**Title of SOP:** Making a valid application to a Research Ethics Committee

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1. **INTRODUCTION**

Research Ethics Committees (RECs) safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical.

RECs are entirely independent of research sponsors (that is, the organisations funding and hosting the research) and investigators. This enables them to put participants at the centre of their research.

All research studies must obtain a favourable opinion from a Research Ethics Committee before commencing.

2. **OBJECTIVE**

The objective of this Standard Operating Procedure (SOP) is to help researchers submit valid applications to NHS Research Ethics Committees and to avoid some of the more common mistakes on ethics forms, which can slow the process of ethical review.

3. **SCOPE**

This SOP applies to all research projects taking place within the South Eastern Health & Social Care Trust.

4. **PROCESS**

4.1 **Integrated Research Application System (IRAS)**

The Integrated Research Application System (IRAS) is a single online system for applying for permissions and approvals for health and social care/community research in the UK. It streamlines the process for seeking relevant approvals, as researchers no longer need to enter the details for a single project in separate application forms.

IRAS can be accessed at [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk).

From 1 April 2009, all new applications to NHS Research Ethics Committees are made using IRAS. The National Research Ethics Service (NRES) online application form is no longer available.

4.2 **Help with Completing the Application Form**

IRAS contains extensive guidance to support researchers in completing their application form.
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The Help page contains links to guidance, FAQs, a quick guide to using IRAS, an index to IRAS forms and questions, example application forms, and question-specific guidance.

An e-learning module has also been added to the IRAS website to help new users familiarise themselves with the application process.

4.3 Site-specific Assessment (SSA)

4.3.1 SSA at NHS sites

The review of site-specific issues is no longer undertaken by the main REC or by any local RECs. Instead, it is now the responsibility of the NHS R&D Office and is integrated into the normal research governance review required for all research conducted in or through the NHS.

The favourable opinion from the main REC is given on condition that permission is given by the R&D Office.

4.3.2 SSA at non-NHS sites

This is the responsibility of the REC system.

The REC undertaking the SSA is known as the ‘SSA REC’ and may be either the main REC or an appropriate local REC. (Designated SSA RECs may be appointed for specialist research units outside the NHS.)

4.4 REC Application Form / Checklist and Guidance

You must apply for ethical review by an NHS Research Ethics Committee (REC) using the form in the Integrated Research Applications System (IRAS). Guidance on completing the form and supporting documentation is available on the IRAS website.

All applications must be accompanied by the research protocol and relevant documents, as per the applicant's checklist (which must also be submitted). Incomplete applications cannot be validated and therefore cannot be reviewed by the REC.

4.5 Preparing to Book the Application

Applicants must ensure that their application is ready to submit when they telephone to book it in for ethical review.

In order to be ready to submit:

- the REC application form must have been completed and ready to be signed by the chief investigator
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- must also have all of the supporting documentation together, as outlined in the REC application form checklist.

All documents:

- must bear version numbers and dates (except where indicated on checklist);
- marked as mandatory on the checklist must be submitted in all cases for the application to be valid;
- should be printed on one side of the paper only;
- when collated, should not be stapled as they will need to be photocopied.

Advance bookings will not be accepted.

4.6 Booking the Application

Once you are ready to submit, you should telephone either:

- your local REC, or
- the Local Allocation System (LAS), or
- the Central Allocation System (CAS).

in order to book an agenda slot at the next meeting of the appropriate REC.

When contacting the REC / LAS / CAS you will be asked a series of questions in relation to the study, so you should have the application form in front of you to help with the booking process.

When booking, you will be offered the first available agenda slot within the UK. You may however, request review by a named committee; if you choose this option the 60-day clock will start from the submission date of the REC and not the date of application receipt. We strongly recommend that you, and in the case of student research, your academic supervisor, attend the meeting. Therefore you should choose a meeting when you will be available to attend.

When the booking process is complete you will be given the name of the REC, a REC reference number and a submission date.

You should submit your application to the REC within four working days of making the booking. (At the discretion of the REC co-ordinator, a later submission date may be agreed provided the application is received no later than the closing date for the relevant meeting.)

4.7 Where to book

There are different types of NHS Research Ethics Committees (RECs) across the UK, reviewing different kinds of studies.

The list below sets out different types of research proposals and where they need to be booked:
Student research
- Single or multi-domain
- Non-CTIMP
- Book with any REC or via the Local Allocation System (LAS) in the Strategic Health Authority

CTIMPs
- Single or multi-domain
- Book using the Central Allocation System (CAS) (to a Type 3 REC)

Medical device study
- Single or multi-domain
- Recommend booking via the Central Allocation System (CAS), but can be booked to any REC / LAS in the Strategic Health Authority

Audit or service evaluation
- Single or multi-domain
- Check with your R&D office that this is not considered research. If it is not research, no ethical review required. Check your organisation’s approval processes

Involves adults lacking capacity to consent
(that is, research falling under the Mental Capacity Act or Adults with Incapacity (Scotland) Act)
- Single or multi-domain
- Book using the Central Allocation System (to a flagged REC)

Involves prisoners / young offenders or other research undertaken in prisons in England and Wales
- Single or multi-domain
- Book using the Central Allocation System (to a flagged REC)

Phase 1 CTIMPs in healthy volunteers only
- Single or multi-domain
- Directly to an NHS REC or Independent Ethics Committee with type 1 recognition. The Central Allocation System can identify the first available agenda slot in the UK for all NHS RECs and Independent Ethics Committees (IECs) that are recognised to review Phase 1 CTIMPs in healthy volunteers. CAS will also take bookings for NHS Phase 1 CTIMPs in healthy volunteers if requested. Bookings for Independent Ethics Committees (IECs) must be made directly with an IEC.

Gene therapy or stem cell clinical trials
- Single or multi-domain
- Book via the Gene Therapy Advisory Committee (GTAC)

Establishing a research tissue bank
- We recommend using the Central Allocation System

Establishing a research database
- We recommend using the Central Allocation System
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Research funded by US Department of Health and Human Sciences
- Book using the Central Allocation System (to a flagged REC)

Research not listed above

Single domain
- Book direct with any REC / LAS

Multi-domain
- Book direct with any REC / LAS

4.8 Central Allocation System

The Central Allocation System (CAS) is the telephone booking service which identifies and allocates applications to an appropriate Research Ethics Committee (REC) for research that falls within one or more of the following categories:
- clinical trials of investigational medicinal products (CTIMPs). CAS can now provide an agenda identification service for all Type 1 RECs which can review Phase 1 CTIMPs in healthy volunteers; CAS will also take bookings for NHS Phase 1 CTIMPs in healthy volunteers if requested. Bookings for Independent Ethics Committees (IECs) must be made directly with an IEC.
- research involving medical devices;
- research involving prisoners;
- research involving adults lacking capacity;
- establishing research tissue banks;
- projects funded by the US Department of Health and Human Services (DHHS); and
- establishing research databases.

When you telephone CAS to book an application for ethical review, the call-taker will ask you a series of questions relating to your study to ensure that it is reviewed by an appropriate REC.

When booking, you will be offered the first available agenda slot within the UK. You may, however, request review by a named committee, but if you choose this option the 60-day clock will start from the submission date for the REC and not the date of application receipt.

4.9 Local Allocation System

A Local Allocation System (LAS) is a telephone booking service which allocates applications to a suitable agenda slot within a local group of Research Ethics Committees.

When you telephone a LAS to book an application for ethical review, the call-taker will ask you a series of questions relating to your study to ensure that it is reviewed by an appropriate REC.

Under some circumstances, you may be advised to contact the Central Allocation Service instead.
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When booking, you will be offered the first available agenda slot within the group of RECs served by that LAS number. You may, however, request review by a named committee but, if you choose this option, the 60-day clock will start from the submission date for the REC and not the date of application receipt.

4.10 After Submission

When the REC co-ordinator receives your application they will check that it is valid.

If you have completed your IRAS form correctly and you have submitted it with all the relevant supporting documents in time for the submission deadline, you will be issued with a validation letter within five working days, confirming that your application is valid.

If possible, you should attend the meeting at which the REC will consider your application. Please check directly with the REC co-ordinator whether this will be in person or by phone.

4.11 Attending a REC Meeting

4.11.1 What you can expect from the Committee

Between 7 and 18 members of the Research Ethics Committee (REC) will be present, together with the REC co-ordinator. It is a formal committee meeting, but the REC will wish to make this a positive and helpful experience.

The REC will be asking questions surrounding ethical issues arising from your application in order to seek reassurance that all ethical issues have been addressed.

The REC will be unable to let you know their decision at the meeting.

4.11.2 What the Committee expects from you

You should be ready to clarify any ethical issues the REC may raise with you.

It would be helpful for you to have a copy of your study documents with you.

You will not need to take notes as the REC co-ordinator will take minutes, which will form part of the decision letter sent to you.

If your study forms part of an academic qualification then it would be advisable to bring your academic or clinical supervisor with you. This gives the REC the opportunity to clarify any points directly with your supervisor.

4.12 After the Meeting

The REC’s decision will be notified to you in writing within 10 working days after the meeting.
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The letter will contain details of any revisions and clarification the REC requires and sometimes the REC may make some suggestions about your research.

If you have any queries or wish to discuss the content of your letter, you should contact the REC co-ordinator or the named person in your decision letter. Your response to that letter would normally be dealt with by the REC chair by way of delegated power (or a sub-committee).

A REC is required to give an ethical opinion on an application within 60 calendar days of the receipt of a valid application.

Where the REC considers that further information is required in order to give an opinion, it may make one request in writing for further information. The period of 60 days will be suspended pending receipt of this information.

5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS etc.

National Research Ethics Service  www.nres.npsa.nhs.uk

Integrated Research Application System  www.myresearchproject.org.uk

6. APPENDICES

None