(h) Where a RTB in England, Wales or Northern Ireland has already obtained a licence from the HTA, a copy of the licence should be enclosed. (It is not mandatory to have obtained the licence before applying for ethical review.)

(i) Where an unfavourable opinion has been given to a previous application related to the same RTB, the additional criteria in paragraph 1.49 apply.

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SSA exemption

11.24 All RTB applications are SSA-exempt. The ethical review applies to the management of the tissue bank as a whole, including arrangements made with collaborators. There is no requirement to apply for ethical approval for individual research sites or centres involved in the collection, storage or use of tissue. However, local collaborators within the NHS will normally require management permission from the NHS care organisation in order to collect tissue or data from NHS patients and supply it to the tissue bank.

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Process of ethical review for RTB applications

11.25 The process of ethical review will generally be the same as for project-based applications. All references to the "Chief Investigator" in Sections 2 and 3 of the SOPs should be read as applying to the person submitting the application.

11.26 Where an unfavourable opinion is issued, the usual options for further review described in Section 7 will apply.

11.27 Substantial amendments to the terms of ethical approval for a RTB (see paragraph 11.29(f)) should be reviewed under the procedures in Section 5 in the same way as substantial amendments to specific research projects.

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General guidance on ethical review of RTBs

11.28 RECs undertaking the ethical review of RTBs should note the following general guidance:

- The review should focus particularly on the following ethical issues:
  - arrangements for the collection of new samples
  - requirements to seek consent from new donors, further consent from previous donors, or consent from relatives where the donors are deceased
  - the terms of informed consent as set out in information sheets and consent forms
  - justification for storage and use of tissue for research without specific consent where not legally required
  - the policy for provision of tissue to researchers, including arrangements for ensuring adequate scientific critique of projects and the conditions under which samples will be released
  - any plans to provide donors with feedback of any clinically significant information obtained in research using their samples.
- Ethical review should be proportionate, balancing the need to protect the safety, rights and well being of donors with the need to facilitate research of value to society as a whole.
- In England, Wales and Northern Ireland the ethical review should generally complement the process of licensing by the HTA rather than duplicate it. RECs are not required to address governance issues that will be covered in detail in the licensing process. These include the suitability of the Designated Individual and other persons named on the licence, premises, facilities and equipment for storage of samples, donor identification and tracking systems, records of consent, security and risk management, arrangements for the disposal of samples, quality systems, internal/external audit, staff training. Although there is an ethical dimension to some of these issues, it is primarily the responsibility of the HTA to set standards and ensure compliance. (This guidance does not apply in Scotland where there is no licensing process.)

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Approval conditions for RTBs

11.29 Standard approval conditions for project-based applications do not apply to RTBs. The main REC should instead issue a set of approval conditions appropriate to RTBs, which should normally include the following:

(a) Approval is given for a period of 5 years, which may be renewed on consideration of a fresh application.

(b) Except in Scotland, a copy of the licence from the HTA should be provided when available (if not already submitted). The REC should be notified if the Authority renews the licence, modifies the licensing conditions or revokes the licence, or of any change of Designated Individual.

(c) Where the applicant has applied for generic ethical approval for projects receiving tissue - without further project-specific applications being required - the following conditions apply to the release of tissue:

- Tissue may only be released for research within the fields of research described in the application form.
- The RTB should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.
- Where samples have been donated with informed consent for use in future research ("generic consent"), the RTB should be satisfied that the use of the samples complies with the terms of donor consent.
- All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e. anonymised or linked anonymised).
- Samples will not be released to any project requiring further data or tissue from donors, or any other contact with donors except under ethically approved arrangements for the feedback of clinically significant information to patients.
- A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the terms of the ethical approval and any other conditions required by the RTB.

(Note: It is not mandatory for RTBs to apply for generic ethical approval on behalf of end users. A RTB may opt to require all researchers receiving tissue to apply individually to a REC for ethical approval using the project-based application form. Where generic ethical approval is sought, it is open to the REC either to give simple ethical approval to the Bank only or to give an approval which includes generic approval for end users.)

(d) The applicant should maintain a record of all research projects for which tissue has been released. The record should contain at least the full title of the project, a brief summary of its purpose, the name of the Chief Investigator, the date on which the project was approved by the RTB and details of the tissue released. The main REC may request access to this record at any time.

(e) An annual report should be provided to the REC listing all projects for which tissue has been released in the previous year. The main REC may request additional reports on the management of the RTB at any time.

(f) Substantial amendments (see paragraph 11.27) should be notified to the main REC using the NRES Notice of Amendment form. The following should always be notified:

- Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the RTB.
- Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.
- Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.
- Request for approval to release tissue to researchers (if not sought as part of the initial application), or changes to the terms of the approval.
- Any significant change to the governance of the RTB.

(g) The main REC should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for liaison with the main REC to another person at the establishment.

(h) The main REC should be notified as soon as possible of any breach of the approval conditions, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the tissue. (Such incidents would also need to be reported immediately to the HTA.)

(i) Plans to close the RTB should be notified to the main REC (and to the HTA) as early as possible and at least two months before closure. The REC should be informed what arrangements are to be made for disposal of the tissue or transfer to another RTB. Where tissue is transferred to another RTB, the ethical approval is not transferable.

11.30 The REC has the discretion to modify these conditions or to attach other approval conditions as appropriate to the application. A template for the approval conditions (SL-AC3) is at Annex J.

11.31 *Research conducted using tissue provided by a RTB under the conditions in paragraph 11.29(c) will be considered to have ethical approval from the REC under the terms of the ethical approval for the RTB*. In England, Wales and Northern Ireland this means that the end user researcher will not require a licence from the HTA for storage of the tissue for use in relation to that research project.

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Project applications relating to tissue held by an approved RTB

11.32 Where a researcher applies for review of a specific project involving tissue held by an approved RTB, the REC reference number for the RTB should be cited in the application. It is recommended that the application should be submitted to the main REC for the RTB ("the tissue bank REC"). This will facilitate the ethical review because the REC will already be familiar with the nature of the tissue and the conditions under which it has been collected. Where for any reason the application is made to a different REC (for example, because an agenda slot is not available at the

tissue bank REC), the REC reviewing the application may consult with the tissue bank REC and request sight of relevant documentation.

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Standard letters for RTB applications

11.33 Changes have been made to standard letter templates on RED for use with RTB applications. The changes include modifications to terminology (for example, amending references to "study", "Chief Investigator" etc) and the guidance given to the applicant (for example, explaining that SSAs are not required). For guidance on the issue of approval conditions with a favourable opinion letter, see paragraphs 11.29-11.30.

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Transitional arrangements for RTBs with an existing ethical approval

11.34 The following provisions apply to any RTB that received ethical approval from a NHS REC prior to the implementation of these SOPs:

- The ethical approval will last until 30 October 2008. During this period the existing approval conditions agreed with the REC will continue to apply unless and until a new application is made.
- A new application may be made at any time under the procedures set out in these SOPs. It is recommended that new applications should be submitted to one of the panel of flagged RECs.
- The previous approval will lapse on 30 October 2008 or when a new application is approved, whichever is the earlier.

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Import and export of human tissue

11.35 The HT Act makes provisions relating to the import and export of human tissue for research purposes. In legal terms this includes the import of tissue from Scotland for

storage for use in research in England, Wales or Northern Ireland; and the export to Scotland for research purposes of tissue from the living or the deceased in England, Wales or Northern Ireland.

11.36 The HT Act empowers the HTA to issue a Code of Practice setting standards and providing guidance on the import and export of human bodies, body parts and tissue. (The draft Code of Practice was published for consultation on 3 October 2006.) The import or export of tissue is not a licensable activity. However, once it is imported the storage of tissue for use in research is licensable unless the research is ethically approved.

11.37 The consent provisions of the HT Act do not apply to tissue that has been imported.

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General policy on ethical review

11.38 It is not the role of the REC system in the UK to review research conducted outside the UK. The same policy applies to review of research-related activities conducted outside the UK in support of UK research, for example arrangements for removal or storage of tissue from overseas donors and for taking informed consent where appropriate. RECs are not required to give an ethical opinion on activities carried out outside the UK. It is more appropriate that the activities are subject to ethical review in the country concerned, taking into account its own legal requirements, ethical guidelines, culture and the language used in the consent process. Equally, it is important that research-related activities conducted in the UK in support of overseas research are ethically reviewed in the UK where they involve tissue from the living or the deceased in the UK.

11.39 The following paragraphs give guidance on applications involving import or export of tissue to or from the UK. (For the purposes of these SOPs, human tissue research or research-related activities undertaken in Scotland are considered to be UK research.)

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Applications relating to import of tissue

11.40 RECs are not required to review applications outside their normal remit under paragraph 3.1 of GAfREC and relating solely to the storage or use of imported tissue for research. The guidance in paragraph 1.84 applies to such applications. Research involving both tissue sourced within the UK and imported tissue should be accepted for review but the REC is not required to address specifically or give an opinion on any issues relating to the imported tissue.

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Applications relating to export of tissue

11.41 RECs should accept for review applications involving the export of tissue from the living or the deceased in the UK for use in research outside the UK. The REC may limit its opinion to the activities to be conducted within the UK. In particular, the REC should consider issues relating to informed consent.

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Standard letters and approval conditions

11.42 When reviewing applications involving import or export of tissue, standard letters may be amended at the discretion of the REC to clarify the terms of the opinion. Standard approval conditions may also be modified.

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Section 12 Research involving adults unable to consent for themselves

Introduction

12.1 This section of SOPs sets out the procedures governing 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 as amended ("Clinical Trials Regulations")

- Non-CTIMPs, where the legal position differs across the UK with important implications for the process of ethical review.

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A. Clinical trials of investigational medicinal products (CTIMPs)

12.2 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. The research provisions of the Mental Capacity Act 2005 do not apply to the conduct of CTIMPs.

New applications

12.3 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.

12.4 When booking the application with the Central Allocation System (CAS), the applicant should declare that the trial involves adults unable to consent for themselves.

12.5 CAS should 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 12.22).

(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.)

12.6 Where the trial is to be conducted at one or more sites in Scotland, *and* the Chief Investigator is professionally based in Scotland, it should 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.

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Ethical review

12.7 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.

12.8 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

12.9 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.

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Expert advice

12.10 The main REC is required by Regulation 15(7) of the Clinical Trials Regulations to obtain advice before giving its opinion on any trial involving adults unable to consent for themselves. The procedures set out in paragraphs 2.49-2.56 should be followed.

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B. Research other than CTIMPs

Mental Capacity Act 2005 (England and Wales)

Scope

12.11 Sections 30-34 of the Mental Capacity Act make detailed provision relating to research involving adults aged 16 or over who are unable to consent for themselves. The Act applies in England and Wales only. It has no application to CTIMPs.

12.12 The application of these provisions is not limited to medical and biomedical research, health-related research or research taking place within the NHS. It applies potentially to research in the context of social care and in any other context where participants could lack capacity to give informed consent.

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Timetable for implementation of the Act

12.13 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 comply fully with the

provisions of sections 30-33 if it is "intrusive research" involving one or more adults unable to consent for themselves. (Guidance on transitional arrangements for ethically approved research starting prior to 1 October 2007 is given in paragraphs 12.37-12.38).

12.14 For the purposes of sections 30-33, "intrusive research" is defined as:

"research that would be unlawful if carried out on or in relation to a person who had capacity to consent to it, but without his consent".

12.15 Applications for approval of intrusive research may be made from 1 July 2007 with a view to complying with sections 30-33 from 1 October 2007.

12.16 The Mental Capacity Act 2005 (Loss of Capacity during Research Project) (England) Regulations 2006 and equivalent Regulations made by the National Assembly for Wales (NAW) also come into force on 1 October 2007. These Regulations (referred to collectively in these SOPs 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.

12.17 Applications for approval for the purposes of the Loss of Capacity Regulations may be made from 1 July 2007 with a view to complying with the Regulations from 1 October 2007.

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Requirements for approval by an appropriate body

12.18 There are two types of approval for research under the Act:

- Approval under section 30 to undertake any "intrusive research" where the participants include one or more adults unable to consent for themselves ("Section 30 approval").

- Approval under the Loss of Capacity Regulations 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").

12.19 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 (referred to collectively in these SOPs as the "Appropriate Body Regulations"), 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 (to whom the functions of the NAW have now transferred by virtue of the Government of Wales Act 2006).

12.20 All RECs established under GAfREC in England and Wales 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.

12.21 An approval by any REC established under GAfREC in England or Wales applies to the conduct of the research in both England and Wales.

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Flagged RECs

12.22 Although legally any REC established under GAfREC in England and Wales may approve research under the MCA, NRES has established a panel of flagged RECs for research involving adults unable to consent for themselves. The list of flagged RECs is published on the NRES website. NRES may make changes to the list from time to time in the light of factors such as the number and pattern of applications, expertise available to RECs, and training.

12.23 The panel includes RECs in Scotland and Northern Ireland for the purposes of research taking place in those countries. (For guidance on research taking place in more than one UK country, see paragraph 12.61.)

12.24 Flagged RECs may generally review multi-domain research involving adults unable to consent. (This is subject to the provisions relating to research taking place in more than one UK country.) They may also review medical devices or research tissue bank applications involving adults unable to consent, even if not flagged for those types of applications. Prison research involving adults unable to consent in England and Wales should be submitted to a REC which is flagged for both types of application.

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New applications for section 30 approval

12.25 The policy from NRES is that all new applications for section 30 approval should be allocated to a flagged REC for review. The applicant 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. For the purposes of the Mental Capacity Act, an adult is a person aged 16 or over.

12.26 When booking the application with the Central Allocation System (CAS), the applicant should declare that the study plans to include adults unable to consent for themselves.

12.27 CAS should allocate the application to a REC in England or Wales, which is flagged for review of research involving adults unable to consent for themselves. Research taking place in England or Wales only should normally be allocated to a flagged REC in England or Wales respectively but may, if necessary, be allocated to a flagged REC in the other country. Research taking place in both countries may be allocated to any flagged REC in England or Wales.

12.28 For procedures relating to research to be conducted in Scotland or Northern Ireland as well as in England and/or Wales, see the guidance in paragraph 12.61.

12.29 Applications involving adults unable to consent for themselves in intrusive research outside the scope of paragraph 3.1 of GAfREC should be accepted for review.

12.30 If a researcher seeks to book a new application involving adults unable to consent for themselves directly with a REC, the Coordinator should decline the booking and advise booking through CAS.

12.31 If such an application is inadvertently booked and submitted to a non-flagged REC, whether directly or through CAS, it should be transferred to a flagged REC as soon as the error comes to light and CAS should be notified.

12.32 Before giving an opinion on any new application for section 30 approval, a REC should obtain expert advice on any clinical, ethical or psychosocial problems that may arise in relation to including adults unable to consent for themselves. The advice may be provided either by a member of the REC, a co-opted member or a referee under the procedures set out in paragraphs 2.53-2.55. The member or referee concerned should be a person with professional expertise relevant to the treatment or care of the population to which the research relates.

12.33 Where a favourable opinion is issued *and* section 30 approval is given to include adults unable to consent for themselves, the opinion letter should include the following additional paragraph:

"Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project."

12.34 It should be noted that there could be cases where section 30 approval is sought but not given on the basis that the research could be carried out equally effectively if confined to participants able to consent for themselves. In these circumstances, a favourable opinion could be given without section 30 approval. The REC would need to be satisfied that appropriate changes had been made to the inclusion criteria and recruitment procedures.

12.35 Where either an unfavourable opinion is given, or a favourable opinion is given but section 30 approval is withheld, the opinion letter should include the following additional paragraph:

"Mental Capacity Act 2005

The committee did not approve this research project for the purposes of the Mental Capacity Act 2005. The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project."

12.36 The Chief Investigator may either appeal or submit a further application under the procedures in Section 7. Any appeal or new application should be allocated to a flagged REC.

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Transitional arrangements for existing research in England and Wales

12.37 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.

12.38 Applications for section 30 approval 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 GAfREC in England or Wales. Supplementary applications should be booked so that an agenda slot at a full REC meeting can be reserved.

- A Notice of Substantial Amendment form should be submitted, together with the supplementary information form for section 30 approval (Form MCA1, published on the NRES website), 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 should review the supplementary application according to the normal SOPs for *new applications*. It should be reviewed at a full meeting with at least 7 members. The REC should communicate a final decision to the Chief Investigator within 60 days; the clock may stop once to request any further information or clarification.

- The Coordinator should use standard letters for new applications but with appropriate modifications. (Further guidance on use of RED and SLs will be issued through the Coordinator's Bulletin.)

- If the REC gives section 30 approval, the Coordinator should insert in the favourable opinion letter the additional text at paragraph 12.33.

- If section 30 approval is not given, the text at paragraph 12.35 should be used. 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. There is no appeal procedure but the researcher may submit a new full application to a flagged REC under option 2 below. If the main REC is itself a flagged REC, the researcher may submit another supplementary application to the main REC, or a new full application to another flagged REC.

- There is no requirement to carry out further SSAs.

<u>Option 2: New application</u>

- A new application may be booked via CAS and submitted to another REC ("the second REC"), which should be a flagged REC. The REC application form should be completed in full.

- The flagged REC should review the application in the same way as any new application for section 30 approval (see paragraphs 12.24-12.36).

- If an unfavourable opinion is given and/or the application for section 30 approval is rejected, the opinion from the original main REC remains in place. The research may continue 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 however submit a further application to the second REC or another flagged REC under the procedures in Section 7.

- 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 under the procedures in Section 7.

- There is no requirement to carry out further SSAs.

12.39 Where application for section 30 approval relates to research previously approved by Scotland A REC (previously the MREC for Scotland Committee A) or a HSC REC in Northern Ireland, the applicant must submit either a supplementary or a new application to a flagged REC in England and Wales ("second REC"). If submitting a supplementary application, the applicant should also provide a copy of the original REC application form and related correspondence for information, as the second REC will have no prior knowledge of the research in this instance. The second REC should confine its review to whether the statutory criteria for section 30 approval are met in England and Wales.

12.40 Where existing research was originally approved by an ethics committee not established under GAfREC (e.g. social care research approved by a university committee), it is not required to comply with sections 30-33 until 1 October 2008. To obtain section 30 approval, a new application should always be made to a flagged REC as under Option 2 above.

12.41 Where existing research is underway without approval from any ethics committee, it is required to comply with sections 30-33 from 1 October 2007. A full application should

be made to a flagged REC as soon as possible. Applications may be accepted after 1 October 2007 but the researcher should suspend research procedures involving adults unable to consent for themselves from that date until approval has been obtained from a flagged REC. Where such participants have been included unlawfully from 1 October 2007, the REC cannot give retrospective approval.

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Applications for section 34 approval

12.42 Where existing research has a favourable opinion from a NHS REC in England and Wales, application for section 34 approval should be made to the main REC for the study by submitting a Notice of Substantial Amendment together with the following:

- The supplementary information form for section 34 approval (form MCA2), which is published on the NRES website.
- A revised protocol incorporating procedures for complying with the Loss of Capacity Regulations.
- An information sheet for consultees.

12.43 Where the research has an existing favourable opinion from Scotland A REC or a HSC REC in Northern Ireland, the applicant should also provide a copy of the original application form and related correspondence (see paragraph 12.39).

12.44 Any application not including all the above documents is invalid.

12.45 The application should be processed according to the normal procedures for substantial amendments. A decision should be communicated to the applicant within 35 days of receipt of a valid application.

12.46 Review of the amendment should include consideration of whether the research may continue to use data or material from participants who have lost capacity, having regard to the Loss of Capacity Regulations. If approved, the Coordinator should insert the following additional paragraph in the favourable opinion letter:

"Mental Capacity Act 2005

I confirm that the committee has approved the protocol for this research to be carried out in relation to a person who [consents] [consented] to take part in the project prior to 31 March 2008 but, before the conclusion of the project, loses capacity to consent to continue to take part in it. I confirm that the committee is satisfied that there are reasonable arrangements in place for ensuring the requirements of the Regulations made under section 34 of the Mental Capacity Act 2005 are met."

12.47 If the amendment is not approved, the researcher may submit a modified amendment in the usual way.

12.48 Where an application for section 34 approval relates to research with approval from an ethics committee not established under GAfREC (e.g. social care research approved by a university committee), or with no previous ethical approval, a full application for ethical review should be submitted to a flagged REC together with Form MCA2. If the REC gives a favourable opinion and section 34 approval, the additional paragraph above should be added manually to the favourable opinion letter.

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Sources of guidance on the Mental Capacity Act

12.49 The Mental Capacity Act Code of Practice is published at: http://www.opsi.gov.uk/acts/en2005/ukpgaen_20050009_en_cop.pdf. Under section 42(4) of the Act, researchers are legally required to have regard to the Code of Practice. RECs should also have regard to the Code of Practice when considering any type of application under the Act, and in particular to the following chapters:

- 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