SoECAT guidance

Are you developing an external funding application for a research project that will involve the NHS? If the answer is yes, you may need to submit a SoECAT with your grant application.

What is a SoECAT?
SoECAT stands for 'Schedule of Events Cost Attribution Tool'. It is designed to identify the NHS-based activities that you plan to undertake during a research project to ensure that any costs associated with undertaking research in the NHS are attributed and recovered correctly. It is not a tool for universities to calculate NHS costs.

What is 'cost attribution' in the context of clinical research?
Research studies involving the NHS can encompass a number of different types of activities, the funding for which is recovered via different mechanisms. The Department of Health and Social Care provides guidance on how activities should be classified to ensure that the costs of research studies are attributed correctly and consistently – this is known as ACoRD (Attributing the Costs of health and social care Research and Development). ACoRD makes a clear distinction between three types of costs: Research costs, NHS support costs, and Treatment costs. Costs are attributed based on the primary purpose of the activity (research or patient care), whilst also recognising the context within which the activity takes place.

Research Costs – activities that are being undertaken to answer the research question; these costs will end when the project ends. These costs are typically requested on a grant application and funded by the funding body. Examples include:

- screening tests/assessments to determine whether a patient is eligible to participate in a study, performed after the patient has been approached to ask if they wish to participate in the study, but before they are accepted onto the study
- Patient randomization
- Investigations, assessments and tests relating to if, how, why and when an intervention/procedure works
- Investigations, assessments and tests where the results are anonymous and unlinked to a patient identifier, or where the individual results will not be reported back to study participants or their clinicians, since such information is collected primarily for the purpose of answering the research question.
- Patient follow-up where the follow-up is not a part of individual patient clinical management
- Cash reimbursements or payments to volunteers to participate in the study
- All costs associated with placebos including but not limited to producing, formulating, disguising, shipping, storing and dispensing placebos, including administering sham treatments, since these costs do not form part of the patient's care and would not continue to be incurred once the study is finished
- Registration of trials, including MHRA clinical trial authorisation fees
- Data analysis needed to answer the questions that the research study is addressing

NHS Treatment Costs - the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the research study had ended. These are funded through normal commissioning arrangements. Examples include:

- Supplying and administering the medicine/device/therapy being studied
- Supplying and administering any active comparators - including medicines, devices or therapies, but not placebo or sham treatments
- Training of clinicians to deliver the treatment

- Investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the research study has stopped

NHS Support Costs - the additional patient care costs associated with the research, which would end once the research study had ended, even if the patient care involved continued to be provided. These are funded primarily through the local Clinical Research Networks (CRNs). Examples include:

- The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project
- Obtaining informed consent from patients where the study is a health research study, taking place within the NHS
- Additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.

The SoECAT will generate a value for each of these three cost types. The NHS research costs determined by the SoECAT will need to be incorporated into the breakdown of funding requested in your grant application, alongside the other research costs (e.g. researcher time commitments, consumables, travel). You may also be required to state the NHS Treatment and Support costs in your grant application.

When is a SoECAT required?

A SoECAT is a mandatory supporting document for grant applications to some UK funders where the proposed research will be undertaken in an NHS or Social Care setting in England, or where an NHS partner is involved in the project. This includes NIHR, MRC, and many medical research charities. It applies to all types of research studies including interventional studies, and projects collecting/using patient data, samples or questionnaires.

Where funding schemes have a two-stage application process (e.g. NIHR Research for Patient Benefit), you may only be required to submit a SoECAT at the second stage. However, you may be asked to state the total NHS Treatment and Support costs in your outline application so it is advisable to seek advice on this at an early stage during proposal development. If you are in any doubt as to whether a SoECAT is required for a grant application please consult the funder's guidance for the call.

Please note that some funders require the submission of a SoECAT even when no NHS Treatment or Support Costs will be incurred. In such cases you will need to complete the front sheet of the SoECAT template and send this to the CRN for validation before submission to the funder. The completion and accuracy of the SoECAT is a sponsor responsibility.

If the grant application is successful the SoECAT should be submitted as a supporting document when applying through the IRAS system for NHS Ethics and/or Health Research Authority approval.

What do I need to do?

Step 1: Complete the SoECAT

The SoECAT is primarily an NHS document. For interventional studies expert knowledge is required about the participant pathway, how the proposed study and will fit into the specific clinical setting, how the research differs from normal practice. It must therefore be completed by the Research and Development (R&D) Office at the lead NHS Trust where the research will be undertaken. The Research and Knowledge Exchange team at Aston can provide some general advice on the process but they do not have the expertise or authority required to complete the template.

Principal Investigators employed by Aston University should contact the R&D Office at the lead NHS Trust where the research will be carried out at an early stage during proposal development. You will need to provide them with information about your research study, such as the study protocol and timeline, and they will work with you to complete the SoECAT. If the project team involves a Co-

Investigator employed by the lead NHS Trust you may find it helpful to involve them in these discussions.
In very rare occasions where a lead NHS site is not identified at the time of submitting the grant application (because site identification will take place as part of study methodology), the local Clinical Research Network (CRN) will support completion of the SoECAT.
Researchers must not complete the template without support from their intended Sponsor.

Step 2: Approval
The completed SoECAT must be approved by the study Sponsor, which may be the lead NHS Trust or Aston University. Study Sponsorship should be discussed and agreed at an early stage during proposal development. Please contact Aston University Research Integrity Office (AURIO) to discuss the Sponsorship of your study.

Step 3: Validation
The completed approved SoECAT must be validated by an AcoRD Specialist within the CRN prior to submitting your grant application. You should allow a minimum of 10 working days for the CRN to review and validate your SoECAT. You will need to send them:

- The completed SoECAT
- Draft grant application/study protocol
- A timeline/Gantt chart detailing any NHS activities
- Email confirmation of the Sponsor's approval
- Details of the funding opportunity that you are applying to (funder, scheme and deadline)

Please note that where a SoECAT is requested by the funder but there are no NHS Treatment or Support costs the front page of the SoECAT template must still be completed and validated by the CRN before submission to the funder.

NHS Trusts as Participant Identification Centres (PICs)
For some the studies conducted by Aston University researchers, an NHS Trust may be required to access participants. If the NHS Trust's role is simply to refer potential participants to the research team at Aston, but all aspects of the research study (e.g., invitation to participate, obtaining consent, collecting data) will be undertaken either on campus or in other non-NHS settings (e.g. community centre) the NHS Trust would be classed as a Participant Identification Centre (PIC).
Activities typically undertaken by a PIC are:

- identify participants for possible participation in studies
- provide information about/or informs patients directly about a study, e.g., a clinician speaks directly to a patient
- advertise opportunities to participate in a specific study, e.g., via posters in waiting rooms

An organisation is not acting as a PIC (and is therefore classed as a research site) when it is responsible for:

- any protocol-specified assessment to determine participant eligibility for a study, e.g., a screening blood test or x-ray
- the recruitment (informed consent) of participants into a research study
- the delivery of research procedures specified in the research protocol

The PIC retains responsibility for the healthcare of the patient outside of the research, but the research site (Aston University) has a duty of care to participants in relation to the research study. Research sites are defined as organisations responsible for participant-related research procedures specified in the protocol, including recruitment and informed consent.
If an NHS Trust's only involvement is as a PIC it is unlikely that any NHS Treatment or Support costs will be incurred. In such cases you should send a copy of your grant proposal or study protocol to the Clinical Research Network and ask them to confirm that there are no NHS Treatment or Support costs

associated with the project. If a SoECAT is required by the funder, you will need to complete the front sheet of the SoECAT template and send this to the CRN for validation before submission to the funder.

Who should I contact for advice?

If you have any queries about whether a SoECAT is required for your grant application please contact the Strategic Funding Manager for your College. You should also discuss your study with the Aston University Research Integrity Office at an early stage.

If your study will involve research being undertaken in an NHS setting please contact the R&D Office at the lead NHS Trust for support in completing your SoECAT.

Clinical Research Network West Midlands are the main contact for projects where an NHS partner is involved but research activity will not be undertaken in an NHS setting or will not use NHS resources. A list of contacts by area of specialty is available here, or you can contact the Study Support team.

Further information and resources

NIHR SoECAT guidance
AcoRD Guidance
Clinical Research Network West Midlands
Aston University guidance on study sponsorship