



*National Patient Safety Agency*

National Research Ethics Service

**Research involving adults unable to  
consent for themselves**

Version 1 June 2007

# Research involving adults unable to consent for themselves

## 1. Introduction

- 1.1 This document gives guidance on applying for ethical review of research involving adults unable to consent for themselves. It deals separately with:
- Clinical trials of investigational medicinal products (CTIMPs), for which UK-wide statutory provision is made by the Medicines for Human Use (Clinical Trials) Regulations 2004 (“Clinical Trials Regulations”) as amended
  - Other research (non-CTIMPs) subject to the Mental Capacity Act 2005 in England and Wales
  - Non-CTIMPs subject to the Adults with Incapacity (Scotland) Act 2000.
  - Non-CTIMPs conducted in Northern Ireland.
- 1.2 Guidance is also given on applications for non-CTIMPs to be conducted in more than one UK jurisdiction.
- 1.3 The main focus of the guidance is on the procedures for applying to research ethics committees (RECs). It is not the purpose of the document to provide detailed guidance on ethical issues, or on the design of research to comply with legal requirements, but other sources of guidance are referred to where applicable.

## 2. Clinical trials of investigational medicinal products (CTIMPs)

### Clinical Trials Regulations

- 2.1 The inclusion in CTIMPs of adults unable to consent for themselves is governed by the provisions of the Clinical Trials Regulations and the Adults with Incapacity (Scotland) Act 2000.
- 2.2 The research provisions of the Mental Capacity Act 2005 do not apply to the conduct of CTIMPs.

### New applications for CTIMPs

- 2.3 Applicants for CTIMPs should indicate on the form sieve if they plan to include adults unable to consent for themselves, and complete the additional set of questions generated by the form. An adult is defined in the Clinical Trials Regulations as a person aged 16 or over.
- 2.4 When booking the application with the Central Allocation System (CAS), the applicant should declare that the trial involves adults unable to consent for themselves.
- 2.5 CAS will allocate the application to a REC, which is both:

- Recognised for the purpose of reviewing CTIMPs in patients (either Type 2 or Type 3, as appropriate), *and*
- Flagged for the purpose of reviewing research involving adults unable to consent for themselves (see paragraph [ ]).

*(Note: Phase 1 trials cannot include adults unable to consent for themselves, as one of the requirements of Part 5 of Schedule 1 to the Regulations is that there are grounds for expecting that administering the investigational medicinal product will produce a benefit to the subject. This is incompatible with the definition of a Phase 1 trial under the Regulations. Therefore trials involving adults unable to consent would never be reviewed by Type 1 recognised RECs.)*

- 2.6 Where the trial is to be conducted at one or more sites in Scotland, *and* the Chief Investigator is professionally based in Scotland, the application will be allocated to “the Ethics Committee” constituted by Scottish Ministers under the Adults with Incapacity (Scotland) Act 2000. This committee is currently the Scotland A REC. If the Chief Investigator is based outside Scotland, the application may be allocated to any other REC, which is both recognised and flagged for the purpose of reviewing research involving adults unable to consent for themselves.

### **Ethical review of CTIMPs**

- 2.7 The main REC undertaking the review of a trial involving adults unable to consent for themselves is required to consider whether the research is justified having regard to the conditions and principles specified in Part 5 of Schedule 1 to the Clinical Trials Regulations. These include provisions for informed consent to be given by the subject’s legal representative. A definition of “legal representative” for this purpose is given in Part 1 of Schedule 1.
- 2.8 NRES has issued an information paper on “*Informed Consent in Clinical Trials of Investigational Medicinal Products*”, outlining the relevant provisions of Schedule 1. This is available at <http://www.nres.npsa.nhs.uk/recs/guidance/guidance.htm#consent>
- 2.9 The ethical review of a CTIMP involving adults with incapacity in Scotland is governed by the provisions of the Clinical Trials Regulations. The provisions of the Adults with Incapacity (Scotland) Act 2000 are superseded by the Clinical Trials Regulations where any conflict arises.

### **3. Research subject to the Mental Capacity Act 2005**

#### **MCA Code of Practice**

- 3.1 The Mental Capacity Act (MCA) Code of Practice has been laid before Parliament and is published at: [http://www.opsi.gov.uk/acts/en2005/ukpgaen\\_20050009\\_en\\_cop.pdf](http://www.opsi.gov.uk/acts/en2005/ukpgaen_20050009_en_cop.pdf)
- 3.2 Under Section 42(4) of the MCA, researchers carrying out research approved under the Act are legally required to have regard to the Code of Practice.

3.3 Any researcher who believes their project could be affected by the Act is strongly recommended to consult the following chapters of the Code of Practice before finalising their protocol and applying for ethical review:

- Chapter 2, setting out the underlying principles of the Act
- Chapter 3, on helping people make decisions for themselves
- Chapter 4, dealing with the assessment of capacity to consent
- Chapter 11, describing the criteria for approval of research.

### **Application of the Mental Capacity Act to research**

3.4 The Mental Capacity Act (MCA) applies to England and Wales only.

3.5 In general, the provisions of the MCA apply only to persons aged 16 or over (referred to in this guidance as “adults”).

3.6 The research provisions of the MCA (sections 30-34) apply to the conduct of “intrusive research” involving adults who lack capacity to consent for themselves. “Intrusive research” is defined in section 30(2) of the MCA as:

*”[research] of a kind that would be unlawful if it was carried out -*

- (a) on or in relation to a person who had capacity to consent to it, but*
- (b) without his consent.”*

3.7 Therefore intrusive research is research that normally requires consent in order to be lawful. Intrusive research is not limited to medical and biomedical research, health-related research or research taking place within the NHS. It could be research undertaken in the context of social care or in any other context where consent is normally a legal requirement.

3.8 In some cases, consent may not be a legal requirement, for example where the research is limited to use of the following:

- Data that has been completely and irrevocably anonymised and is no longer personal data within the meaning of the Data Protection Act.
- Personal data where approval has been given by the Patient Information Advisory Group (PIAG) for processing of the data without consent under Section 60 of the Health and Social Care Act 2001 (see <http://www.advisorybodies.doh.gov.uk/PIAG/Index.htm> for further guidance).
- “Existing holdings” of tissue under the Human Tissue Act 2004, i.e. “relevant material” which was already held prior to 1 September 2006.
- Tissue from the living, which is not identifiable by the researcher and where the research is ethically approved by a NHS REC under section 1(9) of the Human Tissue Act.

3.9 Where researchers are in any doubt about the potential application of the Mental Capacity Act to their research, they are encouraged to seek advice initially from their R&D office or to write to one of the advice points set out at the end of this document.

- 3.10 However, medicinal trials conducted under the Medicines for Human Use (Clinical Trials) Regulations 2004 are specifically excepted from the provisions relating to intrusive research.

### **Loss of Capacity Regulations**

- 3.11 The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006 and equivalent Regulations made by the National Assembly for Wales (referred to in this guidance as the “Loss of Capacity Regulations”) are made under Section 34 of the Act. They provide in certain circumstances for continuation of research involving data or material, which has been taken with consent from a person who subsequently loses capacity before the research ends. The Regulations apply only where the research starts before 1 October 2007 and the person concerned initially consents to participate before 30 March 2008.

### **Requirements for approval under the MCA**

- 3.12 There are two types of approval for research under the MCA:
- Approval under section 30 to undertake any “intrusive research” where the participants include one or more adults unable to consent for themselves (referred to in this guidance as “section 30 approval”).
  - Approval under the Loss of Capacity Regulations made under section 34 to undertake research using data or material obtained before a participant lost capacity (in a study which starts before 1 October 2007 and where the participant gives consent before 30 March 2008) (“section 34 approval”).
- 3.13 Both types of approval must be given by an “appropriate body”. Under the Mental Capacity Act 2005 (Appropriate Body)(England) Regulations 2006 and equivalent Regulations made by the National Assembly for Wales, the appropriate body is a committee:
- (a) established to advise on, or on matters which include, the ethics of intrusive research in relation to people who lack capacity to consent to it, and
  - (b) recognised for that purpose by the Secretary of State or Welsh Ministers.
- 3.14 All RECs established in England and Wales under the Governance Arrangements for NHS Research Ethics Committees (GAfREC, issued by DH in July 2001) are recognised for this purpose both by the Secretary of State for Health and Welsh Ministers, and are therefore appropriate bodies for the purposes of approving research under the Act.
- 3.15 An approval by any REC established under GAfREC in England or Wales applies to the conduct of the research in both England and Wales.

### **Timetable for implementation**

- 3.16 The provisions of sections 30-33 of the Act come into force on 1 October 2007. Any new research starting on or after 1 October 2007 must have section 30 approval and comply fully with the provisions of sections 30-33 if it is “intrusive research” involving one or more adults unable to consent for themselves.
- 3.17 Applications for section 30 approval for new research may be made from 1 July 2007 with a view to complying with sections 30-33 from 1 October 2007.

- 3.18 Research starting prior to 1 October 2007 is not required to comply with sections 30-33 until 1 October 2008, provided it has ethical approval. Where the research is still underway on 1 October 2008, it must have section 30 approval by that date.
- 3.19 Applications for section 34 approval may be made from 1 July 2007 with a view to complying with the Loss of Capacity Regulations from 1 October 2007.

### **New applications for section 30 approval**

- 3.20 Applicants should declare on the form sieve if they plan to include adults unable to consent for themselves in the research.
- 3.21 All applications for research planning to include adults unable to consent for themselves should be booked for review through the NRES Central Allocation System (CAS) by calling 0845 270 4400. This includes both single- and multi-site studies.
- 3.22 Applicants are asked to notify CAS that the research plans to include adults unable to consent for themselves and indicate which UK countries are involved.
- 3.23 All such applications will be allocated to review by a “flagged REC”. This is a panel of RECs appointed to review all new research projects planning to include adults unable to consent for themselves. The flagged RECs are listed in Annex B. Applicants for research in England and Wales may indicate a preference for a particular flagged REC when booking the application with CAS.
- 3.24 Further information about booking is available at <http://www.nres.npsa.nhs.uk/applicants/review/apply/apply.htm#book>
- 3.25 The applicant should complete the Supplementary Information Form for Section 30 Approval (Form MCA1). This form is published as a Word document on the NRES website at <http://www.nres.npsa.nhs.uk/applicants/help/guidance.htm>. Researchers should download the form and enclose it with the main application form. (It is planned to incorporate MCA1 into the electronic on-line form later this year.)

### **Existing research requiring section 30 approval**

- 3.26 Intrusive research involving adults unable to consent for themselves, which has ethical approval and starts prior to 1 October 2007, is not required to comply with sections 30-33 until 1 October 2008. If the research is expected to conclude prior to 1 October 2008, the researcher may opt not to apply for section 30 approval at all. However, if there is any possibility that the research could continue after 1 October 2008, researchers are strongly advised to apply for section 30 approval by no later than 1 April 2008.
- 3.27 Applications may be made in either of the following ways:

#### Option 1: Supplementary application

- A supplementary application for section 30 approval may be submitted directly to the main REC that originally approved the study, provided that this REC is established under GfREC in England or Wales.

- A Notice of Substantial Amendment form should be submitted, together with form MCA1 (see paragraph 3.25), a revised protocol incorporating procedures for complying with sections 32-33 of the Act and an information sheet for consultees. Any application not including these documents is invalid.
- The REC will review the supplementary application according to its normal SOPs for *new applications*. This means it will be reviewed at a full committee meeting with at least 7 members. The REC will give a final decision to the applicant within 60 days; the clock may stop once to allow the REC to request any further information or clarification.
- If section 30 approval is not given, the research may for the time being continue on the basis of the original favourable opinion, but it would be unlawful for any further intrusive research to be carried out on or in relation to adults unable to consent for themselves from 1 October 2008. The researcher may appeal, or may submit a new full application to a flagged REC under option 2 below.
- There is no requirement for further Site-Specific Assessments (SSAs) to be carried out.

#### Option 2: New application

- A new application may be booked via CAS and submitted to another REC, which should be a flagged REC. The REC application form should be completed in full and form MCA1 enclosed (see paragraph 3.25).
- The flagged REC will review the application in the same way as any new application for section 30 approval.
- The opinion issued by the flagged REC will supersede any opinion given by the original main REC for the research. If a favourable opinion is issued, the flagged REC becomes the main REC for the remainder of the study. If an unfavourable opinion is given, the research should be regarded as no longer ethically approved. It would be unlawful for any further intrusive research to be carried out on or in relation to adults unable to consent for themselves from 1 October 2008. The researcher may appeal or submit a further application taking account of the reasons given by the REC for the unfavourable opinion.
- There is no requirement for further Site-Specific Assessments (SSAs) to be carried out.

#### **Applications for section 34 approval**

3.28 All applications for section 34 approval should be made to the main REC for the study by submitting a Notice of Substantial Amendment form together with the following:

- The Supplementary Information Form for Section 34 Approval (Form MCA2), which is published as a Word document on the NRES website at <http://www.nres.npsa.nhs.uk/applicants/help/guidance.htm>. Researchers should download the form and enclose it with the notice of amendment.
- A revised protocol incorporating procedures for complying with the Loss of Capacity Regulations.

- An information sheet for consultees.
- 3.29 The REC will review the application according to its normal procedures for substantial amendments. A decision will be communicated to the applicant within 35 days of receiving a valid application.
- 3.30 If the amendment is approved, the researcher will have lawful authority to carry out further research using the data or material taken with consent from persons who have lost capacity, in accordance with the approved protocol. If the amendment is not approved, the researcher may submit a modified amendment in the usual way.

#### **4. Non-CTIMPs conducted under the Adults with Incapacity (Scotland) Act 2000**

- 4.1 Under the Adults with Incapacity (Scotland) Act 2000 (“AWI Act”), any non-CTIMP to be conducted at one or more sites in Scotland must be approved by “the Ethics Committee” constituted by Scottish Ministers under Regulations made under the Act. This committee is currently the Scotland A REC.
- 4.2 The application should be booked through CAS and will be allocated to Scotland A REC.
- 4.3 For applications to Scotland A REC, questions A24-1 to A24-5 on the on-line form should be completed. *Form MCA1 does not apply.* The application documentation should include an information sheet and consent form for legal representatives.
- 4.4 The Scotland A REC will review the application under section 51 of the AWI Act.

#### **5. Non-CTIMPs conducted in Northern Ireland**

- 5.1 There is at present no specific legislation in Northern Ireland governing the inclusion in research of adults unable to consent for themselves. The legal position is determined solely by the common law.
- 5.2 Where any non-CTIMP is to be conducted at sites in Northern Ireland only, the application will be reviewed by one of the Health and Social Care (HSC) RECs established in Northern Ireland.
- 5.3 For applications to HSC RECs, questions A24-1 to A24-5 on the application form should be completed. *Form MCA1 does not apply.* The application documentation should include an information sheet for relatives or carers and the assent form to be used in the research.

#### **6. Research other than CTIMPs taking place in different UK countries**

- 6.1 Annex A summarises application requirements for non-CTIMPs taking place in different UK countries.



## **7. Approval for research sites**

### **Site-specific assessment (SSA)**

- 7.1 SSA is required for any new application involving adults unable to consent for themselves (except in the case of existing research where a new application is made for section 30 approval under the MCA – see Option 2 in paragraph 3.27).
- 7.2 Applications for SSA should be made by completing the Site-Specific Information Form (SSI Form) and submitting it to the local REC for the site. The site-specific assessor will advise the main REC on the suitability of the site and local Principal Investigator within 25 days of receiving a valid application. The main REC will then confirm ethical approval for the site in writing to the Chief Investigator.

### **Addition of new sites**

- 7.3 In general, the usual NRES procedures apply to addition of new sites. An application should be made for SSA to the local REC for the research site using the SSI Form.
- 7.4 However, where a non-CTIMP is extended to a new country for the first time, the following situations should be noted:
- Where research is extended to England and Wales for the first time, a new application should be made to a flagged REC in England or Wales.
  - Where research is extended to Scotland for the first time, a new application should be made to Scotland A REC.
  - Where research is extended to Northern Ireland for the first time, an application for SSA should be made to a HSC REC. In addition to the usual documentation for SSA, information should be provided about the proposed recruitment procedures in Northern Ireland, together with a copy of the information sheet(s) and assent form(s) to be used. The site-specific assessor will advise the main REC whether the recruitment procedures are suitable for Northern Ireland participants.

## **8. Further guidance on the Mental Capacity Act**

- 8.1 The main source of guidance on the MCA is the Code of Practice (see paragraph 3.1).
- 8.2 The Secretary of State and the Welsh Ministers are required by section 32(3) of the MCA to issue guidance on arrangements for nominating consultees where no willing personal consultee (e.g. a family member or other unpaid carer) can be identified. Draft guidance on nominated consultees is expected to be published for consultation shortly by the Department of Health. Researchers will be required to have regard to the guidance once it is finalised.
- 8.3 The Medical Research Council is preparing detailed practical guidance for researchers on the research provisions of the MCA.

8.4 Summaries of the statutory criteria for section 30 and section 34 approval are available at <http://www.nres.npsa.nhs.uk/recs/tools/tools.htm>.

## **9. Sources of advice**

UKCRC Research and Governance Advice Service:

[rgadvice@ukcrc.org](mailto:rgadvice@ukcrc.org)

NRES Queries Line:

[queries@nationalres.org.uk](mailto:queries@nationalres.org.uk)

## **10. Links to other web pages**

Medicines for Human Use (Clinical Trials) Regulations 2004:

<http://www.opsi.gov.uk/si/si2004/20041031.htm>

Mental Capacity Act 2005 (full text of the Act):

<http://www.opsi.gov.uk/acts/acts2005/20050009.htm>

Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2007:

<http://www.opsi.gov.uk/si/si2007/draft/20075590.htm>

Mental Capacity Act 2005 (Loss of Capacity during Research Project) (Wales) Regulations 2007:

<http://www.opsi.gov.uk/legislation/wales/WSI2007/20070837e.htm>

Mental Capacity Act Code of Practice:

[http://www.opsi.gov.uk/acts/en2005/ukpgaen\\_20050009\\_en\\_cop.pdf](http://www.opsi.gov.uk/acts/en2005/ukpgaen_20050009_en_cop.pdf)

DH guidance page on MCA:

<http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Socialcare/IMCA/MentalCapacityAct2005/index.htm>

Adults with Incapacity (Scotland) Act 2000 (full text of the Act):

<http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm>

NRES guidance on adults with incapacity  
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Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002

[http://www.england-legislation.hms0.gov.uk/legislation/scotland/ssi2002/ssi\\_20020190\\_en.pdf](http://www.england-legislation.hms0.gov.uk/legislation/scotland/ssi2002/ssi_20020190_en.pdf)

25 June 2007

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## Research other than CTIMPs taking place in different countries of the United Kingdom

<i>Countries where sites located</i>	<i>Apply to</i>	<i>Guidance on process</i>
England and/or Wales only	Any flagged REC in England or Wales	Complete the Supplementary Information Form (MCA1) and enclose with your application. Questions A24-1 to A24-5 in the on-line application form do not apply.
Scotland only	Scotland A REC	Complete questions A24-1 to A24-5 in the on-line application form. These will be enabled when you indicate that the research includes sites in Scotland.
Northern Ireland only	Any HPSS REC	Complete questions A24-1 to A24-5 in the on-line application form. These will be enabled when you indicate that the research includes sites in Northern Ireland.
England and Wales	Any flagged REC in England or Wales	Complete the Supplementary Information Form (MCA1) and enclose with your application. Questions A24-1 to A24-5 in the on-line application form do not apply.
England/Wales and Scotland	Two applications should be made: 1. The England/Wales application should be made to a flagged REC in England or Wales.  2. The Scotland application should be made to the Scotland A REC.	Separate application forms should be submitted with separate REC reference numbers. The application form can be duplicated to minimise form-filling.  For the England/Wales application, please complete the Supplementary Information Form (MCA1). (Questions A24-1 to A24-5 in the on-line application form do not apply to this application.)  For the Scotland application, please complete questions A24-

		<p>1 to A24-5.</p> <p>The applications will be reviewed separately having regard to the relevant legislation. Any favourable opinion will apply only to England/Wales or Scotland respectively. Different opinions may be given.</p>
England/Wales and Northern Ireland	Flagged REC in England or Wales	<p>Only one application is required.</p> <p>The main REC will seek advice from a HSC REC on issues relating specifically to participants in Northern Ireland. Any advice will be incorporated in the main review.</p> <p>The applicant should complete the Supplementary Information Form (MCA1) and enclose with the application. This applies only to sites in England and Wales.</p> <p>Questions A24-1 to A24-5 in the on-line application form should also be completed in relation to conduct of the research in Northern Ireland only.</p>
Scotland and Northern Ireland	Scotland A REC	<p>Only one application is required.</p> <p>The main REC will seek advice from a HSC REC on issues relating specifically to participants in Northern Ireland. Any advice will be incorporated in the main review.</p> <p>Questions A24-1 to A24-5 in the on-line application form should be completed, distinguishing the procedures to be followed in Scotland and Northern Ireland.</p>
England/Wales, Scotland and Northern Ireland	<p>Two applications should be made:</p> <p>1. Application for England/Wales/Northern Ireland</p>	<p>Separate application forms should be submitted with separate REC reference numbers. The application form</p>

	<p>should be made to a flagged REC in England or Wales.</p> <p>2. Application for Scotland should be made to the Scotland A REC.</p>	<p>can be duplicated to minimise form-filling.</p> <p>For the application to the flagged REC in England/Wales, please complete both of the following:</p> <ul style="list-style-type: none"> <li>• The Supplementary Information Form (MCA1).</li> <li>• Questions A24-1 to A24-5 in the on-line application form, which should be answered in relation to Northern Ireland only.</li> </ul> <p>For the application to Scotland A REC, please complete questions A24-1 to A24-5 in relation to Scotland only.</p> <p>The applications will be reviewed separately having regard to the relevant legislation. Any favourable opinion will apply only to England/Wales/Northern Ireland or Scotland respectively. Different opinions may be given.</p>
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**Flagged RECs for research involving adults unable to consent for themselves**

**England**

Barking & Havering REC  
Berkshire REC  
Bolton REC  
Bradford REC  
Bromley REC  
Cambridgeshire REC 3  
Camden & Islington Community REC  
Coventry REC  
Dorset REC  
Ealing and West London Mental Health Trust REC  
Essex 2 REC  
Frenchay REC  
Harrow REC  
Liverpool Adult REC  
National Hospital for Neurology and Neurosurgery and Institute of Neurology REC  
Newcastle and North Tyneside REC 2  
Norfolk REC  
North Staffordshire REC  
Northumberland REC  
Nottingham REC 1  
Sandwell and West Birmingham REC  
South East REC  
South London and Maudsley and Institute of Psychiatry REC  
South Sheffield REC  
Southampton & South West Hampshire REC 1  
York REC

**Wales**

North East Wales Health Authority Research Ethics Committee  
South East Wales Research Ethics Committee Panels B, C and D  
Wales Research Ethics Committee

**Scotland**

Scotland A Research Ethics Committee

**Northern Ireland**

HSC Research Ethics Committees 1-3