

**Consultation on Regulations to be made under the
Mental Capacity Act 2005**

Department of Health

June 2006

1. This document aims to give some further context to and explanation of the research regulations.
2. The Mental Capacity Act 2005 provides a statutory framework for people who may not be able to make their own decisions, for example because of a learning difficulties, an illness such as dementia or brain injury or mental health problems. It sets out who can take decisions, in which situations, and how they should go about this.
3. The Act enshrines in statute current best practice and common law principles concerning people who lack mental capacity and those who take decisions on their behalf. In Section 30 to 34, the Act also provides a statutory framework for research involving people who lack capacity to consent to their participation. These provisions balance the importance of properly conducted research into the treatment or care of people who lack capacity with the need to protect their interests and respect their current and previously expressed wishes and feelings.
4. The Act applies to research that is defined as “intrusive”, that is, would normally require the consent of a person with capacity in order to be lawful and which involves a person who lacks of capacity to consent because of an impairment of the mind or brain. It does not apply to clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).
5. The Act requires a researcher to obtain approval from an “appropriate body” which must be satisfied that the research project meets certain requirements set out in the Act. They must also be satisfied that

arrangements are in place to consult a carer about the participant's previous wishes and feelings and to ensure their safety.

6. The Government signalled during the passage of the Act that it wished to retain flexibility in certain aspects relating to research and introduced regulation-making powers to cater for aspects such as:
 - transitional arrangements for existing research projects, especially for long-term studies that may involve people who consented but then lost capacity, and
 - an independent review of NHS Research Ethics Committees and changes to the system of research ethics committees that review social care research.
7. The Department of Health is now consulting on draft Regulations in England that the Secretary of State proposes to make in preparation for the full implementation of the Act, scheduled for 2007. These include regulations under:
 - Section 30(4), specifying the person, committee or other body as the appropriate body
 - Section 34, setting out the arrangements to apply where a person had given consent to a study but who loses capacity before the end of the project.
8. Under the Act, regulations are made by the "appropriate authority" which in England is the Secretary of State and in Wales is the National Assembly for Wales. A separate consultation will be held with respect of Wales. The s34 Regulations are affirmative, that is they are required to be approved by debate in both Houses of Parliament.
9. Further information on the policy intentions of the regulations are included in this document along with the draft text of the regulations. The Department of Health has taken initial soundings from stakeholders to help develop these draft regulations.

Policy intention of the regulations

Section A. Regulations defining the Appropriate Body (s30)

10. Sections 30 (and sections 31-33) of the Act make provision for intrusive research to be lawfully carried out on, or in relation to, a person who lacks capacity where that research
 - is part of a project approved by an 'appropriate body' and
 - is carried out in accordance with the conditions set out in s31-33.
11. Section 30(4) of the Act allows the 'appropriate authority', in this case the Secretary of State for Health in respect of England, to make regulations specifying 'the person, committee or other body' as the appropriate body for approving such research projects involving those who lack the capacity to consent to participation.
12. Draft Regulations under section 30(4) seek to specify the appropriate body in a way which will encompass research ethics committees. The s30(4) regulations are the subject of negative resolution.

Policy intention

13. The need for independent ethical review of medical research is enshrined in internationally recognised statements such as the Declaration of Helsinki. However, the definition of intrusive research in the Mental Capacity Act is deliberately wider than health or medical research. For example, it includes social care research studies. The following are among the possible scenarios listed in the Act's Draft Code of Practice:
 - clinical research into new types of treatments (except clinical trials of medicines that are covered by separate Regulations);
 - health or social care services research to evaluate the effectiveness of a policy intervention or service innovation;
 - research in other fields, (e.g. criminal justice, psychological studies, lifestyle or socio-economic surveys);
 - research on tissue samples (i.e. blood or spare tissue removed during surgical or diagnostic procedures); also covered by the Human Tissue Act;

- research on health and other personal data collected from records; and
- observations, photography or videoing of people without capacity some of which is done covertly so as not to distract the person

All these are classed as 'intrusive' research. Not all of them are invasive, in the sense of physically taking something to or from a person's body.

14. The arrangements for independent research ethics review are already embedded in *The Department of Health's Research Governance Framework For Health and Social Care* (RGF) which sets out the framework for the governance of research in both health and social care. The principles apply to all research within the remit of the Secretary of State for Health. It is a core standard for health care organisations that they have systems to ensure the principles and requirements of the RGF are consistently applied. Health care organisations have to take this standard into account in discharging their duty of quality under Section 45 of the Health and Social Care (Community Health and Standards) Act 2003. The primary purpose of a research ethics committee when considering a proposed study is to protect the rights, safety, dignity and well-being of actual or potential participants.

The draft Regulations:

15. The draft **Mental Capacity Act 2005 (Appropriate Body) (England) Regulation 2006** is attached. It identifies the appropriate bodies as 'a committee [or other body]
- (a) established to advise on, or on matters which include, the ethics of research investigations of the kind conducted, or intended to be conducted, as part of the project, including the ethics of intrusive research in relation to those who lack capacity to consent to it; and
 - (b) recognised for these purposes by or on behalf of the Secretary of State or the National Assembly for Wales
16. During the passage of the Act the Government signalled a wish to retain flexibility in certain research related aspects of the legislation in order to cater for future eventualities such as the independent review of NHS

Research Ethics Committees and any future evolution of the social care ethics system. The draft Regulations do not therefore provide a definitive list of ethics committees; but instead suggest the criterion that appropriate bodies have expertise including the ethics of research falling under the Act.

17. Certain ethics committees will receive training in application of the Act's principles and safeguards in readiness for implementation of the Act. This will ensure that new research projects involving those who lack the capacity to consent to participate can be reviewed by independent committees, consisting of lay and expert members, who are fully conversant with the legislation and its Code of Practice and have the competence to consider the ethics of the proposal.

Section B. Regulations regarding loss of capacity during research (s34)

Policy intention

18. The general policy intention of these Regulations was signalled during the passage of the Bill in Parliament. The Government recognised the importance of a smooth transition to the new arrangements without stopping long-term research studies or causing unnecessary bureaucracy for researchers or research ethics committees. The intention is to:

- minimise bureaucracy and other burdens (e.g. the need for frequent checks of all research participants to assess capacity or identify carers to consult)
- remove the possibility that the requirements of s31 would mean that existing long-term studies could not be approved under the Act, and
- require safeguards or other considerations regarding the rights of participants which are consistent with the principles of the Act.

19. Section 34 of the Act makes allowance for long-term research studies where a person consented to join the study but before the end of the

project has lost capacity. Typically, long-term research studies aim to follow the health of a large section of the population over many decades. Some studies have been running since 1946 (e.g. the MRC National Survey of Health and Development) and during that time some participants will have lost capacity due to ill health, injury or disease.

20. A person's consent to join a long-term study will be valid until they are asked to give (or refuse) consent, for instance when they are asked to give a new sample or measurement or otherwise make a decision to remain in the study. By their nature, long-term studies only make regular periodic contact with the person. They may be analysing or researching information or materials from a person without being aware that he or she has since lost capacity.
21. The legal position affecting samples and information taken in the past from such individuals once the Act is in force is complex because of the interplay between common law, the Data Protection Act 1998 and the Human Tissue Act 2004. In the absence of relevant legal judgments, it is expected that a Court would be likely to consider that consent to use tissues (or data) will survive loss of capacity in certain limited circumstances. It is likely that consent would be held to endure if, when it was given, the participant explicitly consented to continuing use of any data or tissue, which had been obtained with their consent, following any loss of capacity. It would probably not be held to endure where the original consent did not contemplate the loss of capacity and circumstances had changed so that they were no longer the ones to which the original consent applied.
22. During the passage of the Act, Ministers recognised that there needed to be clarity about the status of existing collections or findings so that they did not have to be automatically discarded because of later incapacity. However, it was not felt appropriate to automatically exempt from control those studies started before the Act comes into force. The Act therefore includes provision for regulations (section 34) to provide lawful authority to continue to do research on material or information taken from a person before they lost capacity and before the Act came into force.

Content of the s.34 Regulations

23. The draft **Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006** are attached. Regulation 1 refers to the definition contained in the main Act, guidance on which is available in the Explanatory Notes to the Act and draft Code of Practice.
24. Regulation 2 sets out that the draft Regulations only apply where a person has consented to take part in a research project which started before the Act comes into force (due to be April 2007) but before the end of the project loses capacity.
25. Regulation 3 allows a researcher to continue to use information (e.g. data) or material (e.g. tissue or DNA samples) obtained with consent before the loss of capacity. This is subject to meeting the requirements of Schedules 1 and 2. Schedule 1 requires that an 'appropriate body' has approved a protocol making appropriate provision for such research to be carried on. The appropriate body must be satisfied, in particular, about the arrangements in place to meet the safeguards in Schedule 2.
26. Schedule 2 repeats the relevant safeguards from section 32 and 33 of the main Act. Section 31 criteria do not apply here. The protocol should detail the arrangements that will be put in place once it is known that a particular research participant ("P") has lost capacity. In such an eventuality, suitable steps must be taken to identify a person (next of kin, carer or other person interested in P's welfare) who willing to be consulted about the continued use of information or material previously obtained in the research. The researcher must abide by the views of the consultee, or any other views made by the research participant. If the consultee or the participant objects, further research using the information or material so far obtained must be discontinued.
27. Overall, the Regulations incorporate a simplified version of the approval mechanism and safeguards in the main Act, reflecting the fact that they only apply to material and information gathered with consent, and not to further intrusive research involving those who lack capacity. In practice,

we expect researchers running long-term studies to have already identified what process will be triggered in the event of permanent loss of capacity. If the participant is automatically removed from further study and/or their information or material fully anonymised (i.e. all links to the participant broken), then the s34 Regulations (and s.30-33 of the Act) will not apply. If a researcher wished to continue to use such material or information, then there will need to be measures put in place in accordance with Schedule 2 to respect the views of the participant or the consultee if they wish to be withdrawn. This might mean that previous material or information must be destroyed or fully anonymised.

28. In the longer term, researchers will be encouraged to consider issues relating to incapacity during the original consent (or when giving further consent to an existing long-term study). If the consent clearly anticipates the possible onset of incapacity, it will be possible for ethical approval to be given to research that might otherwise not meet the specific approval requirements under s31 of the Act. For NHS research, any such consent arrangements would be subject to independent ethical review.

Transitional arrangements

29. The draft section 34 Regulations do not apply to existing long-term studies that enrolled people who lacked capacity (for example, ongoing projects involving adults with dementia or learning difficulties). Those projects will need to have approval under section 30 of the Act when it is commenced in 2007. The draft Regulations will also not apply to situations where the researchers wish to go back to a person who lacks capacity in order to take more tissue or DNA samples or data. Minister's have made clear that if a long-term study intends to request new samples or data from a person who lacks capacity within the meaning of the Act, then they will need to abide by the full requirements of the s30-33 of the Act, in particular meeting the section 31 approval requirements for carrying out intrusive research.

30. Researchers who are already conducting REC-approved research that would otherwise be made unlawful by the commencement of s30 of the Act will have a period of grace in which to obtain approval from an appropriate body under s31 or these s34 regulations. This will be done by means of the general transitional and commencement powers. On the assumption that s30 of the Act is commenced on 1 April 2007, we propose allowing researchers until 1 January 2008 to obtain the necessary approval.
31. There are other transitional measures that apply to research between commencement of the Human Tissue Act 2004 (due in September 2006) and the commencement of s30 of the Mental Capacity Act (due in 2007). The draft Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 allow 'deemed consent' for tissue taken for a scheduled purpose if it is for ethically approved research under Regulation 8 of those Regulations. After full commencement of the Mental Capacity Act, consent for the purposes of the Human Tissue Act will be deemed to be in place if the research complies with s.30(1)a and b) or s.34(2) – i.e. these draft Regulations - of the Mental Capacity Act

2006 No. 00

MENTAL CAPACITY, ENGLAND

**The Mental Capacity Act 2005 (Appropriate Body) (England) Regulations
2006**

<i>Made</i> - - - -	2006
<i>Laid before Parliament</i>	2006
<i>Coming into force</i> - -	[1 April] 2007

The Secretary of State for Health makes the following Regulations, in exercise of the powers conferred upon her by sections 30(4) and 30(6) of the Mental Capacity Act 2005⁽¹⁾.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006 and shall come into force on [1 April 2007].

(2) These Regulations apply in relation to the carrying out of research in England.

Appropriate Bodies

2. For the purposes of sections 30, 31 and 32 of the Mental Capacity Act 2005, the appropriate body in relation to a research project is a committee [or other body]—

- (a) established to advise on, or on matters which include, the ethics of research investigations of the kind conducted, or intended to be conducted, as part of the project, including the ethics of intrusive research in relation to people who lack capacity to consent to it; and
- (b) recognised for those purposes by or on behalf of the Secretary of State or the National Assembly for Wales.

Signed by authority of the Secretary of State for Health

Date

Name
Minister of Health
Department of Health

EXPLANATORY NOTE

(This note is not part of the Order)

To be inserted.

⁽¹⁾ 2005 c.9.

2006 No. 00

MENTAL CAPACITY, ENGLAND

The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006

<i>Made</i>	- - - -	2006
<i>Laid before Parliament</i>		2006
<i>Coming into force</i>	- -	2006

The Secretary of State for Health makes the following Regulations in exercise of the power conferred upon her by sections 30(6), 34(2) and (3), 64(1) and 65(1) of the Mental Capacity Act 2005⁽²⁾.

In accordance with section 65(4) of that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement, territorial application and interpretation

3.—(1) These Regulations may be cited as the Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006 and shall come into force on [1 April 2007].

(2) These Regulations apply in relation to the carrying on of research in England.

(3) In these Regulations—

“the Act” means the Mental Capacity Act 2005;

“appropriate body” has the meaning given by section 30(4) of the Act and the Mental Capacity Act 2005 (Appropriate Body) (England) Regulations 2006⁽³⁾.

“P” has the meaning given by regulation 2;

“R” has the meaning given by regulation 3.

Application

4. These Regulations apply where—

(a) a person (“P”)—

(i) has consented before [31 December 2007] to take part in a research project (“the project”) begun before [1st April 2007] but

(ii) before the conclusion of the project, loses capacity to consent to continue to take part in it, and

(iii) research for the purposes of the project in relation to P would, apart from these Regulations, be unlawful by virtue of section 30 of the Act.

⁽²⁾ 2005 c.9. Section 64(1) is cited because of the meaning there given to “prescribed”.

⁽³⁾ S.I. 2006/[].

Research which may be carried out despite a participant's loss of capacity

5. Despite P's loss of capacity, research for the purposes of the project may be carried out using information or material relating to him if—

- (a) the project satisfies the requirements set out in Schedule 1,
- (b) all the information or material relating to P which is used in the research was obtained before P's loss of capacity, and
- (c) the person conducting the project ("R") takes in relation to P such steps as are set out in Schedule 2.

SCHEDULE 1

Regulation 3

Requirements which the project must satisfy

1. A protocol approved by an appropriate body and having effect in relation to the project makes provision for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to continue to take part in it.

2. The appropriate body must be satisfied that there are reasonable arrangements in place for ensuring that the requirements of Schedule 2 will be met.

SCHEDULE 2

Regulation 3

Steps which the person conducting the project must take

1. R must take reasonable steps to identify a person who—

- (a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and
- (b) is prepared to be consulted by R under this Schedule.

2. If R is unable to identify such a person he must, in accordance with guidance issued by the appropriate authority, nominate a person who—

- (a) is prepared to be consulted by R under this Schedule, but
- (b) has no connection with the project.

3. R must provide the person identified under paragraph 1, or nominated under paragraph 2, with information about the project and ask him—

- (a) for advice as to whether research [of the kind proposed] should be carried out in relation to P, and
- (b) what, in his opinion, P's wishes and feelings about such research being carried out would be likely to be if P had capacity in relation to the matter.

4. If, any time, the person consulted advises R that in his opinion P's wishes and feelings would be likely to lead him to wish to withdraw from the project if he had capacity in relation to the matter, R must ensure that P is withdrawn from it.

5. The fact that a person is the donee of a lasting power of attorney given by P, or is P's deputy, does not prevent him from being the person consulted under paragraphs 1 to 4.

6. R must ensure that nothing is done in relation to P in the course of the research which would be contrary to—

- (a) an advance decision of his which has effect, or

(b) any other form of statement made by him and not subsequently withdrawn,
of which R is aware.

7. The interests of P must be assumed to outweigh those of science and society.

8. If P indicates (in any way) that he wishes the research in relation to him to be discontinued, it must be discontinued without delay.

9. The research must be discontinued without delay if at any time R has reasonable grounds for believing that one or more of the requirements set out in Schedule 1 is no longer met in relation to research being carried out in relation to P.

10. R must conduct the research in accordance with the provision made in the protocol referred to in paragraph 1 of Schedule 1 for research to be carried out in relation to a person who has consented to take part in the project but loses capacity to consent to take part in it.

Signed by authority of the Secretary of State for Health

Date

Name
Minister for Health
Department of Health

EXPLANATORY NOTE

(This note is not part of the Order)

To be inserted.

Annex to consultation document

When seeking views on our proposals we follow the '*Cabinet Office Code of Practice on Consultation*'. In particular we aim to:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what our proposals are, who may be affected, what questions are being asked and the timescale for responses
3. Ensure that our consultation is clear, concise and widely accessible
4. Give feedback regarding the responses received and how the consultation process influenced the policy
5. Monitor our department's effectiveness at consultation, including through the use of a designated consultation coordinator
6. Ensure our consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate

We welcome your comments on how well we have adhered to the criteria and suggestions for further improving the consultation process.

Please direct comments or complaints about the consultation process, but not your response to the consultation itself, to:

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