the CT Regulations) is tightly defined, whereas in wider usage the term can sometimes refer to other types of study. See Example E.

I. Clinical trials of medicinal products: These are regulated by the CT Regulations and defined as "interventional investigations or studies undertaken to ascertain the efficacy or safety of a medicinal product in human subjects"²⁹. The CT Regulations contain requirements that apply if adults who lack capacity are to be included in such research. Further guidance on the regulation of clinical trials and how to determine if a study falls into this category is available at www.ct-toolkit.ac.uk. The Medicines and Healthcare products Regulatory Agency (MHRA) can provide advice on an individual basis about whether a proposed trial is covered by the CT Regulations. In addition, an algorithm to help decide whether research is a clinical trial of a medicinal product is available at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/04_2006/clinical_trial_qa_april_2006.pdf.

²⁹ Medicinal products are defined by the MHRA as "substances or combinations of substances which either prevent or treat disease in human beings or are administered to human beings with a view to making a medical diagnosis or to restore, correct or modify physiological functions in humans."

A clinical trial is defined by the MHRA as "an investigation in human subjects which is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, identify any adverse reactions or study the absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products." This definition includes pharmacokinetic studies.
www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=723.

Example E: clinical trial governed by the MCA or CT Regulations

Researchers in an English teaching hospital aim to compare two different neurosurgical techniques for treating severe sub-arachnoid haemorrhage. Many of the potential participants will lack capacity to consent due to the effects of the haemorrhage.

This will not be a clinical trial of a medicinal product and so would fall under the MCA.

The same unit also wishes to perform a study comparing the effects of a new anti-fibrinolytic drug on outcome after sub-arachnoid haemorrhage.

This research is a clinical trial of a medicinal product.

2. All other ‘intrusive’ research in England and Wales involving adults who lack mental capacity to consent falls under the MCA, which contains specific requirements for the conduct of such research. Intrusive research in this context is described as that where: “if a person taking part had capacity, the researcher would need to get consent to involve them”³⁰. It specifically excludes research that falls under the CT Regulations.

3. Research in Scotland is governed by the AWIS. This contains requirements for “surgical, medical, nursing, dental or psychological research”³¹. The Act gives specific requirements which are broadly similar to the MCA but have some differences in their detail. Section 4.2.3 below summarises the position in Scotland.

4. Table 5 summarises the legislation relevant to research involving people in different parts of the UK.

³⁰ MCA Code of Practice at 11.6.

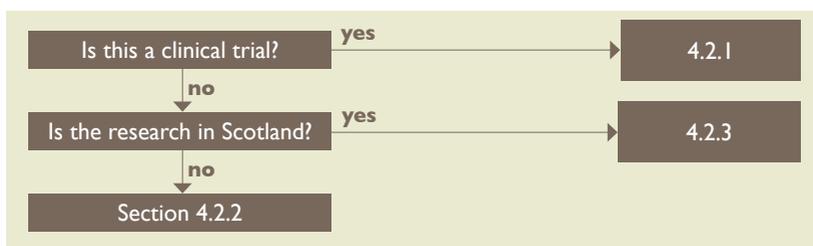
³¹ AWIS 2000 at 51(3).

Table 5: Summary of relevant legislation

	England and Wales	Scotland	Northern Ireland
The Medicines for Human Use (Clinical Trials) Regulations 2004 (CT Regulations)	yes	yes	yes
Adults With Incapacity (Scotland) 2000 (AWIS)	no	yes	no
Mental Capacity Act 2005 (MCA)	yes	no	under review
Human Tissue Act 2004	yes	mostly no ³²	yes
Human Tissue (Scotland) Act 2006	no	yes	no
Data Protection Act 1998	yes	yes	yes
Human Fertilisation and Embryology Act 1990 ³³	yes	yes	yes

4.2. Requirements for research

This section summarises the requirements of the different laws and regulations that apply to research involving adults who lack capacity to consent. In italics are points of good practice that are additional to the legal requirements. In order to refer to the correct section, the key questions are:



³² Of relevance, section (45) of the Human Tissue Act relating to DNA analysis also applies in Scotland. For further guidance on the use of human tissue in research, please refer to separate MRC publications.

³³ At the time of publication in October 2007, a draft Bill amending this Act was being prepared.

4.2.1 Clinical trials (all of the UK)

Clinical trials that fall under the CT Regulations are defined above (section 4.1): In order to comply with the CT Regulations, a trial must be approved by a recognised research ethics committee (REC) and licensed by the MHRA. All clinical trials must comply with the Good Clinical Practice (GCP) guidelines issued by the International Conference on Harmonisation. In relation to adults who lack mental capacity to consent, the GCP guidelines have specific requirements that must be met. These are summarised here. Please note that there are separate requirements for research in emergency situations, which is discussed in section 4.3.

Trial design

- A clinical trial must relate directly to a life-threatening or debilitating clinical condition from which a potential participant suffers. (Note that this differs from the requirements for other types of research, which must be relevant to the condition or impairment causing the loss of capacity.) See Example F.

Example F: clinical trials that relate directly to a participant's condition

1. Researchers have designed a trial studying adults with head injury and impaired consciousness. They wish to assess the effects of a 48-hour infusion of corticosteroids on survival and neurological disability.

This trial relates directly to the cause of the impaired consciousness in this group of patients.

2. A trial is underway comparing the efficacy of two different dietary plans on blood glucose control in late-onset diabetes. Mrs F has advanced dementia and diabetes. Her family have read about the trial and request that she be included. The researchers consult the REC as to whether they could approve an amendment to the protocol to allow incapacitated adults to be included.

In this case the study (which is not a clinical trial of a medicinal product) does not relate to the cause of the impairment of Mrs F's capacity – which is dementia.

It would therefore not be possible for the REC to approve this amendment.

However, if it were a clinical trial comparing oral and subcutaneous insulin Mrs F's participation could be approved. This is because the study would then be a clinical trial of a medicinal product and would relate directly to a condition – diabetes – from which Mrs F suffers.

- There must be grounds to expect that administering the medicinal product to be tested in the trial will produce a benefit to the participant that outweighs the risks (or will result in no risk at all).
- The clinical trial is essential to validate data obtained:
 - in other clinical trials involving participants who are able to give informed consent, or
 - by other research methods.
- No incentives or financial inducements may be given to a participant or their legal representative, except provision for compensation in the event of injury or loss³⁴.

Consent by legal representative

- Consent by a legal representative is required if consent to participate was *not* given prior to the loss of capacity.
- If the proposed study participant refused consent to participate before the loss of capacity, he or she cannot be included in the trial.
- In England, Wales and Northern Ireland the legal representative is:
 - A person independent of the trial, who by virtue of their relationship with the potential study participant is suitable to act as their legal representative for the purposes of that trial, and who is available and willing to so act for those purposes.
Or if there is no such person:
 - A person independent of the trial, who is the doctor primarily responsible for the medical treatment provided to that adult.
 - Or a person nominated by the relevant healthcare provider.
- In Scotland the legal representative is:
 - The guardian or welfare attorney (this is a person appointed to deal with matters of personal welfare by an individual prior to his or her loss of capacity).
Or, if one has not been appointed:
 - The nearest relative.

³⁴ MRC policy is that, as in other research, payment of legitimate expenses of participants or representatives directly related to participation in the trial is generally considered acceptable.

Or, if that person is not available:

- The doctor responsible for the medical treatment of the patient if they are independent of the study, or a person nominated by the healthcare provider.

- The legal representative should have an interview with a member of the investigating team, during which the following should be discussed or made available to them:
 - Objectives, risks and inconveniences of the trial and the conditions under which it is to be carried out.
 - Contact details for further information.
 - Their right to withdraw the participant from the trial at any time without detriment.

- After such discussions, the legal representative may give their ‘informed consent’ for the person to participate in the clinical trial. In relation to clinical trials, this consent is taken by the CT Regulations to represent the ‘presumed will’ of the participant.

Views of the participant

- The potential participant should receive information about the trial and its risks and benefits according to his or her capacity to understand this information.

- If the person in question is capable of assessing the information referred to above and forming an opinion about it, then an explicit wish to refuse participation or to withdraw from the clinical trial at any time must be given serious consideration by the investigator.

- Although the law requires only ‘consideration’, it is good practice to comply with any such request. The only exception would be if not participating or withdrawing from the trial would be detrimental to the participant’s health. In this situation, researchers should also consider whether the objection is short-term or relating to factors that could be altered, such as the research environment. Researchers should discuss a decision to keep a participant in a study in this situation with the clinical team caring for the participant and with their legal representative.

4.2.2 Other research (England and Wales)

In the UK excluding Scotland, ‘intrusive research’ that does not involve a clinical trial is governed by the MCA, which has specific requirements for such research (see Table 6).

Table 6: When does the Mental Capacity Act 2005 apply?

It applies to:

‘Intrusive research’, that is, any research project that would require consent from adults who have capacity as a matter of law.

But does not apply to:

- Research that falls under the CT Regulations (see section 4.1).
- Research carried out in Scotland (see section 4.2.3) or Northern Ireland (see section 4.2.4).

Requirements of the MCA

The requirements of this Act are discussed in its accompanying Code of Practice³⁵. In order to comply with the MCA, the following requirements must be met by researchers:

1. REC approval (by a recognised committee).
2. Consulting relatives/carers/others.
3. Safeguards to protect participants.

1. Ethical approval for the project or study

There are several questions set out in the MCA that must be considered before ethical approval can be granted. Researchers should ensure that they address these in their application for REC approval. The REC must be recognised by the Department of Health (England) or the Welsh Ministers for the purpose of approving research that falls under the Act. At the time of publication, all such committees are part of the National Health Service REC system – further guidance on recognised committees can be obtained from the National Research Ethics Service (NRES)³⁶.

- *Is the research study related to the impairing condition or its treatment?*

As discussed in section 3.1, an adult deemed to lack capacity to consent to take part in a research study must have impaired or disturbed functioning of their mind or brain. To be approved, the proposed research *must be connected with a condition which may cause, contribute to or result from this impairment of function of the mind or brain or its treatment*. This means that participation cannot be approved if the condition being investigated by the study is completely unrelated to the reason for mental incapacity. The link between the study and the reason for the potential participant’s lack of capacity should be explained in the application for ethical approval.

³⁵MRC policy is that, as in other research, payment of legitimate expenses of participants or representatives directly related to participation in the trial is generally considered acceptable.

³⁶National Research Ethics Service: www.nres.npsa.nhs.uk

- *Could the study be done involving only adults with capacity to consent?*

Researchers should enrol participants who lack the capacity to consent to take part only if there is reason to believe that the study could not be done as effectively if it involved only adults who could give consent. This is illustrated in Example G below.

Example G: studies where it is not necessary to include adults who lack capacity to consent

Researchers wish to assess changes in blood levels of immune factors following insertion of an invasive monitoring device into an artery. The team are based in intensive care and so they are seeking REC approval to include in the study unconscious patients in the intensive care unit who will frequently require such venous access. However, the scientists consider that these patients will not be able to consent to take part in the study. They therefore decide to instead enrol patients who require the placement of such lines before elective surgery and from whom consent could be sought. *This study is related to treatment for the condition causing the impairment of capacity, but it could be done as effectively in patients who are able to consent to participation.*

- *Does the study have the potential to benefit the participant?*

If so, then the expected burden of taking part in the research should be proportionate to the possible benefits. Researchers should consider what will be required of participants, including any possible discomfort, restriction of mobility or use of their data or tissue. This should be weighed against the potential for the study to be of direct benefit to those taking part. Potential benefits are discussed further in the MCA Code of Practice³⁷.

- *Is there unlikely to be any benefit to the participant?*

If so, the research must fulfil *all* of the following objectives:

- It must be investigating the cause, treatment or care of people with similar conditions.
- The risks of the project must be 'negligible' (see the discussion in section 2.2 on levels of risks).
- The project must not significantly interfere with freedom of action or privacy.
- The project must not be unduly invasive or restrictive.

³⁷MCA Code of Practice 2005 at 11.14.

The MCA Code of Practice states that “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”³⁸.

2. Consulting carers or others

The MCA stipulates that before any decision is taken to involve a particular person in research with REC approval, researchers must identify a ‘consultee’ who is willing to be consulted about the person’s participation. There are two possible types of consultee:

1. If available, the researchers must consult a ‘personal consultee’. This is someone who cares for the potential participant or is interested in his or her welfare other than in a professional capacity or because they are paid to do so. The researcher must take reasonable steps to identify such a person.
2. If a personal consultee is not available, the researcher must consult a ‘nominated consultee’. This person must have no connection with the project. Researchers must include in the protocol submitted to the REC the arrangements for identifying and consulting with this person. In emergency circumstances, a consultee does not need to be consulted prior to enrolment in the study. The conditions under which this can happen are clearly defined – see section 4.3.

Difficulty in finding a *personal consultee* may arise if the person most appropriate to be consulted is a *paid* carer. This could occur, for example, if the potential participant had no relatives or only distant relatives. The MCA specifically requires that the person consulted is not paid for the care he or she provides to the potential participant. The consultee may hold power of attorney³⁹ for the patient or be a court-appointed deputy, so long as this is in a personal (not professional or paid) capacity – for instance, a participant’s solicitor would be excluded from being a personal consultee.

The MRC recommends that it is good practice to involve any paid carers who are close to the participant in the decision-making process – even if the decision has to be taken by an independent nominee.

It is important that personal nominees appreciate that this is a voluntary role and that they are not under any pressure to agree to fill this position if they do not wish to do so. This should be made clear by the researchers.

³⁸ MCA Code of Practice at 11.19.

³⁹ The MCA 2005 allows an adult to assign power of attorney to another person prior to loss of capacity; the power assigned may extend to financial affairs and/or personal welfare.

Regarding a *nominated consultee*, the MCA Code of Practice has a wide interpretation of what ‘connected to the project’ means. It could exclude anyone connected with the actual project, members of the research team or anyone with a wider connection, for instance people with a direct link to the funding body or the ethics committee that approved the project. Further guidance is available from the Department of Health (England)⁴⁰ and the Welsh Assembly Government⁴¹ as to how this person should be chosen.

In practice, a person should be identified who can understand the project and take a view, as described in Table 7, on the intended participation. This may be, for example, another clinician or healthcare worker in the unit where the research is being undertaken (who is not connected with the research project). It need not be restricted to one person for each project but may be more appropriate to have several people available to give advice. Researchers should set out in the protocol and ethical approval application who they propose to consult in this category in the event that a suitable carer is not available.

Table 7: Consultees: information requirements

The consultee should be given the following information about the study:

- Why they are being approached.
- The role of a consultee.
- Explanation that acting as a consultee is completely voluntary.
- Details of the study (as would be given to a participant with capacity).

The consultee should provide the following information:

- Advice on whether the participant should take part in the study.
- What, in their opinion, the participant’s views and feelings would have been on taking part in the project had they retained capacity.

If the consultee advises that the person in question would not have wanted to take part in the project, that person must not be recruited. Similarly, the participant must be withdrawn from the project if at any time the consultee is of the opinion that the participant would not have wished to continue. An exception can be made if the participant is receiving treatment as part of the project and the researcher has reasonable grounds to think that withdrawal of this treatment would cause a significant risk to their health. To apply this exception, the researcher needs to give good reasons for the treatment to continue. Discussion with the medical team and the representative of the patient will be essential.

⁴⁰Department of Health (England): www.dh.gov.uk

⁴¹Welsh Assembly Government: www.wales.gov.uk/index.htm.

3. Safeguards to protect the interests of patients

Once a participant is enrolled in a study, several measures must be taken to ensure protection of the participant's interests:

- Nothing should be done which the participant seems to object to (unless it is to protect them from harm).
- Nothing should be done which would be contrary to an advance directive or any other statement by the participant. *This only applies if the researcher is aware of such an expression of wishes. Researchers should find out from relatives and carers what the participant's views were on relevant issues prior to loss of capacity. They should specifically ask whether any relevant advance directives or expressions of wish are available and, if so, keep a record of them.*
- The interests of the participant must always outweigh those of science and society.
- The researcher must withdraw the participant if any of the conditions for his or her inclusion in the research project no longer apply.
- The participant should be withdrawn from the study if he or she gives any indication of not wanting to continue to take part (unless the project involves treatment and it is considered that continuation of this is in the patient's best interests).

Research involving human tissue samples

Research (outside Scotland) using human tissue must comply with the Human Tissue Act 2004. This generally requires consent for the use of tissue for research, subject to certain exemptions. The law allows adults without capacity to be included in such research, providing that the research is conducted in accordance with the CT Regulations or MCA as discussed in section 4.1.

4.2.3 Other research (Scotland)

In Scotland, research that does not fall under the CT Regulations is governed by the Adults with Incapacity (Scotland) Act 2000 (AWIS). The Act regulates the involvement of incapacitated adults in research⁴². It has similar requirements to the MCA but has some differences. Its requirements are set out in full below. In order to comply with the AWIS, the following conditions must be met:

1. Nature of the research

It must not be possible to carry out research of a similar nature on an adult who has capacity to consent, *and* the research must be into the causes, diagnosis, treatment or care of the adult's incapacity; or the effect of any treatment or care given during his incapacity to the adult which relates to that incapacity.

⁴²Adults With Incapacity (Scotland) Act 2000 section 51.

2. Risks of the research

Participation entails no foreseeable risk, or only a minimal foreseeable risk and imposes no discomfort, or only minimal discomfort, on the adult.

3. Benefits of the research

The research must either be of real and direct benefit to the participant or, where the research is not likely to produce real and direct benefit, it can be carried out if it will contribute significantly to scientific understanding of the adult's incapacity and thus will benefit the participant directly, or benefit other people with the same incapacity.

4. Consent

Consent must be obtained from any guardian or welfare attorney who has the power to consent to the adult's participation in research or, where there is no such guardian or welfare attorney, from the adult's nearest relative. In addition the potential participant must not indicate unwillingness or objection to participation in the research.

5. Ethical committee review

All research must be approved by the REC stated under the AWIS regulations. At the time of publication, this committee was the Scotland A REC. The NRES Central Allocation System can direct applications appropriately.

The ethics committee is required to consider⁴³:

- Objectives, design, methodology, statistical considerations and organisation of the research.
- Relevance of the research and study design.
- Justification of predictable risks and inconveniences weighed against the anticipated benefits for research participants and future participants.
- Suitability of the lead researcher.
- Adequacy of the written information and procedures for obtaining consent.
- Arrangements for recruitment of participants.

⁴³The Adults With Incapacity (Ethics Committee) (Scotland) Regulations 2002 No. 190.

4.2.4 Other research (Northern Ireland)

As at October 2007, the recommendations from a review of mental health legislation in Northern Ireland were being considered. Further guidance relating to this region will be issued once available. At present, there is no specific legislation applicable to research involving adults who lack capacity. All research must be approved by an ethics committee and must comply with common law principles.

4.3 Requirements for research in emergency situations

Specific allowance is made for research in emergency situations when it may not be possible to consult as required by the various laws. These allowances apply to research which fulfils the other requirements of the relevant legislation but where it is not possible to obtain the consent or agreement of a consultee before participation in a clinical trial or other study begins. This exception can only be relied upon until it is possible to consult or seek consent in the normal manner.

4.3.1 Clinical trials in emergency situations (all of UK)

The CT Regulations were amended in 2006⁴⁴ to allow patients to be recruited into trials in emergency situations. This is now possible if:

- Treatment is being given or is about to be given to a person who lacks capacity *and*
- Due to the nature of the clinical trial and the particular circumstances, it is necessary to take action for the purposes of the trial *but*
- It is not practical to meet the conditions required for consultation *and*
- The ethics review committee has approved the procedure for such recruitment.

When designing such a study researchers should consider the arrangements that will be made. In the information provided to the REC it should be explained why it is necessary to include participants in the trial before consent can be sought from a legal representative. The researchers should also document what steps will be taken to obtain appropriate consent once a participant has been recruited and how they will address refusal of such consent. Two examples (H and I) are provided below.

⁴⁴The Medicines for Human Use (Clinical Trials) Amendment (no.2) Regulations 2006. SI 2006 No. 2984.

Examples of clinical trials requiring immediate recruitment

- H.** A large multinational study is examining the effectiveness of pre-hospital thrombolysis for cardiac arrest⁴⁵. The trial involves recruitment of participants before they arrive at hospital. The trial includes only patients who have suffered a cardiac arrest and so no participants are able to give consent to inclusion.
- I.** A multicentre clinical trial is being set up to compare the effectiveness of two antiepileptic drugs in pregnant women with eclampsia. Many of these patients will be temporarily unable to consent due to their medical condition. They may be unaccompanied when they arrive at hospital and/or have an eclamptic fit. When designing the protocol, the researchers addressed the various possibilities for obtaining consent. This included discussing the trial with women at particular risk of eclampsia and obtaining consent prior to the condition occurring. Careful communication was important, as it can be difficult to identify which women may actually develop eclampsia – the researchers did not wish to unnecessarily alarm women who would not then require therapy. They also considered how consent would be obtained if a woman was enrolled in the study before she had consented, and decided that this could be through a relative before the woman regained capacity, or from the participant herself when she regained capacity.

4.3.2 Other research in emergency situations (England and Wales)

The MCA allows patients to be recruited into research studies in an emergency without consultation with a relative or carer. However, recruitment in an emergency can only occur if treatment needs to be given to the patient as a matter of urgency and enrolment into the research also has to be done as a matter of urgency. If there is not time to consult, as described in section 4.2, the researcher should have agreement from a registered doctor who is independent of the project. If this is also impractical, recruitment into the study may occur if it is done in accordance with a protocol already agreed by an ethics committee. See Example J.

⁴⁵European Journal of Clinical Investigation. 2005 May;35(5):315-23.

Example J: Research in an emergency situation

A research study is proposed to examine the changes in certain inflammatory markers in acute trauma patients who are unconscious on admission to hospital. The study involves taking initial blood and urine samples on admission to intensive care and regular samples thereafter. When such patients are admitted there will often not be a relative immediately available with whom to discuss the study. The samples would be taken from intravenous lines inserted to manage the patients' clinical condition. In the protocol the researchers propose that, where available, a consultant anaesthetist unconnected with the study will be consulted about inclusion of each patient. Where this is not possible, for instance at nights or weekends, the patients will be enrolled into the study and baseline and further blood tests and data collected. However, as soon as a relative or unpaid carer is available they will be consulted about the continued participation of the patient in the study. If and when the patient regains consciousness the research project will be fully explained and they will be able to choose whether their data should remain in the study cohort. The approved this protocol.

4.3.4 Other research in emergency situations (Scotland)

At this time there is no provision for recruitment into non-clinical research in an emergency without the consultative steps described in section 4.3. This means that such research cannot be lawfully carried out in Scotland at present. If researchers believe that this may affect a study they are considering, they should seek further advice from the MRC or the Scotland A REC.

4.3.5 Data Protection Act 1998 and research in emergency situations (all of UK)

It has been established⁴⁶ that data may be processed for research in emergency situations involving incapacitated adults *providing* information about this work is given to them on recovery of capacity. At this point they may refuse to participate in the research, including refusal to allow further processing of data already collected. This makes the use of data for research purposes in this situation acceptable in relation to the Data Protection Act. Any research must always also comply with any other legal requirements such as the MCA, AWIS or CT Regulations.

⁴⁶Time to get our Acts together. Reid CL and Menon DK. *BMJ*: 355; 415.

Glossary

AWIS	Adults with Incapacity (Scotland) Act 2000
CT Regulations	Medicines for Human Use (Clinical Trials) Regulations 2004
HTA	Human Tissue Authority
HTAct	Human Tissue Act 2004
ICH GCP	International Conference on Harmonisation: Good Clinical Practice
MCA	Mental Capacity Act 2005
MHRA	Medicines and Healthcare products Regulatory Agency
NRES	National Research Ethics Service (formerly COREC)
REC	Research Ethics Committee

Further Reading

Mental Capacity Act Code of Practice:

www.opsi.gov.uk/acts/acts2005/related/ukpgacop_20050009_en.pdf

Department of Health (England) guidance:

www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Socialcare/IMCA/MentalCapacityAct2005/index.htm

National Research Ethics Service guidance:

www.nres.npsa.nhs.uk/applicants/help/guidance.htm#awi

Full text of Mental Capacity Act 2005:

www.opsi.gov.uk/acts/acts2005/50009--b.htm#30

Full text of Adults with Incapacity (Scotland) Act 2000:

www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm

Full text of Medicines for Human Use (Clinical Trial) Regulations 2004:

www.opsi.gov.uk/si/si2004/20041031.htm

Declaration of Helsinki:

www.wma.net/e/policy/b3.htm

(at the time of publication the World Medical Association was consulting on a revision of the Declaration)

This MRC guidance is based upon the previous 1992 guidance and updated in October 2007 in light of subsequent legislation.

Comments or questions should be addressed to Dr Catherine Elliott at:

MRC Head Office

20 Park Crescent

London

W1B 1AL

Email: **catherine.elliott@headoffice.mrc.ac.uk**

A person unable—

- (a) to **understand** the information, the information, the information, the information,
- (b) to **retain** that information that information that information that information,
- (c) to **use** or weigh **measures** the process of measures the process of measures the process of measures,
- (d) to **communicate** by talking, using other means).

A person unable—
(a) to **understand** the information relevant to the decision, or
(b) to **retain** that information,
(c) to **use** or weigh that information in the process of making the decision, or
(d) to **communicate** his decision (whether by talking, using sign language or any other means);