

Guidance on nominating a consultee for research involving adults who lack capacity to consent

*Issued by the Secretary of State and National
Assembly for Wales in accordance with section
32(3) of the Mental Capacity Act 2005*

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Prepared by Scientific Development and Bioethics Division, Department of Health

Nominated Consultee Guidance

| DH INFORMATION READER BOX | |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Policy | Estates HR / Workforce Management Planning / Performance Clinical |
| | Commissioning IM & T Finance Social Care / Partnership Working |
| Document Purpose | Gathering INFORMATION |
| ROCR Ref: | Gateway Ref: 8371 |
| Title | Guidance on nominating a consultee for research involving adults who lack capacity to consent |
| Author | DH Scientific Development and Bioethics Division |
| Publication Date | 22 Jun 2007 |
| Target Audience | Organisations with an interest in issues relating to research involving people who lack capacity, including those who represent researchers, research ethics committees, those who may act as consultees and people who might take part in with such research. |
| Circulation List | Voluntary Organisations/NDPBs |
| Description | Consultation on new guidance on nominating a consultee for research involving adults who lack capacity to consent |
| Cross Ref | Mental Capacity Act 2005 Code of Practice (DCA) |
| Superseded Docs | N/A |
| Action Required | N/A |
| Timing | By 14 Sep 2007 |
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First published 22 June 2007

Published to DH website, in electronic PDF format only.

<http://www.dh.gov.uk/consultations>

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Introduction

The Mental Capacity Act 2005 establishes a framework for the protection of the rights of people who lack capacity to make a decision for themselves. The Act also includes safeguards for the conduct of research involving those who may not be able to consent due to an impairment, for example because of learning disabilities, and illness such as dementia or brain injury or mental health problems.

The Act's provisions are designed to ensure that the interests and safety of people who lack capacity are protected when they participate in research and to ensure that their current and previously expressed wishes and feelings are respected. Anyone carrying out research to which the requirements of the Act apply must act in accordance with the provisions of the Act in order for the research to be lawful. The Mental Capacity Act Code of Practice¹ provides more information on the general research provisions in the Act and researchers have a duty to ensure that they act in accordance with its requirements.

The Act requires that any research project that is subject to the Act is approved by an appropriate body as defined in the "Appropriate Body" Regulations.² The Regulations refer to a committee established to advise on the ethics of intrusive research in relation to people who lack capacity to consent to it and which is recognised for that purpose by the Secretary of State or the National Assembly for Wales (referred to here as a REC).

The REC must be satisfied that the research meets the relevant requirements relating to the nature, risks and benefits of the research and the arrangements in place to meet the other safeguards in the Act. In particular, the Act requires that before a person who lacks capacity ("P" in the Act) is enrolled in an approved project, a suitable person is identified who can act as a consultee and advise the researcher ("R") on whether the person who lacks capacity would want to be involved in the project.

The Act requires the researcher to take steps to identify a consultee who has a role in caring for the person who lacks capacity or is interested in that person's welfare but is not paid or acting in a professional capacity (a "personal consultee"). The Act recognises that in some cases the researcher may not be able to identify such a consultee because the person who lacks capacity has no family or friends who are willing and able to fulfil this role. Alternatively, there may be carers willing to act as consultee but who may not do so because they are paid carers or are acting in a professional capacity, such as care worker or legal advisor.

In such situations, section 32(3) of the Act requires that the researcher must act in accordance with guidance issued by the Secretary of State and the National Assembly for Wales and nominate a person to act as a consultee (a "nominated consultee"). This guidance sets out the principles to which researchers must adhere in nominating a consultee and provides advice on ways of meeting this requirement in different research settings.

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The Mental Capacity Act does not affect research that is a clinical trial within the meaning of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). Those regulations include similar principles for the involvement of a “legal representative” when enrolling an adult who lacks capacity in a clinical trial.

Research in emergency situations

This guidance also covers the Act’s provisions on emergency research. This relates to special circumstances where it might not be possible to consult family or friends before the research must start. For example, research which is part of emergency trauma care may need to start in the first few minutes after an injury or illness.

Glossary of terms

The Act: the Mental Capacity Act 2005

P: a person without capacity to make the decision at the material time

R: the researcher

Personal Consultee: Someone who knows the person who lacks capacity in a personal capacity who is able to advise the researcher about P’s wishes and feelings in relation to the project and whether P should join the research (s32(2))

Nominated Consultee: Someone who is appointed by the researchers to advise the research about P’s wishes and feelings in relation to the project and whether P should join the research (s32(3))

Research Ethics Committee (REC): A research ethics committee recognised by the Secretary of State or National Assembly for Wales as the “appropriate body” for the purposes of the Act.

Sponsor: The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study

Chief Investigator: In a multi-site study, the leader responsible for the conduct of the study as a whole.

Principal Investigator: The leader responsible for the conduct of the study at a particular research site.

Roles and responsibilities

In order to ensure that arrangements are in place to identify and support a consultee under the Mental Capacity Act a variety of individuals and bodies need to consider the arrangements at a local level. These include:

- Researchers: The sponsor, Chief Investigator and (in the case of a multi-site study) all local Principal Investigators must be familiar with the requirements of the Act and ensure that

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members of their research teams are aware of their responsibilities.

- The sponsor or organisation providing care should have a local policy on the selection and training of the nominated consultees for research taking place within that organisation.
- The REC needs to be familiar with the guidance so that they can judge the researcher's proposed arrangements for the specific projects.

Identifying a consultee

Section 32 of the Act requires that a researcher must take reasonable steps to identify someone who is willing to be consulted about the person who lacks capacity's participation in the approved project. Ideally, the consultee will be someone who knows the person who lacks capacity well but is not acting in professional or paid capacity (a personal consultee). If this is not possible, the researcher must nominate a third party unconnected with the research who is willing to act as a nominated consultee.

The researcher's proposals to identify a consultee must respect the principles of confidentiality. Further guidance on access to information about a person who lacks capacity is given in Chapter 16 of the Code of Practice. The REC must be satisfied that suitable arrangements are in place, for example by requiring the initial contact with potential consultees to be made by the treating clinician or carer or in accordance with an approval from the Patient Information Advisory Group (PIAG) (a statutory body for which provision is made in section 252 of the NHS Act 2006).

Personal Consultee

A personal consultee could be:

- a family member, carer or friend
- an attorney acting under a Lasting Power of Attorney (LPA)
- a court appointed deputy, provided that they had a relationship with the person, or personal knowledge of, the person lacking capacity before their appointment as deputy (for example a deputy could be a family member).

The personal consultee may not be someone who is caring for the person who lacks capacity or interested in his or her welfare in a professional capacity or for remuneration.

A number of people may be capable of acting as a personal consultee. Usually it will be someone with a close personal relationship with the potential subject, for example their next of

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kin, spouse or partner (including same sex partners), adult child or parent. Other relatives or a close friend may be considered.

In accordance with the general principles of the Act, the researcher must make every effort take into account what the wishes of the person who lacks capacity are about whom to consult and to act in accordance with any relevant previous statement or wishes, however made, including non-verbal forms of communication. Where the individual closest to the patient does not feel able to take on the role of consultee, they may suggest that someone else takes on the role, or ask that a nominated consultee be appointed to act on his or her behalf.

What does “reasonable steps” mean?

The researcher is required to take reasonable steps to identify a person who is able to act as consultee. This means that the researcher has a degree of flexibility, in accordance with the approval from the REC, about to what extent it is necessary to approach distant or remote relatives or friends. In some circumstances, it will be possible to establish that the person who lacks capacity has no close relatives in regular contact and that it would be more appropriate to identify a nominated consultee who has more regular contact with the person who lacks capacity.

What must the consultee do?

The personal consultee must be prepared to be consulted by the researcher about the possible involvement of the person who lacks capacity in the project. This means that they must be willing to do it and able to understand the information provided about the project. The precise form of this information is not specified in the Act but should be similar to the information that would ordinarily be given to a person with capacity who was being asked to consent to take part in a research project. The REC should be satisfied that the information given to a consultee is accurate, thorough and easy to understand. The information they receive should not be coercive but make clear that they are not obliged to undertake the role of consultee if they do not wish to do so

In addition to the normal participant information leaflet it will also be necessary to explain to the personal consultee that they are being asked for advice on whether the person who lacks capacity should take part in the project. For example, they should consider whether the person who lacks capacity would be content to take part or whether doing so would upset them. The consultee must also give their opinion on what the person who lacks capacity's wishes and feelings would have been about taking part in the study when they had capacity. For example, whether the person had previously expressed specific or general support for research of this nature. If the consultee advises that the person would not have not wanted to take part then the researcher must abide by this.

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In practice, it may be helpful to remind the consultee that he or she is not being asked for advice on their personal views on participation in the specific project or research in general. The consultee must set aside any views they may have about the research and consider only what P's views and interests are. A consultee should be asked to consider the broad aims of the research and the practicalities of what taking part will mean for person who lacks capacity. The consultee should consider the person who lacks capacity's past views on the overall nature of the research. It is also essential to consider their present views and wishes, for example, that study involves activities in the afternoon when the person who lacks capacity is most tired so would find it a strain or conversely that it involves an activity that the person who lacks capacity particularly enjoys.

A person who has agreed to act as a consultee may find it helpful to have independent advice about their role, and it is good practice to ensure that this can be provided. Suitable independent sources of advice might be people who have undertaken the general preparation to act as a nominated consultee (see below).

Nominated consultee

The Act requires that researchers follow this guidance in determining how to nominate a consultee in accordance with section 32(3) of the Act. Where no personal consultee is available, the researcher must nominate a person who has no connection with the project and who is willing to be consulted about the participation of a person who lacks capacity in an approved research project.

It is good practice for all research that involves adults who lack capacity to address the arrangements for nominating a consultee when seeking approval from the REC. This will enable the REC to consider the variety of circumstances where a readily identifiable personal consultee might not be available. Examples include:

- Where no family member or friend is willing or able to act as consultee.
- Where the family or friends live a long distance away and/or are not in frequent contact with the person who lacks capacity.
- Where the regular carers of the person who lacks capacity are paid (e.g. care home staff or nurses).
- Where someone is acting in a professional role (e.g. their GP or solicitor).

Role of paid carers or healthcare professionals

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It is important to note whilst a paid carer or someone with a professional relationship to P may not be a personal consultee it does not bar them from being the nominated consultee. It is therefore possible that a paid carer or GP for the person who lacks capacity could act as the nominated consultee, provided they had no connection with the research project. It would be for the researcher to satisfy the REC that the arrangements were appropriate to the nature of the study. An example might be people in a care home who have no close family but are close to a member of the care home staff. In this case, the care staff could be approached to act as a nominated consultee. However, it would not be appropriate to approach a member of the care staff if the research was being sponsored by the care home or if the home and its staff are the focus of the research (i.e. have an organisational interest in its outcomes).

In some healthcare settings, a doctor or care professional primarily responsible for the medical treatment of the person who lacks capacity might be the most appropriate nominated consultee. It will be important to ensure that this person has no connection with the project (see below) and in particular, that he or she is free from potential influence, such as being junior to a member of the research team. Researchers should refer to the DH Research Governance Framework for Health and Social Care and other relevant professional codes, including guidance from the General Medical Council. These have general safeguards against conflicts of interest and other forms of professional misconduct

Role of local research organisations

In order to support research involving those who lack capacity it is good practice for research-active Trusts, Social Care Organisations, Universities or Charities to identify local mechanisms to provide access to people suitable to act as nominated consultees under the Act. For example, the care organisations involved – Trusts or Local Authorities – could liaise with others in local research networks and patient or consumer groups to establish a suitable panel of people who can act as nominated consultees. The National Research Ethics Service can also offer advice on local implementation of plans to support the identification of potential nominated consultees.

There is no requirement for the panel of potential consultees to belong to a specific profession. Examples of potential nominated consultees might include other clinical staff or lay persons not connected with the project, social workers, non-Executive members of the Trust Board, Hospital Chaplains or other spiritual advisors, Caldicott Guardian or patient advocates. There may also be a role for the Independent Mental Capacity Advocate, depending on local arrangements.

There will also be a role for the research organisation, working with the appropriate Research Ethics Committee or Clinical Ethics Committee, in ensuring that the panel has the appropriate training and support. The information, and prior training, should draw attention to the requirement of the Code of Practice and this guidance.

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The local arrangements should also cover the provision of advice and support to personal consultees and nominated consultees advising on research projects in their organisation. The information given to a consultee should also clarify their legal obligations under the Act.

What are the duties of the nominated consultee?

The nominated consultee is required to perform the same role as a personal consultee (see above) in advising the researcher about the person who lacks capacity's participation. The nominated consultee will need to receive relevant information about the project. They must also consider how the person who lacks capacity's wishes and interests would incline him or her to decide if he or she had the capacity to make the decision.

The nominated consultee may not know the person who lacks capacity. In determining what the person's wishes and feelings about the research would be if they had capacity, the nominated consultee should attempt to seek views from any family or friends or paid carers who may not be willing or able to act as a consultee. Where appropriate, other professional colleagues with an interest in the person who lacks capacity's welfare or condition, such as members of the care team not involved in the research, may be approached for a view.

In some cases, the duty of the nominated consultee to seek views on the person's presumed wishes and feelings will have to be balanced against a duty of confidentiality regarding sensitive aspects of the condition that the person who lacks capacity is in. Examples include research involving mental health or sensitive matters relating to the care of young adults with learning disability. The Code of Practice (Chapter 16) gives general advice on confidentiality and duties under the Act. The REC will wish to be satisfied about arrangements regarding confidentiality when giving approval.

What does "no connection with the project" mean?

A nominated consultee must have no connection with the project. In deciding whether someone is 'connected with the project', researchers should consider a wide range of possible connections to the particular study. For example, the consultee should not be someone who is involved or has a financial or professional interest in the progress of the research. They should have no direct professional or personal links with members of the research team. They should also not have wider connections such as direct links to sources of funding for the study or with the REC that approved the project. However, some connections will be irrelevant. It is unnecessary, for example, to exclude people whose only connection is working in the same hospital or local authority as the researcher, or living in the same street. Researchers will need to consider the nature of a person's possible connection with a project as these arise and should err on the side of caution when they do so.

Guidance from the General Medical Council or General Social Care Council and professional bodies gives further advice on preventing against conflicts of interest and other forms of professional misconduct

Emergency care research

If research is to take place in connection with urgent medical treatment, the Act allows for an alternative approach to the requirement for consultation. Examples might include severe head injury, cardiac arrest or septic shock that would make the person unable to consent to research. If the emergency care research must take place before it is possible to consult in the usual way, then the person who lacks capacity can be enrolled in an approved project with either:

- the agreement of a doctor who is not connected with the project, or
- in accordance with a procedure previously agreed by the REC where it is not reasonably practicable to obtain agreement from a doctor who has no connection with the project.

In the case of research taking place in a healthcare setting, for example in Accident and Emergency or Intensive Care, then the researcher should take steps to identify in advance appropriate doctor(s) to cover out of hours emergencies. Any doctor identified to agree to the inclusion of a person in an approved project must have no other connection with the project. As indicated elsewhere in the guidance, they must be provided with appropriate information about the nature of the study, the inclusion and exclusion criteria and their duties under the Act.

In research situations outside of a healthcare organisation, for example those involving paramedics, it may be possible that a personal consultee is available at the scene. However, it may not be reasonable to expect that person to absorb information and advise on the enrolment of the person who lacks capacity into an approved study. In such cases, the REC should agree when approving the study the arrangements to be taken by the paramedic or other nominated individual in deciding whether to enrol that person.

Any such decision should take due account of the views, however expressed, by the person being treated or by their family or friends who are with them.

In the absence of any information to the contrary, it is justifiable for a doctor or other healthcare professional to assume that a potential subject would wish to receive an intervention which has the greatest chance of saving his or her life or improving (or minimising detriment to) his or her health. Where there is genuine uncertainty about the relative benefits or harms of the standard treatment and the research treatment (equipose), it may be reasonable to assume (other things being equal) that a potential subject would wish to enter the approved research project.

As soon as the emergency is over arrangements must be made to seek consent in the usual manner or to seek advice from a consultee on the continued participation of the person who lacks capacity in the study.

Loss of capacity during a research project

Some people who consent to join long-term research studies may lose capacity to consent before the study ends. The Act makes provision for some such cases via the “Loss of Capacity during Research Project” Regulations.³ These Regulations allow a simplified means of obtaining lawful authority to continue to use tissue samples or data obtained before loss of capacity provided the person consented before 31 March 2008 to join a project that started before 1 October 2007. Separate guidance is available on the application of the Act to research where a person consented to join a study started after 1 October 2007 but loses capacity before the end of the project.

The Regulations require that a researcher submit a protocol which is approved by the REC. The protocol must cover the arrangements that will be made once it becomes known that the person has lost capacity. Schedule 2 of the Regulations sets out the requirements to identify or nominate a consultee which are similar on those in section 32 of the Act. That person should be provided with information about the project and with information on the nature of the consent given by the participant when they joined (or re-consented) to their samples being collected. The arrangements for selecting a consultee should take account of the guidance above and be agreed by the REC.

The role of the consultee is similar to normal research situations. They must advise on whether the research subject would want to allow samples or data collected before loss of capacity to continue to be used in the study. The fact that the person who lacks capacity had originally consented to join the research project, and the extent to which future incapacity was considered at that time, will be important aspects to draw to the attention of the consultee. However, the researcher must take due heed of any advice from the consultee that continued involvement in the study would be contrary to the wishes of the person who lost capacity. For example, the person may have originally consented to their medical records being accessed, but following the onset of a severe mental health condition, the consultee may advise that if the person were aware of the continued use of their data it would worsen their condition.

It should also be made clear to the consultee that they are not being asked to agree to the collection of further samples or data. Any future contact of that nature would require the project to be approved separately in accordance with the Act.

Summary

This guidance on the identification and support for a consultee under the Act is intended to provide a flexible framework for researchers to adapt to specific types of projects and the local arrangements for research. The Act's core principles emphasise the importance of respecting the wishes of the person, both previously made and at the time that the research is undertaken. Researchers need to plan in advance and to be able to satisfy the REC that the arrangements they propose for consultation address this core duty.

The researcher will also need to ensure that the consultee is approached and supported in a way that enables them to fulfil their role free from actual or perceived conflicts of interest.

Where appropriate, the sponsor and/or local research organisation should to ensure access to advice and support for personal and nominated consultees, and if necessary, a panel of suitably experienced and qualified people to act as a nominated consultee.

Annex A: Further sources of information

Mental Capacity Act 2005. Code of Practice. Public Guardianship Office.

Making decisions: A guide for family, friend and other unpaid carers. Published by The Mental Capacity Implementation Programme.

Making decisions: A guide for people who work in health and social care. Published by The Mental Capacity Implementation Programme.

Using patient information and involving service users in research. A guide for researchers applying to the Patient Information Advisory Group: Patient Information Advisory Group (PIAG)

Research: The role and responsibilities of doctors. General Medical Council.

References

- 1 Mental Capacity Act 2005 Code of Practice, available at www.guardianship.gsi.gov.uk
- 2 Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 and the Mental Capacity Act 2005 (Appropriate Body) (Wales) Regulations 2006
- 3 Mental Capacity Act 2005 (Loss of Capacity during Research Project) Regulations (England) Regulations 2007 (SI2007/679) and Mental Capacity Act 2005 (Loss of Capacity during Research Project) Regulations (Wales) Regulations 2007