Section 1: New applications for ethical review

Summary

New applications must be submitted by the Chief Investigator (CI) on the national REC application form. Only one application for ethical review should be made for any research study in the UK. The ethical opinion should be given within a maximum of 60 days.

Applications are generally divided into two types, clinical trials of investigational medicinal products (CTIMPs), and all other research. The review of CTIMPs is governed by the EU Clinical Trials Directive, incorporated into UK law by the Medicines for Human Use (Clinical Trials) Regulations 2004.

Section 1 outlines the process for allocating applications to Research Ethics Committees (RECs), depending on the type of research and the number of NHS domains involved.

The Clinical Trials Regulations require CTIMPs to be reviewed by RECs that are legally "recognised" by the United Kingdom Ethics Committee Authority (UKECA). There are three types of recognised committee:

Type 1: Phase 1 clinical trials in healthy volunteers taking place anywhere in the UK
Type 2: Clinical trials in patients taking place in one NHS domain only
Type 3: Clinical trials in patients taking place anywhere in the UK.

NHS RECs that are not recognised by UKECA are referred to as "authorised" RECs and can review any NHS research other than CTIMPs.

Operation of the REC system is facilitated by a Research Ethics Database (RED). All new applications are entered on RED and assigned a unique REC reference number. The database generates documentation such as standard letters (SLs), minutes and agenda.

The NRES Central Allocation System (CAS) is a telephone booking service, which allocates certain types of application to recognised RECs throughout the UK. All CTIMPs in patients, and research involving sites in more than one NHS domain, are allocated through CAS. Phase 1 CTIMPs in healthy volunteers are booked directly with a Type 1 recognised committee. Other applications are booked directly by phone with a Local Research Ethics Committee in the NHS domain where the research is to be conducted. Applications are given a REC reference number and booked at a meeting for review.

Applications and supporting documentation must usually be submitted within 4 days of booking the application. The application form must be submitted both electronically and on paper with signatures. The REC Co-ordinator then has 5 working days to validate the application and respond to the applicant. Section 1 defines the "validation date" and the criteria for validating an application.

Guidance is given on transferring applications. In some cases a REC is not permitted to review an application and transfer to another REC is *mandatory*. Where the transfer is for operational reasons (e.g. a meeting is to be cancelled), the applicant is offered an *optional* transfer but may choose to wait for the next meeting of the first REC.

Finally, this section gives guidance on dealing with applications submitted retrospectively or which are outside the remit of a NHS REC.

Section 1 New applications for ethical review

General requirements for submission of new applications

1.1 An application for ethical review of a research study should be made by the Chief Investigator for that study. Applications may not be submitted by the sponsor(s) on behalf of the Chief Investigator. The Chief Investigator should be professionally based in the United Kingdom. For international studies with a co-ordinating investigator outside the UK, a health professional based in the UK should be nominated as the Chief Investigator responsible for the conduct of the research in the UK.

1.2 Only one application for ethical review should be submitted in relation to any research protocol to be conducted within the UK. In the case of multi-site studies requiring site-specific assessment as part of the ethical review, the procedures in Section 4 apply. In the case of international studies, an application must be made to an ethics committee in the UK, whether or not the study has a favourable ethical opinion from a committee outside the UK and whether or not it has started outside the UK.

1.3 In the case of research projects with separate protocols governing one or more sub-studies in addition to the main study, a full application should be submitted for each protocol.

1.4 All new applications for ethical review to a Research Ethics Committee (REC) in the UK should be submitted on the electronic standard NRES application form, as published on the website of the National Research Ethics Service (http://www.nres.org.uk/). The standard application form may be revised from time to time by NRES Head Office. (See paragraph 1.8 for additional documentation required for a valid application.)

1.5 Applications should be booked for review prior to submission (see paragraph 1.21-1.33 for detailed booking procedures). Bookings should be made either direct with a local Research Ethics Committee in the domain in which the research is to be conducted, or through the NRES Central Allocation System (CAS), depending on the type of application.

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Allocation of new applications

1.6 With certain exceptions, which are set out in paragraphs 1.34-1.38, new applications for ethical review should be booked and allocated for review as in Tables A and B. Circumstances in which applications may be transferred to another REC, and the procedures to be followed, are described in paragraphs 1.61-1.75.

A. Clinical trials of investigational medicinal products (CTIMPs)

Type of CTIMP	*Booking procedure*	*Allocation*
Phase 1 trial in healthy volunteers	Direct with Committee	Type 1 recognised ethics committee (either NHS REC or private committee).
Single domain trial in patients	Via CAS	Type 2 or Type 3 recognised NHS REC.
Multi-domain trial in patients	Via CAS	Type 3 recognised NHS REC.

B. All other research

Type of study	*Booking procedure*	*Allocation*
Single domain study	Direct with Committee (or exceptionally via CAS if study is likely to be extended beyond the domain)	Normally to NHS REC within the domain.
Multi-domain study	Via CAS	Normally to Type 2 or Type 3 recognised NHS REC, but CAS may allocate to any NHS REC if appropriate.

Research sites and domains

1.7 The research domain(s) is the area(s) of the UK in which the research sites are located and in which the research is actually *conducted*. It is not relevant where the research participants are resident, or which Primary Care Trust is responsible for the participants' primary care. The only domains where the research is conducted are those in which participant-related research procedures specified in the protocol - including recruitment and informed consent - are carried out. Referral of a patient (possibly from another domain) for assessment and possible recruitment is not part of the conduct of the trial. The following are not considered to be research sites:

- Clinicians or clinical units making referrals to the research team
- Research units undertaking support functions, e.g. project management, site monitoring, data analysis, report writing.

1.8 A "domain" is defined as follows:

- In England, the area covered by a NHS Strategic Health Authority
- In Wales, the area covered by one of the regional offices of the NHS Wales Department
- In Scotland, the area covered by a NHS Health Board
- The whole of Northern Ireland under the aegis of Health and Personal Social Services.

1.9 Guidance on the definition of a "research site" is set out in paragraphs 4.10-4.18.

1.10 Where the Chief Investigator plans eventually to conduct a study at sites in two or more domains, it should be allocated for review as a multi-domain study, even where research sites have so far been identified in one domain only.

1.11 In rare cases, a study may be taking place at a single research site spanning the boundaries of two domains. If the study is a CTIMP, it should be allocated by CAS to a Type 3 REC. If it is not a CTIMP, the application may be made direct to the relevant local REC.

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Allocation of CTIMPs to recognised ethics committees

1.12 A CTIMP must be reviewed by an ethics committee that (a) is recognised by UKECA under the Clinical Trials Regulations *and* (b) is recognised to review the appropriate type of CTIMP.

1.13 The terms of recognition for an ethics committee specify that it is recognised in one or more of the following categories:

Type 1 Committees recognised to review phase 1 CTIMPs in healthy volunteers taking place at any site in the United Kingdom.

Type 2 Committees recognised to review CTIMPs in patients (whether Phase 1 or later phase) taking place only at sites within the domain of the REC, i.e. an area defined by the geographical remit of the REC's appointing authority (see paragraph 1.8).

Type 3 Committees recognised to review CTIMPs in patients (whether Phase 1 or later phase) taking place at any site in the UK.

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Non-interventional trials

1.14 Trials of medicinal products which are "non-interventional" (see definition in the Glossary) are not classified as CTIMPs and do not require review by a recognised REC. They should be allocated in accordance with the normal procedures for non-CTIMPs.

1.15 The MHRA has published guidance on the interpretation of the statutory definition of CTIMP and non-interventional trials (see algorithm at Annex F). If a REC receives an application that has incorrectly been declared to be a non-CTIMP, the Co-ordinator should treat it as invalid (see paragraph 1.60). The application form will not contain a EudraCT number or all the supporting information required about a CTIMP, and it may also have been received by a REC without appropriate recognition. The application should be revised and re-booked as a CTIMP through CAS. Where there is doubt about the classification of a trial, it is the responsibility of the Chief Investigator or sponsor to seek authoritative advice from the MHRA. The REC should

proceed with the ethical review but advise the applicant of the possible consequences if the application has been wrongly classified. The applicant may be required to provide written evidence from the MHRA as part of the single request for further information (see Section 3).

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Studies involving healthy volunteers

1.16 Any clinical trial of an investigational medicinal product in which the participants are healthy volunteers should be regarded as a Phase 1 CTIMP (see definition in the Glossary) and submitted direct to a Type 1 recognised REC. There are, however, some research studies involving healthy volunteers that are not clinical trials and/or do not involve investigational medicinal products. Such studies should be allocated in accordance with the normal procedures for non-CTIMPs.

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Phase 1 trials in patients

1.17 A phase 1 CTIMP in patients may legally be reviewed by any Type 2 or Type 3 recognised REC. However, where a REC does not have the expertise to review such trials it may be agreed that it will not be allocated any Phase 1 trials.

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Allocation of non-CTIMPs

1.18 Recognition of ethics committees by UKECA legally applies only to the review of CTIMPs. In legal terms, applications relating to non-CTIMPs may be reviewed by any authorised REC. However, for operational purposes CAS will use the recognition criteria to determine the allocation of multi-domain non-CTIMPs. In practice such studies will normally be allocated to Type 3 RECs, although where special circumstances apply they may be allocated to a Type 2 REC or exceptionally to an authorised REC at the discretion of the Operations Director. Such circumstances might include the following:

- No suitable agenda slot is available at a Type 3 REC
- Another Committee has reviewed a previous, closely related study
- Another Committee has special expertise in the research field
- The study is to be conducted at a small number of sites spanning a domain boundary.

1.19 Single-domain non-CTIMPs should normally be booked direct with the appropriate local REC. (Exceptionally the applicant may opt to book through CAS if the study is likely to be extended beyond the domain.) The Chief Investigator should normally approach first the local REC for the area in which the research is to be conducted. If an agenda slot is not available, the applicant may approach any other REC within the domain. Where no local REC is established within the domain, or no agenda slot is available within the domain, the application may be submitted to a local REC in another domain within the OREC area, or exceptionally in another OREC area.

1.20 In the case of multi-site research that is to be conducted within a single domain, the applicant should normally approach first the local REC for the lead site. If an agenda slot is not available, the applicant may approach a REC for one of the other trial sites or any other REC within the domain.

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Procedures for booking and submitting applications

Telephone bookings

1.21 An applicant intending to submit a new application should first contact either the REC Office or CAS, as appropriate, in order to:

- Seek advice on the correct allocation of the application
- Book an agenda slot at the next meeting of the appropriate REC
- Obtain a REC reference number for the application, which should be entered on the application form prior to submission
- Check the closing date for submission of the application.

1.22 When giving advice, the REC Co-ordinator or CAS Co-ordinator may use model booking checklists issued by NRES Head Office. It is especially important to check

the correct allocation, taking into account the type of study and the number of domains in which the applicant plans to conduct it. It may also be useful to make a preliminary check of the validity of the application.

1.23 Co-ordinators should check that the applicant is ready to submit the application before accepting the booking, and give advice on the procedures for submission. Once the booking has been accepted, confirmation of the booking should be sent to the applicant by e-mail, together with the REC reference number and the closing date for receipt of the application. In the case of bookings made by CAS, the Co-ordinator of the REC to which the application has been allocated should also be notified by e-mail.

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Submission of application documentation

1.24 Applications through CAS should be submitted to the REC to which the application has been allocated within the next 4 working days in order to retain the booking. In the case of local applications, REC Co-ordinators may require that the application should be submitted within 4 working days *or* at any specified time until the closing date for the next meeting.

1.25 When booking agenda slots well in advance of the closing date for the next meeting, REC Co-ordinators should consider the need to give an ethical opinion within 60 days of receipt of a valid application. Applicants who intend to submit an application to a REC more than two weeks ahead of the closing date for the next meeting should normally be advised to contact another REC within the domain that is able to offer an earlier meeting slot. Bookings may be accepted more than two weeks ahead of the closing date provided that the application itself is received within two weeks of the closing date. If the application is received earlier than this, the Co-ordinator should normally arrange for it to be transferred (see paragraphs 1.62-1.63).

1.26 A complete paper copy[1] of the application form should be submitted to the appropriate REC office by the date specified by CAS or the REC Co-ordinator. The

[1] In the case of a CTIMP, the Clinical Trials Regulations allow for the Chief Investigator to sign the application by means of an electronic signature (see Glossary). Where an applicant for a CTIMP proposes to use this facility instead of submitting a paper copy with ink signature, the Co-ordinator

form should cite the online form lock code on each page and contain all relevant signatures in ink. The REC office should then upload the online version of the form electronically into RED using the lock code.

1.27 The applicant should also submit, by the specified date, a paper copy of the completed application checklist and all supporting documents as indicated on the checklist. One copy of each supporting document is required except where stated on the checklist.

1.28 Additional photocopying of application documentation for REC members is the responsibility of the REC office.

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Bookings with CAS – taking account of the applicant's preferences

1.29 Applicants making a telephone booking with CAS should be offered the first available meeting slot at an appropriate REC. If the applicant agrees, the application should be assigned to this meeting.

1.30 The applicant may decline the first available slot if he/she has a preference for a particular REC that is either geographically convenient or has prior knowledge of closely related research (for example, it has reviewed an earlier phase trial of the same medicinal product). CAS should check that the preferred REC is recognised to review the application. If so, the application should be assigned to the next meeting of this REC. If its next agenda is full, the applicant may opt to wait for the following meeting, or other options may be discussed.

1.31 Once a suitable agenda slot has been agreed with the applicant, CAS should book the application, and advise both the applicant and the REC of the REC reference number.

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should consult the OREC Manager for advice. Electronic signature should not be permitted in the case of non-CTIMPs.

1.32 If the applicant declines the next available agenda slot in order to secure a slot at their preferred REC, the validation date (see paragraph 1.45) will be the closing date of the meeting to which the application is assigned.

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OREC allocation systems

1.33 OREC Managers have the discretion to introduce systems for central allocation of applications to RECs within their areas of responsibility, subject to the approval of the Operations Director at NRES.

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Special allocations

Applications involving prisoners

1.34 Except in Scotland, any application in which the research participants include prisoners[1] (as declared on the application form at A24) should be allocated through CAS to the RECs designated by NRES Head Office to review such research. In Scotland, the application may be made direct to the relevant REC if the research is within a single domain; if it is multi-domain, it should be allocated through CAS.

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Applications involving adults with incapacity in Scotland

1.35 Any application in which the research participants include adults in Scotland who are physically or mentally unable to consent for themselves (as declared on the application form at A24) should be allocated through CAS.

1.36 If the application is a CTIMP, *and* the research is to be conducted at one or more sites in Scotland, *and* the Chief Investigator is professionally based in Scotland, it

[1] A prisoner is defined for this purpose as any inmate of the prison services of England and Wales, Scotland or Northern Ireland. This does not include patients detained under the Mental Health Act at special hospitals or other psychiatric secure units, or juvenile offenders detained in local authority secure accommodation or secure training centres.

should be allocated by CAS 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 professionally based outside Scotland, the application may be allocated to any Type 3 recognised REC. 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 applies.

1.37 If the application relates to a research study other than a CTIMP, and the research is to be conducted at one or more sites in Scotland, there is a legal requirement under the Adults with Incapacity (Scotland) Act 2000 for the research to be approved by "the Ethics Committee" constituted by Scottish Ministers under the Act. The application should therefore be allocated by CAS to the Scotland A REC. This applies even where the Chief Investigator is professionally based outside Scotland. The provisions of the 2000 Act apply to the ethical review of such research in relation to participants in Scotland.

1.38 For guidance on site-specific assessments and the addition of further sites involving adults with incapacity in Scotland, see paragraphs 4.88 and paragraph 5.68 respectively.

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Applications involving medical devices

1.38A Applications involving research into medical devices should normally be booked through CAS and allocated to the RECs designated and trained to review such research. Applicants planning to conduct the research in a single domain have the discretion to book locally with a REC within the domain. However, booking through CAS is strongly recommended.

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Applications involving research tissue banks

1.38B Applications for ethical review of research tissue banks (RTBs, see section 11) should normally be booked through CAS and allocated to the RECs designated and trained to review such applications. Applicants have the discretion to book locally with a REC within the domain. However, booking through CAS is strongly recommended.

1.38C It is also recommended that specific project applications involving use of stored tissue from ethically approved RTBs should be submitted to the "tissue bank REC" (see paragraph 11.31).

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Entry of applications on the Research Ethics Database (RED)

1.39 Applications should be entered on the Research Ethics Database (RED) at the time of the telephone booking, either by the CAS Co-ordinator or the REC Co-ordinator, as appropriate.

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Applications submitted without prior booking

1.40 If an application has been submitted without prior booking by the applicant, it will not have a REC reference number or an agreed agenda slot, and may also have been submitted to a REC that is unable to review it.

1.41 In such cases, the Co-ordinator should:

- Enter the application on RED, whether it is to be retained or transferred, and generate a REC reference number.
- Consider whether the application can be accepted for review at the next meeting of the REC. If so, the application should be booked.
- Inform CAS if the study should have been booked via CAS.
- If the application cannot be accepted for review, arrange transfer in accordance with the procedures in paragraph 1.61-1.75.

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Reserved agenda slots at recognised RECs

1.42 Recognised RECs will receive bookings both through CAS and direct from applicants. A specified number of agenda slots at each meeting should be reserved for CAS allocation by agreement of the OREC Manager and the Chair of the REC. All bookings made by CAS should be notified to the REC Co-ordinator. If a reserved slot remains unfilled one week prior to the REC's closing date for submission of applications, it may be re-allocated by the REC Co-ordinator to a local applicant; if so CAS should be notified.

1.43 The agenda of some RECs may be filled entirely by allocation from CAS. The number of agenda slots at RECs should be agreed between the OREC Manager, the Chair and the Operations Director at NRES.

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Validation of applications

The validation date

1.44 The period of 60 days, within which an ethical opinion must be given, begins when a valid application is received by any REC.

1.45 The relevant date ("the validation date") is the working day on which the complete application, including all relevant signatures and all supporting documents, is delivered to the address of the REC, either in electronic or paper format. This applies whether or not the Co-ordinator or another member of the REC office staff is present to receive the application. Where packages are not date stamped on receipt, the date of receipt should be presumed to be the working day after the day of posting (1st class post) or the third working day after posting (2nd class post).

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Decision on validation

1.46 It is normally the responsibility of the receiving REC to decide whether or not the application is valid and to notify the applicant. Notification should normally be given within 5 working days of receiving the application. Where an application is transferred to another REC, responsibility for validation passes to the REC to which the application is transferred (see paragraphs 1.72-1.75).

1.47 The decision whether or not an application is valid should normally be made by the REC Co-ordinator. The agreement of the Chair is not required.

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Validation criteria

1.48 An application should be accepted as valid if it meets all the following criteria:

(a) The applicant's checklist has been completed and submitted.

(b) All documents listed in the checklist have been submitted. (The checklists indicate which documents are mandatory for all applications.)

(c) Part A of the standard application form has been submitted, together with the applicant's declaration in Part B and other sections of Part B where applicable. (In some cases the SSI form should also be submitted initially – see paragraph 1.50). The form should be submitted on paper citing the on-line form lock code on each page. The form must be in typescript.

(d) All relevant sections and questions in the application form have been completed (see paragraph 1.51), the text is in English and the print is clearly legible.

(e) The application form has been signed by the Chief Investigator and a representative of the lead sponsor (all applications); by the lead Medical Physics Expert and lead Clinical Radiation Expert (research involving the use of radiation); and by the educational supervisor (applications submitted by students). The Chief Investigator must sign the top copy of the form. It is

acceptable for other declaration pages with signatures to be submitted separately where practical difficulties arise in signing the top copy of the form. It is also acceptable to enclose a signed letter making the appropriate declaration as an alternative to signature on the form itself.

(f) Short curriculum vitae (a maximum of two pages is recommended) have been submitted for the Chief Investigator and, in the case of student applications, for the educational supervisor.

(g) A research protocol, or an equivalent document such as a project proposal, has been submitted. The protocol should be complete; it is not acceptable to submit amendments alongside the protocol.

(h) Supporting documents have been marked with version numbers and dates in the case of the research protocol, information sheets, consent forms, letters to participants or others with an interest in the research, and any other documentation to be used in the research that is not already scientifically validated and referenced. (CVs and documents related to insurance, indemnity or funding should be dated but do not require version numbers.)

(i) The sponsor has been named on the application form. Where there is more than one sponsor, one of the co-sponsors must be named as the lead sponsor for the purpose of correspondence on the REC application.

(j) Evidence has been provided, in the case of trials with a sponsor(s) or Chief Investigator outside the NHS, that the sponsor(s) and Chief Investigator have insurance or indemnity to cover any potential liability arising from the research (see paragraphs 3.52-3.58). (In the case of research sponsored by a NHS body or with a Chief Investigator who is employed by the NHS, NHS indemnity will be ensured when final management permission is given for the research.)

(k) In the case of a CTIMP, the European Clinical Trials Database (EudraCT) number has been entered on the application form.

(l) The Chief Investigator is professionally based within the United Kingdom.

(m) In the case of a CTIMP, either the sponsor or the sponsor's legal representative is established within the European Economic Area.

(n) In the case of a CTIMP in which the sponsor has appointed a legal representative, evidence has been provided (in the form of a letter from the legal representative or contract with the sponsor) confirming that the legal representative has agreed to undertake this role. The legal representative may be a person or an organisation. No legal qualifications are required.

1.49 Where an unfavourable opinion has been given to a previous application related to the same research project, the following criteria also apply:

(o) A copy of the unfavourable opinion letter has been provided

(p) A covering letter has been provided, explaining how the new application addresses the reasons given for the unfavourable opinion.

(q) Any changes to study documents have been highlighted and documents given revised version numbers and dates where applicable.

1.50 An SSI form should also be submitted if the Chief Investigator is also the Principal Investigator for a local site covered by the main REC ("the lead site"). In such cases, the main REC should carry out the site-specific assessment (SSA) (see Section 4) for the lead site alongside the ethical review. However, no SSI form is required to be submitted initially if either of the following apply:

(i) In the case of a study declared on the application form as being SSA-exempt, no SSI form needs to be submitted at any stage of the process unless the main REC subsequently decides that SSA is required (see paragraph 4.20).

(ii) In the case of a study with one or more Principal Investigators requiring SSA, no SSI form needs to be submitted initially if the main REC has no responsibilities for any of the research sites. In such cases, the Principal Investigator(s) should submit SSI form to the relevant local RECs for SSA once the main REC has validated the application.

1.51 It is essential that Part A of the application form is completed in full. Where further details are requested if a particular box is ticked, these must be provided. In particular, where the applicant indicates at A45 that referees' or other scientific critique reports are not enclosed, he/she must justify this and describe the process of scientific review. If there is no evidence to show that scientific review has taken place prior to submission, the application may be considered invalid.

1.52 Evidence from care organisations of their agreement *in principle* to the conduct of the research is highly desirable and should be encouraged, particularly for single-site research, but is not a criterion for validation except where the care organisation is the sponsor (see 1.48(e)). The process for securing final research governance approval to proceed with the research from care organisations and/or employing organisations is separate to the process of ethical review.

1.53 Although not a formal validation criterion, it is also highly desirable that applicants provide evidence in writing that project funding has already been obtained. This is particularly important for studies that are not commercially sponsored and require significant financial support from non-NHS bodies. If the ethics application has already been made, and the funding body requires changes to the protocol, it could be necessary to submit substantial amendments or even to withdraw and re-submit the application. Co-ordinators should offer guidance to applicants about this where appropriate.

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Validation letters

1.54 If an application is valid, the REC Co-ordinator should notify the Chief Investigator using one of the following letters:

SL1 Validation of study requiring SSA
SL2 Validation of SSA-exempt study.

1.55 A copy of the validation letter should be sent to the sponsor of the research. Where more than one sponsor has been named on the application, only one of the sponsors needs to be notified. The co-sponsors should notify the REC as to which of them will be the main contact point for communications with the REC.

1.56 Co-ordinators should also send a copy of the validation letter to the appropriate care organisation in the case of any single-site research, or in the case of multi-site research where it is the REC for the lead site as well as the main REC for the application. Other care organisations at which it is planned to conduct multi-site research should be notified by the relevant REC when the application for SSA is validated (see paragraph 4.42).

1.57 The validation letter includes an invitation to the Chief Investigator to attend the REC meeting (see paragraphs 2.25-2.30). The Co-ordinator should insert details of the arrangements for the meeting, including any specific information about local meeting procedures. It may be helpful to enclose a list of members, including professional background and any specific areas of interest.

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Invalid applications

1.58 In the case of an invalid application, the REC Co-ordinator should notify the Chief Investigator of the reasons why using SL3. The application is void and should be deleted from the agenda for the next meeting. The Chief Investigator may re-book and re-submit the application, in which case it should be treated as a new application. The Co-ordinator should re-enter the application on RED and allocate a new REC reference number. The 60 day time period for review of the application does not start until a valid application is received.

1.59 Where an application is invalid but the outstanding information or documentation appears relatively straightforward, Co-ordinators may be able to follow this up with the applicant informally without needing to issue SL3. Where this occurs, the validation date is the date on which the last part of the information required for a valid application is received by the REC office.

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Applications validated in error

1.60 Where an application has been validated in error, the Co-ordinator should make every effort to address the matter with the applicant prior to the meeting. At the discretion of the Chair, further information may be distributed to members or tabled at the meeting. Wherever possible, the REC should proceed with the ethical review. Minor issues relating to the validity of the application may be addressed at the meeting or in the request made by the REC for further information or clarification following the meeting. If, however, the issues are fundamental, the application may need to be withdrawn or rejected.

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Transfer of applications to another REC

Mandatory transfer

1.61 The REC that receives an application ("the receiving REC") should arrange for "mandatory transfer" to another REC ("the second REC") as soon as possible in the following circumstances:

(a) The application relates to a CTIMP, and the receiving REC is not recognised by UKECA to review any CTIMP or is not recognised to review the appropriate class of CTIMP.

(b) The receiving REC is an authorised REC (i.e. not recognised by UKECA) and the research will not be conducted within a domain(s) for which the REC is authorised to conduct ethical review. (Exceptionally, the REC may retain the application where arrangements have been agreed with the relevant appointing authorities for the REC's scope to be extended beyond its own domain.)

(c) One of the members or deputy members of the receiving REC is named in Part A of the application as the Chief Investigator or another key investigator/collaborator in the research.

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Optional transfer

1.62 In addition, the receiving REC may arrange for "optional transfer" of an application for one of the following reasons:

(a) The application has been submitted more than two weeks ahead of the next closing date for applications.

(b) The application has not been booked in advance and cannot be accepted because the agenda for the REC's next meeting is full.

(c) The next meeting of the REC is to be postponed or cancelled due to a risk that it will not be attended by sufficient members.

(d) The application would be more appropriately reviewed by another REC.

(e) One of the members or deputy members of the receiving REC is deemed to have a significant potential conflict of interest in relation to the application.

1.63 Optional transfers under (a) (b) or (c) in paragraph 1.62 should normally take place only after consultation with the Chief Investigator by phone or e-mail, and with his/her agreement. The Chief Investigator should be offered the opportunity to have the application transferred to another REC that is able to review the application earlier than if it were retained by the receiving REC. If the application is transferred, the validation date remains the date on which it was first received by the receiving REC. However, the Chief Investigator may opt not to transfer the application and to delay review of the application until the next available meeting of the receiving REC. In this case the validation date will be the closing date for submissions to that meeting.

1.64 Although transfers under paragraph 1.62(a) (b) or (c) should normally be with the Chief Investigator's agreement, the REC Co-ordinator may proceed with the transfer with the approval of the OREC Manager if the Chief Investigator cannot be contacted.

1.65 An optional transfer under paragraph 1.62(d) should take place only after consultation with the OREC Manager and with his/her agreement.