St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)
Schedule of Event Costing Attribution Tool (SoECAT) Validation

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SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
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Associated JRES documents

SOPs	WPDs	Docs	LOGs
	General Research Definitions Working Practice Document JRESWPD0023		

Contents

1. Background

The Schedule of Events Cost Attribution Template (SoECAT) was developed and implemented across the United Kingdom by a partnership of organisations, including the Department of Health and Social Care (DHSC); NHS England and NHS Improvement (NHS E/I); Health Research Authority (HRA); NIHR Clinical Research Network (CRN); the devolved administrations (NHS Research Scotland, Health and Care Research Wales, Northern Ireland Public Health Agency); NHS Research and Development Forum; research funders and research active NHS organisations.

The SoECAT tool is for use with non-commercial research studies in the four UK nations. The SoECAT tool uses the 'Attributing the cost of health and social care Research and Development; (AcoRD) principles. AcoRD provides a framework to identify, attribute and recover the various costs associated with research in the NHS in a transparent, robust and consistent manner. The primary purpose of the SOECAT tool is to ensure that site-levels costs are appropriately attributed according to the AcoRD principles at the time of application for research funding and hence to ensure that site level Research Costs are met via that funding.

Research studies comprise of several activities which for the purpose of agreeing funding arrangements, are attributed to one of the three broad categories

- Research Costs – the costs of the research itself that end when the research ends. The activities are being undertaken purely to answer the research question.
- NHS Treatment Costs – the patient care costs, which continue to be incurred if the patient care service in question continued to be provided after the research had stopped
- NHS Support Costs – the additional patient care costs in research which would end once the research study has stopped, even if patient care involved continued to be provided.

For non-commercial studies the funding arrangements for research, NHS treatment and NHS support costs are:

- Research Costs – are met by the grant funder(s) through the award of a research grant. However, there are some specific research activities where the costs will be met by the Department of Health if they are funded by an AMRC charity.
- NHS Treatment Costs – are met through the normal commissioning process.
- NHS Support Costs – met through the Local Clinical Research Network of the National Institute of Health Research.

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the Sponsor representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) outlines the procedure within the JRES for the Schedule of Events Costing Attribution Tool (SoECAT) validation process.

This SOP only applies to St George's sponsored non-commercial studies.

4. Definitions

For general research-related acronyms used in this SOP, refer to the General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

This SOP is to be followed by all JRES responsible staff.

Any SOPs produced by the JRES must be used in conjunction with any relevant SGHFT and SGUL policies and procedures.

6. Procedure

6.1 Roles and Responsibilities

Research Governance Facilitator Officer AcoRD Specialist

The NIHR has established a network of AcoRD Specialists based across the local CRNs.

The Research Governance Facilitator Officer's (RGFO) will be trained and signed off to be the AcoRD specialists alongside the Head of Research, Research Delivery and Development Manager and Deputy Research Delivery and Development Manager for St George's.

The Research Delivery and Development Manager and/or Deputy will maintain a list of authorised RGFO AcoRD Specialists.

The RGFO as the AcoRD specialist is responsible for.

- Signposting St George's researchers and staff to resources and training to understand the principles of AcoRD and the difference between a Research Cost, Treatment Cost and NHS Service Support Cost
- Providing specialist advice and support to St George's researchers and staff for the activity attribution on the SoECAT
- Supporting attribution queries for St George's studies
- Assisting St George's staff to understand the SoECAT requirements, including service support or excess treatment costs for St George's studies
- Validating the SoECAT for submission to the funder
- Validation is a process of confirming the attribution is correct, not the costs.
- Sending validated SoECATs to South London CRN to facilitate the Excess Treatment Costs triage process, when applicable

Research Finance Officer (Pre-Award)

The Research Finance Officer (Pre-Award) if responsible for.

- Acting as the first point of contact for the lead grant applicant.
- Checking the costs within the grant application against the validated SoECAT to ensure that research costs are appropriately costed and included in the grant application.
- Reviewing the SoECAT to ensure there is no duplication of research cost funding in the grant application

Lead Grant Applicant

The Lead Grant Applicant will typically be the proposed Chief Investigator or delegated individual for the research proposal which is to be led by St George's. They can be leading on the study or leading at St George's as a collaborator. In most circumstances the Lead Grant Applicant will be the named person on the grant application.

The Lead Grant Applicant is responsible for.

- Informing the RFO (pre-award) and RGFO AcoRD Specialist in a timely manner of the grant deadlines and timelines. Any changes to the research proposal or grant application and the grant outcome (when notified by the funder).
- providing the draft protocol/study summary outlining the study delivery activities in a timely manner
- Where possible the lead grant applicant will complete the first attempt of the SOECAT for the grant application

- The lead grant applicant will need to be available to the RGFO AcoRD Specialist to support the completion and validation of the SoECAT. Should the lead grant applicant be away during this time they are responsible for assigning an appropriately training delegate.

6.2 Schedule of Events Costing Attribution Tool (SoECAT)

6.2.1 Principles and function of the SoECAT

- The SoECAT functions as a cost attribution template but is not intended primarily as a costing tool
- The SoECAT will only reflect the activities undertaken at site as per the protocol.
- The SoECAT will form part of the IRAS application document set where the research is to take place in the NHS or Health and Social Care (HSC).
- The SOECAT will form part of the UK Local Information Pack, that the sponsor or authorised delegate will share with participant NHS/HSC organisations to support the arranging of local capacity and capability.
- The SoECAT provides the Excess Treatment Cost (ETC) per participant value, which informs the ETC process.
- The values in the SoECAT use baseline costing methodology from the NIHR CRN interactive Costing Tool (iCT) before commercialisation is added. It is not expected that a simple template value will reflect the exact costs at each NHS provider/site.
- The SoECAT generates the following values
  - **Excess Treatment Cost (ETC) value** – an indication of the potential overall ETC value of the study
  - **NHS Support Cost value** – an indication of the potential overall NHS Support Costs. The values generated do not represent the cost value of the NHS support that will be provided. This is only eligible for NIHR portfolio adopted studies. Where the study is not eligible for NIHR portfolio adoption the cost will fall under research costs.
  - **Research Cost value** – an indication of the site-level research costs which are required to deliver the study. Funder application forms are designed to include all research costs. The SoECAT will help inform completion of the funder's application form (but do not have to be the same if applicants deem costs to be different). Where the study is AMRC funded the research costs are broken up in Research Cost Part A and Research Cost Part B categories. The AMRC Funder members directory lists all charities recognised as AMRC funded charities.

- SoECATs must be authorised by an authorised AcoRD Specialist prior to submission for research costs funding.
- In some circumstances some funders may not require a SoECAT but a SoECAT should still be completed for any non-commercial study eligible for NHS Support Costs (or their equivalent in a social care setting) or Excess Treatment Costs (ETCs).

6.2.2 When is a SoECAT required

The National Institute for Health Research (NIHR) requires NHS Trusts/Universities to provide the SoECAT when they are the sponsor of a clinical research study in the following situations:

- For grant applications to NIHR, Research Councils and NIHR non-commercial partner research funders, where the call relates to studies that may involve participants under an NHS or Health/Social Care duty of care. NIHR non-commercial partners include most medical research charities– the full list is here.
- For research involving participants under an NHS or Health/Social Care duty of care which is funded by any non-commercial body (this includes clinical research studies which are industry funded but University/NHS sponsored) intended for the NIHR CRN Portfolio. It is beneficial for research to be on the NIHR CRN Portfolio, and JRES will seek include clinical research studies on the Portfolio where possible.
- For the IRAS Form application where a SoECAT has been produced for the grant application.

6.3 AcoRD Principles and funding streams

6.3.1 AcoRD Principles

NHS Service Support Costs

- Only eligible for NIHR portfolio adopted studies.
- Covers all activity that would end once the research study in question has stopped, even if the patient care continued to be provided. Activities are primarily concerned with the safety of the patient, or a duty of care to the patient, during the study.
- For Example, consent, eligibility screening, initial approach of participant, screening databases for potential patients.

Treatment Costs

- These are 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 stopped. The assumption with AcoRD is that all research will be successful.
- For example, supplying & administering the medicine/device/therapy being studied, training of clinicians to deliver the intervention/treatment, investigations/tests which would continue after the study ended
- There may be a difference between the Treatment Costs and the costs of the existing standard treatment. These costs can be less (cost saving) or greater than the cost of standard treatment which is referred to as Excess Treatment Costs.

Research Costs (Part A)

- Research Costs (Part A) are activities that are being undertaken to answer the research question and only exist because the research exists.
- Research Costs are met by grant funders through the award of a research grant.
- For example, questionnaires, attendance at Site initiation visit, archiving, randomisation, placebo, follow-up

Research Costs (Part B)

- You will only be eligible to apply for Research Costs (Part B) when the funder is a member of the Association of Medical Research Charities (AMRC) charity.
- Research Costs (Part B) are activities that are being undertaken to answer the research question and only exist because the research exists.
- For example, trial coordination and management, data collection, regulatory preparation and compliance
- These costs are picked up by the Department of Health through the NIHR funded staff already embedded within the Trust

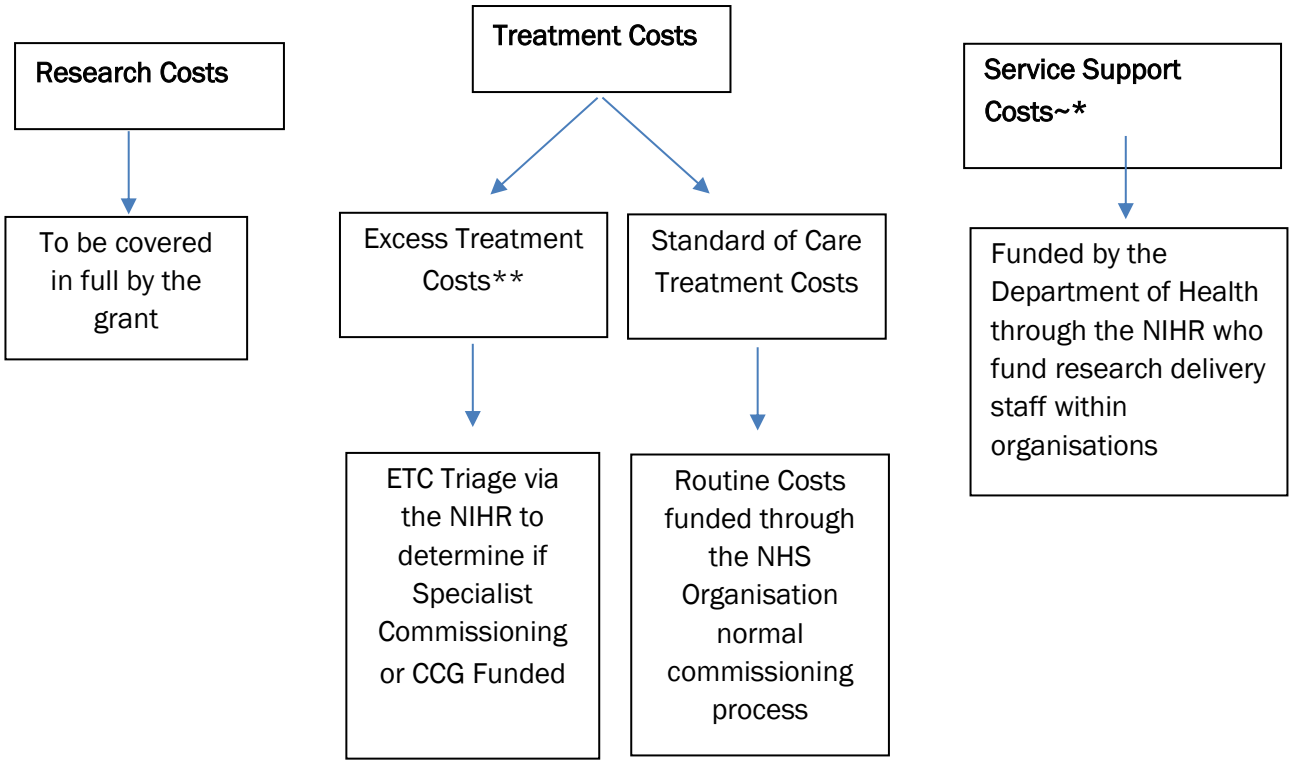
6.3.2 Useful Resources

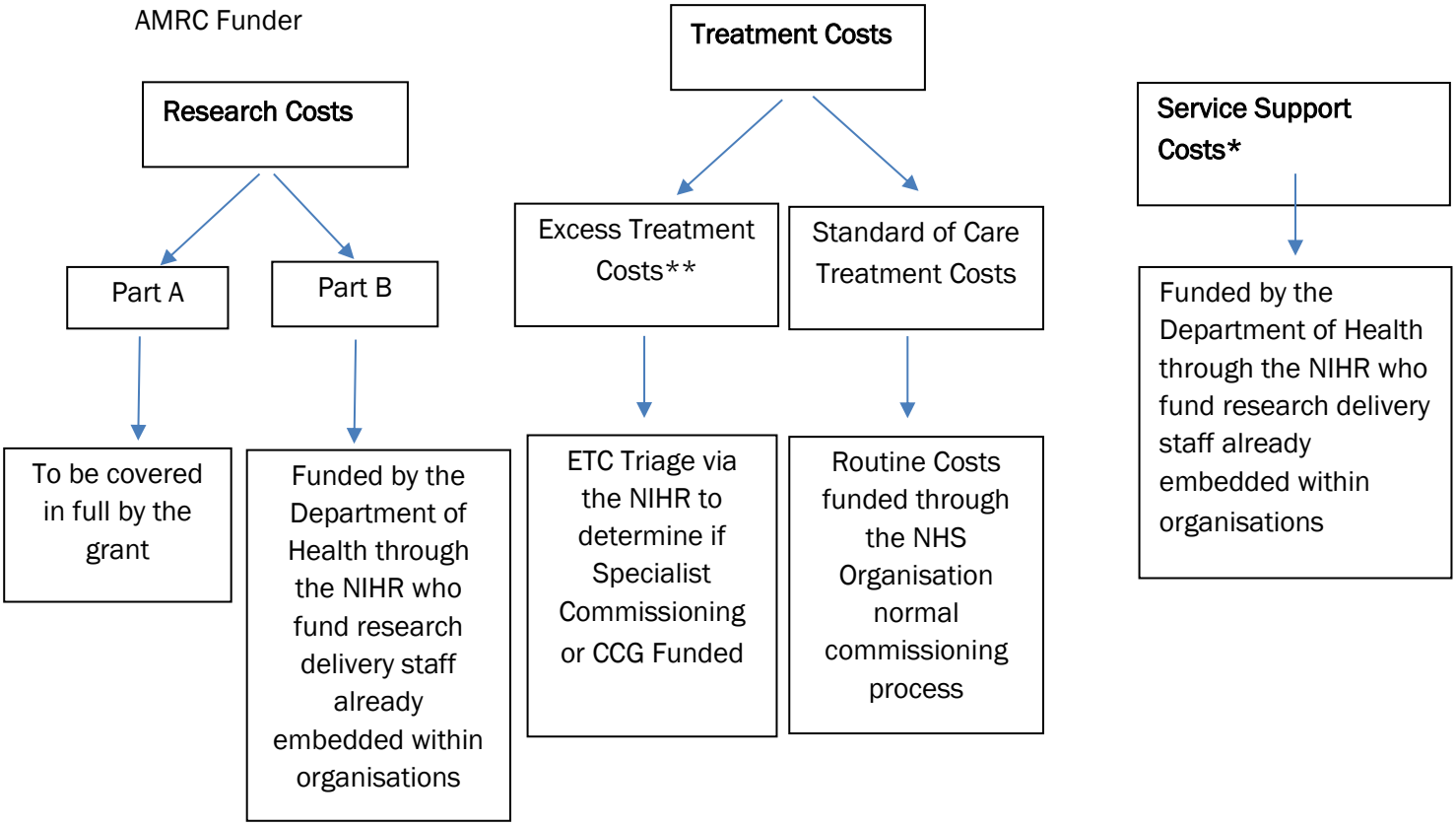
- The List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs Annex A provides useful examples of activities which fall under each AcoRD attribution
- NIHR Non-Commercial Partners List provides a list of the non-commercial partners approved by the NIHR. Studies that are funded by a NIHR non-commercial partner are automatically eligible for consideration for NIHR CRN support.
- Annex B – Department of Health and Social Care Attribute the costs of health and social care Research & Development (AcoRD) FAQs provides useful responses to frequently asked questions
- AMRC Funder members directory lists all charities recognised as AMRC funded charities.
- How to complete a SoECAT provides step by step information about each tab of the SoECAT and how to complete them

- Online SoECAT Guidance provides advice on the SoECAT for grant awards, IRAS submission, Excess Treatment Costs process etc
- Online SoECAT Top Tips Infographic

6.3.3 Funding Streams

Non-AMRC Funder





*Where the study is not eligible for NIHR CRN portfolio adoption then Service Support costs are not eligible and will come under Research Costs.

** Where a study is non-portfolio NHS England will not approve the excess treatment costs. These costs will come under Research Costs.

6.4 SoECAT Validation Process

6.4.1 For St George's studies with external funding (pre-award)

Stage 1: Pre-Award Grant application

1. The lead applicant notifies the JRES Funding Officer at research@sgul.ac.uk about their intention to apply for a grant, as soon as possible.
   1.1 The RFO will sent out an email acknowledging receipt and confirming next steps (appendix 2). The email will outline the minimum document set, information needed and the JRES timelines for pre-award funding (appendix 1).
   1.2 Should the RGFO AcoRD specialist be notified first they are to forward the notification to the RFO.

2. On receipt of the required documents and information the RFO will introduce the lead applicant to the RGFO AcoRD specialist by sending an email (appendix 3) to researchgovernance@sgul.ac.uk.
   2.1 Where the study is a Clinical Trial of an Investigations Medicinal Product (CTIMP) or device trial the request needs to copy in the Head of Research and the CTIMP Sponsorship team at sponsor@sgul.ac.uk.
   2.2 The assigned RFGO AcoRD specialist will introduce themselves to the lead applicant no later than 2 working days after being notified and advise them of the SoECAT validation requirements and process. Where possible the lead applicant will be asked to complete a first draft of the SoECAT (appendix 4).
   2.3 The assigned RGFO AcoRD specialist will act as the main point of contact for the SoECAT completion and validation.
   2.4 The RFGO AcoRD specialist will create an EDGE record for the grant application, under 'concept' status, generate a JRES R&D number and add the Pre-Award SoECAT Validation attribute to EDGE.
   2.5 The RFGO AcoRD specialist will meet with the lead applicant to complete the SoECAT. The lead applicant's advice will be required to clarify the planned participant pathway, how the proposed study will fit into the specific clinical setting and how the research differs from normal practice. The SoECAT must therefore be completed with the support of the lead applicant.
   2.6 The SoECAT is completed as a study wide tool, incorporating the site level activities for all sites, based on the protocol. Where activity may vary (e.g., routine care) the RFGO AcoRD specialist will work with the lead applicant to reflect the most common routine care pathway in the SoECAT.

2.7 Where the RFO is meeting with the lead applicant to discuss the grant proposal they will invite the RFGO AcoRD specialist to avoid any duplication of discussions, and vice versa.

2.8 The RFGO AcoRD specialist may need to seek expert knowledge/advice (e.g., pharmacy, imaging, costings for investigations)

2.9 The RFGO AcoRD specialist will work with the lead applicant to complete the SoECAT. The JRES aims to complete the initial SoECAT validation for the pre-award grant within a minimum of 5 working days or at least 4 working days prior to the grant application deadline.

3. Where funding schemes have a two-stage application process (e.g., NIHR Research for Patient Benefit), the lead applicant may only be required to submit a SoECAT at the second stage. However, it may be a requirement of the grant application that the total NHS Treatment and Support costs are added in the initial application. Therefore, the RGFO AcoRD specialist will complete the SoECAT review at pre-award stage 1 to support the grant application at stage 1.

4. Where a SoECAT is requested by the funder but there are only research costs, or the study does not intend to apply for NIHR portfolio adoption the SoECAT must still be completed and validated to allow the RFO to add the research costs to the grant application.

5. Once the SoECAT is completed the RGFO AcoRD specialist will validate the SoECAT and return to the RFO and lead applicant for inclusion in the grant application (appendix 5).

5.1 This will need to be provided a minimum of 4 working days prior to the grant deadline to enable the RFO sufficient time review the research costs and include in the grant application.

5.2 Where the study is a CTIMP or device trial the SoECAT will require validation from the Head of Research Governance and Delivery.

6. The RFGO AcoRD specialist will ensure the Pre-Award SoECAT Validation attribute is updated and upload the validated SoECAT to EDGE.

7. Throughout the grant application process the study plan may change or be adapted.

7.1 The lead applicant will keep the RFO and RFGO AcoRD specialist informed of the grant timelines, requests, and any feedback/outcomes/decisions throughout the process

7.2 The lead applicant will ensure the RFGO AcoRD specialist and RFO are informed of any changes so that the SoECAT and grant costings can be updated to reflect any changes.

8. The RFGO AcoRD specialist will ensure any pre-award updated validated versions of the SoECAT are sent to the grant lead and RFO and uploaded to EDGE.

Stage 2: Grant Awarded (Post Award)

9. The RFO (pre-award) team will notify all relevant individuals including the lead applicant and the RFGO AcoRD Specialist if the grant has been successful and awarded.

10. If there are any excess treatment costs (ETC) identified in the validated SoECAT the RFGO AcoRD specialist will submit for triage.

10.1 Where the SoECAT is completed on the excel spreadsheet the RFGO AcoRD Specialist will send the validated SoECAT and grant award letter to CRN South London Study Support Service team for ETC triage and approval.

10.2 Where the SoECAT has been completed online the RFGO AcoRD Specialist will upload the grant award letter on CPMS and submit for ETC triage and approval

11 Any amendments which will have an impact on the activity included in the SoECAT will require a re-validation of the SoECAT (e.g., addition of new intervention). The RFGO will be responsible for supporting the re-validation of the SoECAT.

11.1 If the re-validation changes the ETC value, the RFGO AcoRD specialist will need to resubmit for ETC triage (step 10)

11.2 If the re-validation changes the research costs, the RFGO AcoRD specialist will need to flag to the RFO (post-award) team as this may have an impact on the post-award funding.

11.3 Once re-validation is complete the RFGO AcoRD Specialist will upload the re-validated SoECAT to EDGE.

11.4 Where sites are in setup or open the RFGO AcoRD Specialist will forward the updated SoECAT to the Chief Investigator to disseminate to participating sites.

6.4.2 St George's sponsored studies without external funding

1. When the Chief Investigator requests sponsorship of a clinical research study that has no external funding, they are responsible for informing the JRES Research Governance & Delivery Team how the resources required to conduct the clinical research study will be provided.

2. Some studies will always need a SoECAT, due to their complexity and the potential for high costs. This applies to studies in the following IRAS categories:
    - Clinical trial of an investigational medicinal product
    - Combined trial of an investigational medicinal product and an investigational medical device
    - Clinical investigation or other study of a medical device
    - Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
    - Basic science study involving procedures with human participants
    - This also applies for multi-centre studies

3. A SoECAT may not be required if a study is single centre and falls under the following IRAS categories

- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database
- This also applies for single centre studies

4. If a SoECAT is not required, the JRES Research Governance & Delivery Team will be able to approve sponsorship and submission of the IRAS form without a SoECAT.

5. If the study is not simple and/or the resources required are not clearly identified from other areas (e.g., clinical salaries covered by the care group), then the JRES Research Governance & Delivery Team can request that a SoECAT is completed.

6. If a SoECAT is required:

6.1 The CI or delegated individual will need to complete the SoECAT template and send this and an outline of the protocol to the JRES Research Governance & Delivery Team.

6.2 The RFGO AcoRD Specialist will check the SoECAT to ensure that all activity is captured and will work with the CI or delegated individual to make any changes.

6.3 The RFGO AcoRD Specialist will attribute the activity following the DHSC 'AcoRD' Principles, and then validates the SoECAT.

6.4 The CI will need to identify where the costs detailed in the SoECAT will be covered from. It is possible that external funding may be required for the clinical research study to proceed if it cannot be identified where the costs will be covered from.

7. Please note that unfunded/solely internally funded research is unlikely to be eligible for adoption to the NIHR CRN Portfolio and therefore the NIHR CRN funded service support infrastructure will not be available for these projects. As such, resource required (outside of routine care) will be considered a cost to the project.

8. Where there is no external funding, if a SoECAT is required it will be reviewed and approved within four to six weeks.

7. References

8. Appendices

Appendix 1: JRES Funding Timelines

Extracted from Applying for Funding (sgul.ac.uk)

Type of research grant application	Minimum number of days
Non-clinical research projects	
Project just involving St George's University and/or Trust (or where St George's is part of a project led elsewhere)	10 working days
Project led by St George's University and/or Trust and includes other UK collaborators	15 working days
Project led by St George's University and/or Trust and includes other international collaborators	20 working days
Clinical research projects – not interventional/drug trials	
Project just involving St George's University and/or Trust (or where St George's is part of a project led elsewhere)	15 working days
Project led by St George's University and/or Trust and includes other UK collaborators	20 working days
Project led by St George's University and/or Trust and includes other international collaborators	25 working days
Clinical research projects – interventional/drugs trials	
Project led by St George's University and/or Trust (or where St George's is part of a project led elsewhere)	20 working days
Project led by St George's University and/or Trust and includes other UK collaborators	25 working days
Project led by St George's University and/or Trust and includes other international collaborators	30 working days

Appendix 2: Email from RFO to Lead Grant Applicant; Introduction

From: RFO

To: Lead Grant Applicant

Subject: : [Applicant Name] – [Funder Name]

Attachment: Joint Research and Enterprise Services – support and timelines for research grant applications document

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Dear [Lead Grant Applicant],

Thank you for contacting us and for the information provided. I attach a document that summarises the support JRES can offer and advises on lead times required.

The team and I prioritise applications that are within the lead times. Using the table at the bottom of page 3 of the attached document, **please would you advise on the type of application and confirm we have been left at least the minimum time to respond and support?**

Our intention is to do what we can to assist as many quality applications as possible whilst at the same time ensuring internal and external policies are met. We have a formal checklist to go through to ensure this and to help you develop the project design and objectives. Internal approval is required, as a minimum, however, depending on the size of the application and type of project, we may also need to seek the Deputy Principal or the Associate Medical Directors approval too (if the project is or involves a clinical trial).

Please would it be possible to provide the following information as soon as possible:

i) A copy of the funding opportunity; preferably a link to the call on the funder's website
ii) Proposed start date
iii) Proposed end date
iv) A copy of the draft application and/or project summary
v) Copy of the protocol, if available, if not a research plan and scientific objectives: These are the weblinks to the protocol template and guidance.
vi) If the NHS is involved a copy of the Schedule of Events Cost Attribution Template (SoECAT): These are weblinks to the guidance and template.
vii) Lead applicant or collaborator

Best Wishes,

Appendix 3: Email from RFO to RFGO notifying RFGO of grant application

From: RFO

To: researchgovernance@sgul.ac.uk; Head of Research (if CTIMP/Device); sponsor@sgul.ac.uk (if CTIMP/Device)

Subject: [Applicant Name] – [Funder Name] – request for SoECAT Validation – [Deadline]

Attachments: Documents provided by lead grant applicant (e.g., summary, draft grant application)

Dear RFGO,

Please accept this email as notification of a new grant application requiring SoECAT validation

Lead Grant Applicant Name & Email	
Funder	
Deadline for grant	
Deadline for validated SoECAT	
Grant pre-fix number	

[please add any additional relevant information available e.g. planned meeting dates]

Best Wishes

Appendix 4: Email from RFGO to lead grant applicant, initial contact

From: RFGO

To: Lead Grant Applicant

Subject: [Applicant Name] – [Funder Name] – SoECAT Validation – [Deadline]

Attachments: SoECAT excel template (if applicable); Guidance documents (where relevant)

Dear [Lead Grant Applicant],

Please allow me to introduce myself, I am the AcoRD Specialist who will work with you to support you in completing the SoECAT and validating the AcoRD attributions for your grant submission.

In order to meet the deadline for your grant submission we will need to have the SoECAT completed and validated by [deadline].

Can you please provide your availability for [add timeframe] so we can set up a meeting to go over your SoECAT.

If you haven't already done so can you please make a start on completing the SoECAT/online SoECAT and return to me, before the meeting.

I've attached some initial guidance to assist you with your first draft [amend as relevant]

- Guide to AcoRD attributions
- Guide to the SoECAT (excel)
- Guide to the online SoECAT

If you have any questions please don't hesitate to get in contact

I look forward to working with you

Best Wishes,

Appendix 5: Email from RFGO to lead grant applicant and RFO confirming SoECAT has been validated

From: RFGO

To: Lead Grant Applicant; RFO; delegated individuals involved in review; Subhir Bedi (CTIMP/Device)

Subject: [Applicant Name] – [Funder Name] – SoECAT Validation – [Grant Pre-Fix Number]

Attachments: Validated SoECAT

Dear [Lead Grant Applicant] and [RFO]

Please find attached the validated SoECAT.

Study/Proposal Title	
Funder	
AMRC Funded	(Y/N)
R&D Number	
Grant Pre-Fix Number	
NIHR Porfolio Eligible	(Y/N)
Excess Treatment Costs	(Y/N)

Please do let me know if you have any queries or need to make any adjustments.

All the best with your grant application.

Best Wishes,

Appendix 6: Pre-Award SoECAT Validation EDGE attribute

- Added to study level
- The drop down list of ‚Lead RFGO AcoRD Specialist' options will be managed by the Research Development and Delivery Manager/Deputy to ensure only authorised AcoRD specialists appear on this drop-down list.

-