NIHR | National Institute for Health and Care Research

Interactive Costing Tool Study Resource Review:

Part of the National Contract Value Review process

Standard Operating Procedure

Version: 2.3
Stage 2 implementation
September 2024

Document Control

This document is issued and maintained by the NIHR Research Delivery Network (CRN) for England with relevant Devolved Administration content provided by the equivalent organisations.

Document Information	
Document Title	Standard Operating Procedure for NIHR Interactive Costing Tool Study Resource Review
Version	Stage 2 implementation - October 2023
Supersedes	October 2023
Function	Describing the Study Resource Review of the Interactive Costing Tool (iCT) for all commercial contract studies, which forms part of the National Contract Value Review process outlined by NHS England (NHSE) in the National Directive
Effective Date	August 2024
Audience	Staff with aspects of their role relating to commercial contract research set-up, costing and contracting
Expectation	
Purpose	To define the process for a commercial representative and CI site representative or nominee to capture the National Study Resource Requirements within the Interactive Costing Tool prior to the creation of site-specific versions for participating sites .
Terminology	• *NHS Costing Expert* refers to the credentials of the individual undertaking a costing review • *iCT Study Resource Reviewer Role* refers to the specific functional role or system profile within the iCT itself. • *iCT Site Representative Role* refers to the specific functional role or system profile within the iCT itself assigned to a participating site for each study . • *iCT Company Representative Role* refers to the specific functional role or system profile within the iCT itself used by a commercial company to access and use the iCT. • *Study Resource Review* refers to the specific functional activity within the iCT to capture the agreed resource requirements for the study from which site specific version are created. • *National Contract Value Review process* refers to the collective process creation of a study specific iCT to creation of site specific version for inclusion in the UK model agreements.
Version History	
Version 2.3	• Table updated in template email 4 to capture frequency and cost of activities which are being escalated. • New email template 5 for Lead CRN to use when notifying Lead NHS Site and sponsor of an escalation. • Escalations for screen failure items is addressed in the escalation policy • Incorporating feedback from users to improve the escalation process

	• Wording added to template email 1 to support the use of the Lead Site Review Checklist and point 1.5.3 added to the process to provide more information on its use.
Version 2.2	• Updated escalation policy based on feedback - addition of site ability to escalate items that are present in the protocol schedule of activity but do not meet the 5% financial threshold. Change to Standard Email 4 to accommodate this.
Version 2.1	• Updates to reflect new escalation policy from February 2024 • Incorporating feedback from users to simplify
Version 2	• Significant updates to reflect move to Stage 2 National Contract Value Review
Version 1.2	• Section 1.3 - Update to reflect that Northern Ireland will now complete study resource review. • Section 4.5.5 and Appendix 4 - Additional template email (4) for LCRNs to use when there has been an error identified by a site with process clarity provided.
Version 1.1	• Section 2.4 - Update to process for marking study resource review as complete and addition of flowchart. • Appendix 4, Standard email 3 - Additional template email and guidance for LCRNs on re-assigning reviews • Section 2.2.5 - Additional guidance on reverting submissions • Section 1.3.5 - Additional guidance relating to non-nhs sites.
Version 1.0	*Document Creation*

Quick Links

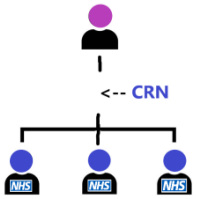
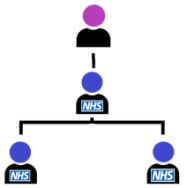
A - INTRODUCTION

Purpose

The NHSE National Directive for commercial contract research outlines the requirements for commercial research costing and contracting in the NHS.

This Standard Operating Procedure outlines how the NIHR interactive Costing Tool enables the co-creation of research site resource requirements, working in partnership between the commercial representative and Lead NHS site representative. This forms part of the work towards implementation of a National Contract Value Review process.

The requirements of the study are captured within the interactive Costing Tool, in line with the study documentation intended for regulatory submission. This takes place prior to the sharing of site-specific versions for use by any further Participating Organisations.

 NIHR quality check of consistency between protocol and costing prior to company sharing with all sites	MOVES TO	 NHS Costing Expert, with CI, undertakes National Contract Value Review, prior to company sharing with all sites

The Study Resource Review:

- promotes understanding of the national approaches to speed up costing and contracting of commercial contract research
- supports the Chief Investigator (or Lead NHS site representative) and study team to work with the commercial representative in ensuring appropriate resource requirements are defined and aligned with study documentation intended for regulatory submission
- provides expert input into resource requirements for use by further Participating Organisations and/or Devolved Administrations
- removes requirement for local adjustments
- is undertaken through the dedicated system profile: the iCT Study Resource Reviewer Role

The Study Resource Review is an informed agreement on the resource, duration and activities required to deliver the research at any site in line with the study documentation intended for regulatory submission.

The SOP describes the process steps to deliver the defined activity and does not include comprehensive guidance on content or 'how to' undertake appropriate commercial contract negotiations. This is determined by the individuals delivering the activity based on their specialist experience and knowledge.

User support

All user support for the interactive Costing Tool, including the latest national tariff within the tool is accessed here.
Further user support is available through the CRN via your local CRN/DA contact.
Additional guidance, standards documents and peer support is available via the Teams Community of Practice. Contact your local CRN/DA to gain access.

Process Analytics

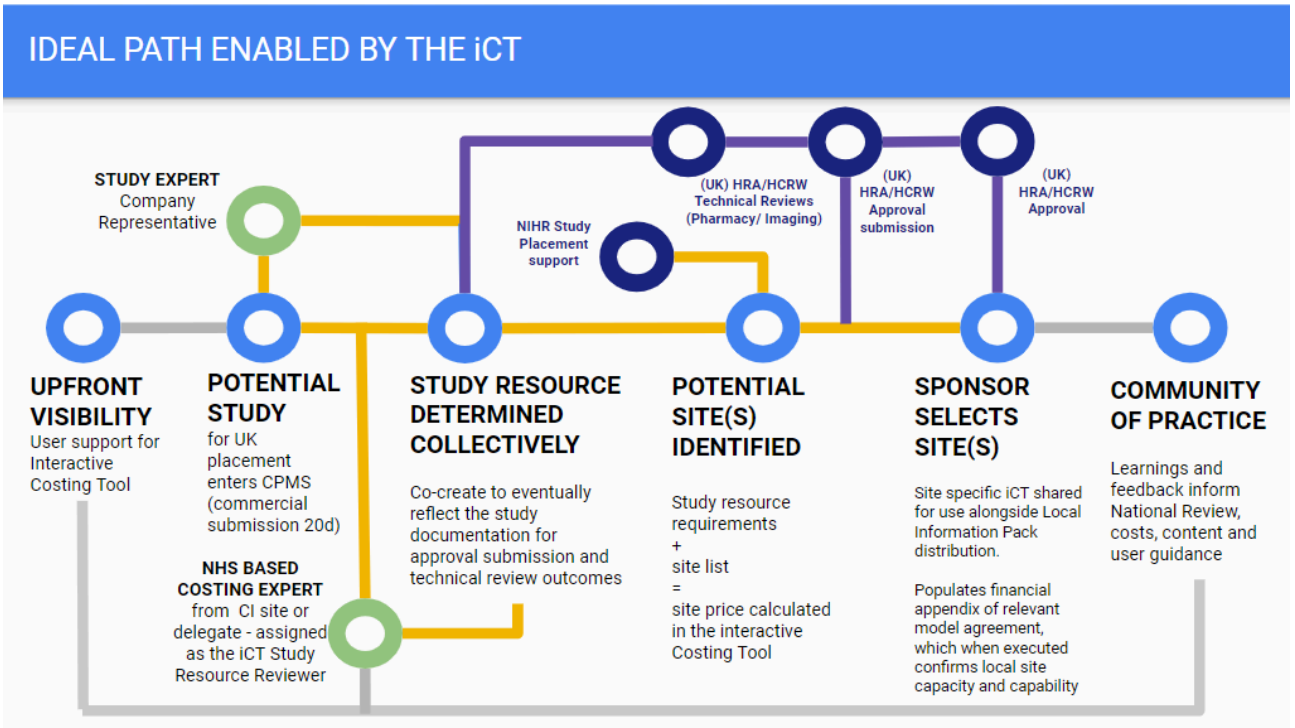
As part of the Central Portfolio Management System (CPMS), the interactive Costing Tool can auto generate timestamps for key activities including:

- Date of submission to initiate a Study Resource Review
- Date of iCT Study Resource Reviewer assignment
- Date Study Resource Review complete
- Date Site Representative(s) assigned

And can be analysed with other study dates for an overview study specific set-up timelines

- Date of Approval Submission
- Date of Approval
- Date of site confirmed (contract signature)

Figure 1: Interactive Costing Tool Study Resource Review Flowchart



B – SUBMISSION FOR NATIONALLY COORDINATED STUDY RESOURCE REVIEW USING THE INTERACTIVE COSTING TOOL

1.1 A Study Resource Review (SRR) applies to all commercial contract studies planning to run in the NHS. Where there are only non-NHS sites participating in the study (eg dentists, community pharmacies, care homes), an iCT is not required nor appropriate. The CRNCC will

revert the study resource review and advise the company that should they add NHS sites at a later date, a full review under NCVR will be required.

1.1.1 Completion of the iCT may be initiated at any stage of study planning and be revised as the study documentation is being developed.

1.1.2 CRNCC and LCRN teams should signpost commercial representatives to resources that can support them to input the information required - User Support for the tool is available on the NIHR website and through the NIHR Support for Industry webpages.

1.2 Submission of the interactive Costing Tool requires the population of supporting information within the commercial services facilitated through the NIHR CPMS.

- Submission for SRR is in line with submission via IRAS to the regulatory authorities (these must be done in parallel).
- Chief Investigator (Lead NHS Site) is confirmed and provided as part of the submission.
- Should the above not be met, the request can be reverted. When reverting the study resource review, check the Commercial study submissions - Status - Service Offerings Status, for any other services listed. Where there is an additional service, email crncc.support@nihr.ac.uk, advising that the study resource review requires reverting. The CRNCC will then make the necessary manual changes.

1.3 The CRNCC will use the CI (Lead NHS Site) information to allocate the request to a Lead CRN or Devolved Administration via the single point of contact inbox for commercial services (NCVR@hscni.net for Northern Ireland) within a maximum of 3 working days. The company representative will be cc'd to enable direct communication.

1.3.1 Where the Chief Investigator is located in a private site, the CRN CC will ask the Company Representative for the Lead NHS Organisation to assign an NHS Costing Expert as the iCT Study Resource Review role.

1.3.2 Where there are only non-NHS sites participating in the study (eg dentists, community pharmacies, care homes), an iCT is not required nor appropriate. The CRNCC will revert the study resource review and advise the company that should they add NHS sites at a later date, a full review under NCVR will be required.

1.3.3 If the company informs the allocated CRN/DA that the Lead NHS site or CI has changed/been allocated in error, the allocated LCRN/DA should pass the request on to the correct lead LCRN/DA. Standard Email 3 in Appendix 2 can be used for this purpose and allocated LCRN/DAs should use the relevant single point of contact (SPOC) email address for that region.

1.3.4 For single site studies, the single participating site should be allocated the review regardless of Chief Investigator location. The allocated Lead CRN/DA should follow the principles in 1.3.3 to reallocate it to the Lead CRN/DA for the single participating site if necessary.

1.4 The Local CRN or devolved administration teams will identify the NHS costing expert(s) based on the study information (such as therapy area, study type or required infrastructure e.g. Clinical Research Facility, Experimental Cancer Medicine Centre). LCRNs/DAs should create and follow local procedures for doing this.

1.4.1 If a willing and available NHS Costing Expert is not identified in the Lead CRN, then the request will need to be re-allocated. The Lead CRN should:

- Investigate the decline with the Lead NHS Organisation to determine the reasoning, and to see whether they can provide support to allow them to take on the review.
- If this is unsuccessful, the Lead CRN should then contact the Sponsor Representative to determine if they can suggest a second site.
- If they do not, or if the suggested site is unable to conduct the review, the Lead CRN should use the following principles:
    - When site information is available, in conjunction with the sponsor, another participating NHS organisation will be identified. The Lead CRN should contact the participating Local CRNs/DAs to request this (standard email 2 in Appendix 2).
    - If this fails, a non-participating site in another region can be considered. The Lead CRN should contact all Local CRNs/DAs to request this (standard email 2 in Appendix 2).

1.5 The Lead CRN/devolved administration support team will introduce the NHS Costing Expert(s) to the company representative using Standard Email 1 in Appendix 2. The Lead CRN should also share a copy of the NCVR Lead Site Review Checklist with the reviewer.

1.5.1 Lead CRN/DA will assign the identified NHS costing expert to the role of 'iCT Study Resource Reviewer' within CPMS. A generic account can be used to conduct the review, with the relevant Partner Organisation responsible for overseeing access.

1.5.2 This is done via the 'add study contacts' route, visible for the National Portfolio Manager role in CPMS which each LCRN Industry Single Point of Contact email is assigned.

1.5.3 The use of the NCVR Lead Site Review Checklist is encouraged to be used for all NCVR Study Reviews to help with the continuous improvement of quality and consistency across the UK.

1.6 Study documentation and operational information is required to inform the Study Resource Review and should be uploaded electronically to CPMS. This falls under the remit of the NIHR CRN Confidentiality Agreement.

1.6.1 Any further information or updates can be uploaded into the system. This may include the outcomes or contact details of any centralised technical review (e.g. Pharmacy or Imaging) accessed through pre-approval support.

1.6.2 To enable information to be shared directly by the Company Representative with the NHS Costing Expert assigned the iCT Study Resource Reviewer role, a CDA between the Company and Lead Site could also be established. A model Confidentiality Agreement is available on IRAS to avoid delays with standardised terms across the NHS. The Lead Site may already have a Confidentiality Agreement in place with the Company from previous feasibility interactions.

1.6.3 The Company provides the NHS costing expert assigned as the iCT Study Resource Reviewer with all documentation and operational information relevant to the costing review, including any outlined in the HRA/HCRW Approval or devolved administration equivalent submission minimum document set.

1.6.4 The NHS costing expert assigned as the iCT Study Resource Reviewer and Company Representative clarify the review timeline requirements at the point of introduction and/or sharing of the iCT to reach a mutual agreement that considers the needs of all parties, aiming to enable sharing the iCT with participating sites at the point of sharing the local information pack:

a) If all necessary study information is provided, the aim is to complete the review within 30 working days.

b) In some cases, technical manuals may not yet be available. If information from the technical manuals is required, the reviewer should request it from the company representative. If the company representative can provide the required information from the manuals, the review can continue.

C – NATIONALLY COORDINATED STUDY RESOURCE REVIEW

2.1 The NHS costing Expert assigned as the iCT Study Resource Reviewer works in partnership with the company representative and Chief Investigator to complete a review of the content of the Interactive Costing Tool against the protocol/schedule of events and other relevant study documentation to ensure national consistency.

2.1.1 This is the mechanism to ensure accurate creation of the resource requirement for the study and provide a high quality Interactive Costing Tool that reflects all the activities described in the protocol/schedule of events ahead of sharing with any other Participating Organisations. Communication outside the interactive Costing Tool functionality is encouraged to maximise understanding and efficiency. Ensure any amendments are made directly into the tool to maintain the full audit trail.

2.1.2 It is a study level review of the activities, resource and time allocations. The NHS Costing Expert will discuss revisions and amendments to timings and costs with the Chief Investigator and any other relevant support teams to ensure all aspects of delivery have been considered.

2.1.3 The Study Resource Review may be revised and updated prior to sharing with participating sites to reflect the study documentation as the regulatory and approval submission documentation is developed.

2.1.4 Where the iCT submitted is of poor quality, for example missing arms or a significant volume of protocol activities missing, the iCT Study Resource Reviewer reserves the right to revert the iCT to the company. It is recommended that this is discussed with the Local Industry Operations Manager as they could involve the CRN CC Business Development Manager where the company is a key account. This is not to prolong timelines, it ensures NHS resources are utilised efficiently and improves future submission quality.

2.2 When making adjustments to the Interactive Costing Tool during Study Resource Review:

2.2.1 Changes are related to the protocol/schedule of events to provide the justification for any changes to minimise negotiations. For example inclusion of missing procedure, investigation or visits as per the protocol/schedule of events.

2.2.2 Time changes are included under the assumption that these will be nationally acceptable and include context for any participating organisations to consider.

2.2.3 All adjustments and comments or justifications are included directly and made visible through the interactive Costing Tool functionality.

2.3 Once the iCT Study Resource Reviewer has completed their review, they must record this by changing the ‘status’ of the service 20d to ‘complete’ within CPMS interactive Costing Tool. Completion of this task will auto-generate a ‘service complete’ email to the company representative, and grant them access to the iCT again.

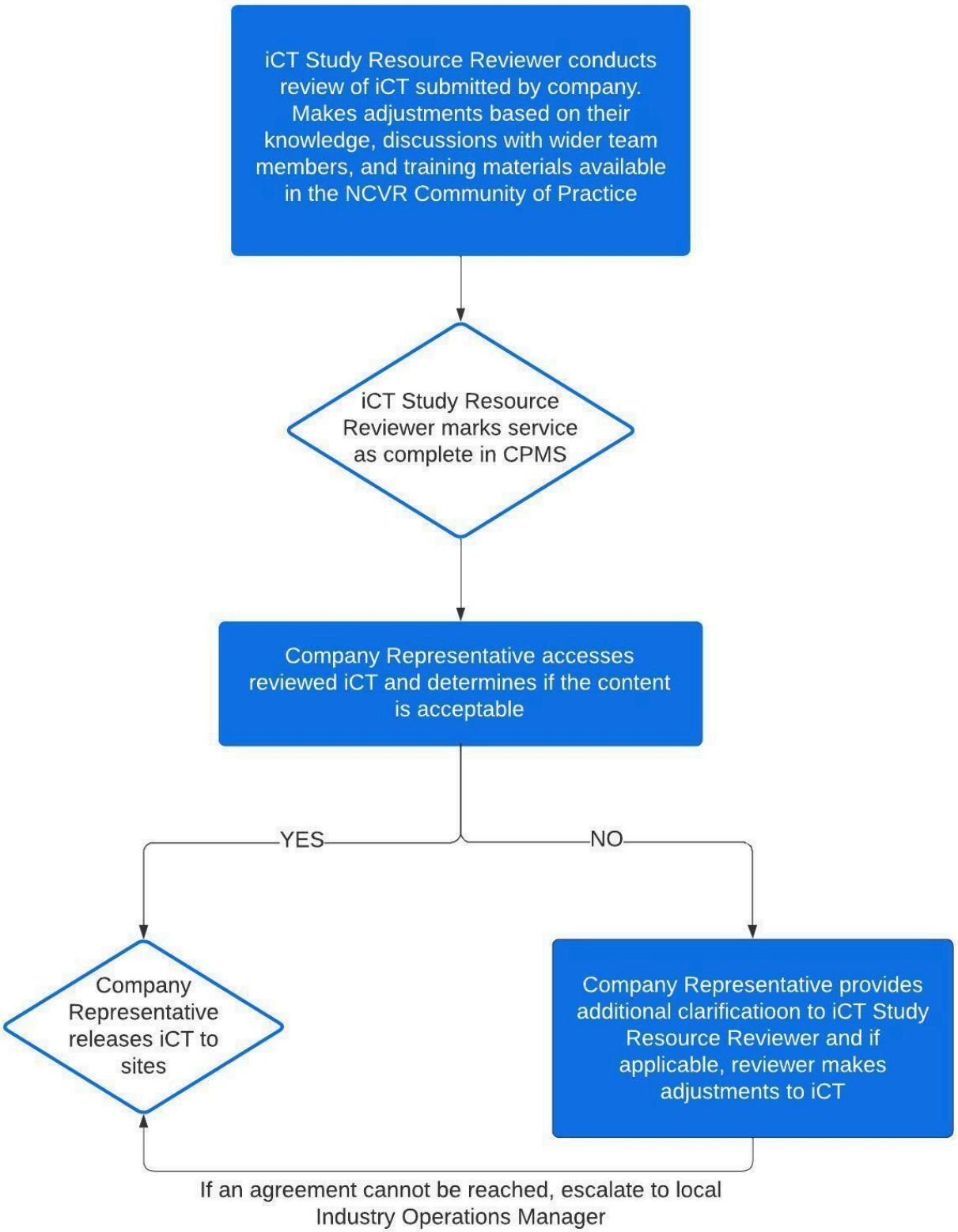
2.3.1 The Company Representative is then in control of when to release the iCT to the participating sites. They can do so immediately after the Study Resource Review if they are in agreement with the provided costs.

2.3.2 If they need to provide further context/understanding to the iCT Study Resource Reviewer on particular items they can do so prior to release to sites. The reviewer and the company representative can both still edit the iCT once the review has been marked as complete. After completion, the iCT will move to the ‘Interactive Costing Tool’ section of CPMS which can be accessed via the left hand navigation bar in CPMS.

2.3.3 If a single account has both Study Resource Reviewer and Site Representative roles attached to it, they will no longer be able to edit the review (as Site Representative overrides the Study Resource Reviewer permission). If this occurs and the reviewer needs to edit the study level tool, Lead CRN can remove the Site Representative permission.

2.3.4 See Figure 2 for a flow chart of the process.

Figure 2: Process for marking the Study Resource Review as complete flowchart



2.4 Protocol amendments impact study resource requirements received ahead of generating and sharing site prices with participating sites can be adjusted within the iCT. Any amendments after this time will need to be negotiated by each participating site.

D – COMMERCIAL REPRESENTATIVE CREATION OF PARTICIPATING SITE PRICES

4.1 Based on the study level cost, the subsequent price for each Participating Organisation is calculated through the creation of site specific versions.

4.2 The relevant 'iCT Site Representative' is added to the CPMS study record as per the interactive Costing Tool functionality and is the responsibility of the iCT Company Representative.

4.2.1 The Company Representative confirms to each iCT Site Representative whether the study has undergone a National Contract Value Review.

4.3 Each participating NHS Trust is mandated to accept the prices generated by the iCT for their organisation. This is with the exception of Phase I, IIa and ATMP trials which will be subsequently brought into the programme at a later date. **Note - there is currently (April 2024) a pilot programme assessing these studies for NCVR.**

4.4 Each participating Primary Care GP Practice is mandated to accept the prices, if they have committed to this position via the CRN/DA. The list of GP Practices in this position is here. Any practices not on this list can continue to negotiate directly with the Company Representative.

E – ESCALATION PATHWAY FOR MISSING ITEMS

4.4.1 If a participating site identifies an issue with the content of a nationally reviewed iCT, they should escalate to their Local CRN/DA using the following process:

4.4.2 Local site uses mandatory email template 4 to inform Local CRN/DA of the issue.

4.4.3 Local CRN/DA conducts validity assessment within 2 working days. Should the local CRN/DA request clarifications from the site, the site must provide further information within 2 working days, otherwise the request will be rejected. The validity assessment involves confirming the following:

- The request has been submitted on the mandatory email template.
- The escalated item does not fall within the 70% Overhead, 20% Capacity Build or Market Forces Factor. See here for information on these categories.
- The escalated items are not related to adjustments to staff timing.
    - The cost of the items totals >5% of the overall direct cost for the study (visible in the iCT homepage) **OR** the item is present in the Schedule of Events in the protocol and has been missed in the review **OR** the Lead CRN issues a waiver to this criteria, where the total cost is <5% but there would be a significant impact on the site.
- Movement of items between tabs is generally not a valid escalation, except for the following circumstances and is only applicable in relation to use of December 2023 versions of the mCTA:
    - Movement of screening activity into the 'Unscheduled activities' tab;
    - Unscheduled activities which should be part of the per patient budget

  NOTE: this will be null and void once a new version of the mCTA is released by the HRA which addresses the associated wording for screen failures.

4.4.4 If the escalation is deemed valid by the Local CRN/DA, they must enter the details into the NCVR Escalations App. This will send an automated email to the Lead CRN/DA.

4.4.5 Please note that both Wales and Northern Ireland are unable to access the NCVR Escalations app and the following emails should be contacted instead with details of the escalation;

Wales - Research-FundingSupport@wales.nhs.uk
Northern Ireland - NCVR@hscni.net

Please still log the escalation on the app so that we can track all escalations.

4.4.6 The Lead CRN/DA must forward the escalation to the Company Representative and Study Resource Reviewer (SRR) (contacts available in the Participating Sites tab of the CPMS record) within 1 working day **using mandated email template 5**.

4.4.7 The Company Representative and Study Resource Reviewer must then work together to determine if the escalated item should be entered into the study level budget. This must be completed within 10 working days.

4.4.8 If the Company Representative is happy to add the cost, there is no need to wait for approval from the national reviewer.

4.4.9 If the Company Representative does not agree with the cost, a resolution must involve the national reviewer.

4.4.10 Should 7 working days pass without a resolution, the Company Representative and Study Resource Reviewer must escalate to the Lead CRN Industry Operations Manager or equivalent. The Industry Operations Manager/equivalent will act as a senior escalation point to support the resolution.

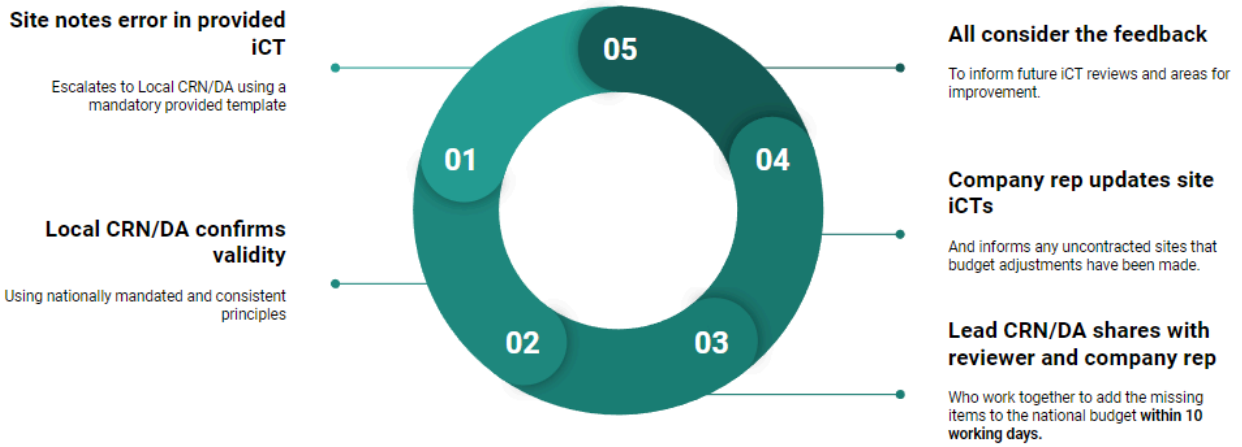
4.4.11 Any items added will be nationally applicable, and therefore incorporated into the budgets of any site that is yet to sign contracts. There are two ways to do this in the iCT once the adjustment has been made in the study level iCT:

- Company representatives delete and re-issues site level budgets to reflect new changes.
- Company representatives make manual changes in each site level budget.

4.4.12 The Company representative informs uncontracted sites of budget updates.

4.4.13 Study Resource Reviewer notifies the Lead CRN on the outcome of the escalation review.

4.4.14 Lead CRN marks the escalation as resolved in the NCVR Escalations App. This sends an automatic email to the Local CRN. Local CRN informs the escalating site of the outcome.



APPENDIX 1: SIMPLIFIED PROCESS (REDUCED DETAIL)

See here for an Infogram which outlines these 6 simplified steps.

Step 1:
Interactive Costing Tool (iCT) is populated by the company representative within the Study Resource Review service in parallel application for HRA/HCRW Approval.

Step 2:
CRNCC will validate the service submission by the company representative, ensuring that necessary documentation and Chief Investigator/Lead NHS site details are attached and notify the relevant Local CRN where the Lead NHS site is based, or Devolved administration team that a review is required.

Step 3:
Local CRN team supports the assignment of a Study Resource Reviewer.

Step 4:
Within 30 working days (aligned to HRA/HCRW study wide review timelines or Devolved Administration alternative), iCT Study Resource Reviewer completes Study Resource Review in partnership with the Chief Investigator and the company representative.

Step 5:
The Study Resource Reviewer changes the ‘status’ of the service 20d to ‘complete’.

Step 6:
Company representative assigns Site Representatives in CPMS and creates and activates the site specific iCTs. Sites accept the costs with no negotiation (subject to exceptions - Phase I, IIa, ATMP studies and GP Practices who have not confirmed voluntary adherence to NCVR).

APPENDIX 2: STANDARD EMAILS FOR LCRNs

STANDARD EMAIL 1 - Lead LCRN to send to Company Representative once NHS Costing Expert has been identified.

cc in CRNcc.support@nihr.ac.uk

SUBJECT: Study Resource Review request for [PROTOCOL REF] - NIHR CRN - CPMS ID: xxxxx

Dear [insert company contact]

CPMS ID: XXXXX - 'STUDY ACRONYM'
Protocol Ref: xxxx

Thank you for requesting our Study Resource Review Service. I am pleased to introduce you to [insert name of reviewer], who is the NHS Costing Expert who will work with you to determine the resources required for the above study. We have granted [insert name of reviewer] access to the interactive Costing Tool (iCT) in CPMS.

Please communicate directly with your assigned NHS Costing Expert to agree a mutually acceptable timeline for completion. Study documentation and operational information is required to inform the Study Resource Review and should be uploaded electronically to CPMS. Please share any documents you have with your reviewer now to ensure that the review can start as quickly as possible. This falls under the remit of the NIHR CRN Confidentiality Agreement. Should you wish to provide it directly to the NHS Costing Expert, there is a template Confidentiality Agreement available via IRAS Help.

Attached to this email is a checklist for the Study Resource Reviewer to use when reviewing the study budget. The checklist has been produced through input across the R&D Community to help improve the quality and consistency of the NCVR Study Review across the UK.

There are a number of resources available to support your understanding of the process:

Why a UK National Contract Value Review? - Infogram

How the iCT user roles support UK National Contract Value Review - Infogram

iCT User Role Profile - Company Representative - Infogram

iCT User Role Profile - Study Resource Reviewer - Infogram

iCT User Role Profile - Site Representative - Infogram

iCT Guidance and Supporting Information - Including Tariff

National Escalation Pathway - Infogram

If you have not yet submitted for NIHR CRN Feasibility Services, please do so as soon as possible. This will enable you to access NIHR Support for your study and avoid any delays to sites accessing the costing tool. Section E of our Accessing Feasibility Services guidance document provides step by step instructions on how to do this.

Once the Study Resource Review is complete, you can release the agreed template to your participating sites. NHS trusts are mandated to accept the costs with no local negotiation. Many primary care sites have voluntarily committed to accepting the costs with no local negotiation (see here). Site Representatives can escalate errors in the review via their Local CRN Industry Team. **We would advise that you inform your participating sites that the study has been assessed under National Contract Value Review.**

As part of our services, we offer a Study Start-up Call to all our commercial partners to discuss the set-up of your study in the UK, and identify and resolve any challenges you may be facing. If this is something you would like to take advantage of, please let us know.

Kind regards,

Lead LCRN

STANDARD EMAIL 2 - Lead LCRN to send to Local CRNs/DAs to request re-allocation where they do not have a reviewer with capacity/capability

SUBJECT: Study Resource Review request for [Short Title] - NIHR CRN - CPMS ID: xxxxx

Dear Local CRNs,

CPMS ID: XXXXX - 'STUDY ACRONYM'
Protocol Ref: xxxx

We currently do not have a Study Resource Reviewer available in our region for this request.
Delete depending on applicability: [We are contacting you because one or more of your local sites is listed as a Participating Organisation in CPMS] **OR** [We are contacting you as no Participating Site is available to conduct the review].

Delete/amend depending on applicability: Below are sites that are currently listed as formally selected by the Sponsor:

- *Insert site details*

Please can you let us know by *[INSERT DATE- NO LONGER THAN 3 WORKING DAYS]* (if you are able to conduct this on our behalf, and provide the name of the NHS Costing Expert to enable us to make the introduction to the Company Representative.

Kind regards,

Lead CRN

STANDARD EMAIL 3 –Allocated LCRN to send to Lead LCRN SPOC address, when reassigning review following new details of the CI/Lead Site from the company.

SUBJECT: Study Resource Review request for [Short Title] - NIHR CRN - CPMS ID: xxxxx

CC in -CRNcc.support@nihr.ac.uk

Dear XXXX LCRN,

CPMS ID: XXXXX - 'STUDY ACRONYM'
Protocol Ref: xxxx

The above Study Resource Review has been allocated to our Local CRN. After discussion with the company, we now understand that the Chief Investigator/Lead NHS site is based in your region. We are therefore forwarding this to you for action.

Chief Investigator Name:
Site Name:

CRNCC team cc'd for information.

Kind regards,

Local CRN

STANDARD EMAIL 4 – Mandatory email for sites to submit an escalation request to their Local CRN

The following email template must be used by sites to escalate a cost item. Escalations not on this standard template will not be accepted by the Local CRN/DA.

Dear Local CRN/DA,

CPMS ID:
Study Title:

Our site has reviewed the content of the iCT for the above study which has had a review conducted under the NCVR process and we require items to be escalated. I confirm the following:

- The costs are not covered by the descriptions provided of the 70% overhead, 20% capacity build or local Market Forces Factor.
- The costs do not relate to timing adjustments to the per patient budget.
- DELETE AS APPROPRIATE - [The items represent >5% of the per patient budget]/[The items are part of the Schedule of Events in the protocol]/[We request a waiver of the 5% budget threshold due to significant local impact - *provide additional details*]

Tariff Code	Cost Description and Justification	Tariff cost or estimated cost (If non-tariff).*	Frequency of activity**

*For non-tariff procedures add staff grade and time. For non-tariff investigations the activity cost excluding capacity building allowance and indirect costs and MFF

** add each visit, all or some participants, and/or unscheduled activities as appropriate

Kind regards,

Site

Standard Email 5 - Mandated for Lead CRN use when sending an escalation to the Lead NHS site and Sponsor

The below email is to be used to forward the NIHR CRN Escalation App output to the Sponsor and Lead NHS Site. Please make every effort to tidy the email output before forwarding on.

Dear Sponsor/CRO and Study Resource Reviewer,

CPMS ID:
Study Title:

Please see the escalation below for this study. Please note that Escalations should be reviewed within **10 working days from the date of this email**. If there are any issues in meeting this timeframe please let us know so that we can communicate with the escalating site. Please remember that study set-up at participating sites can be impacted through any delays to review of this escalation.

Any items which the sponsor is happy to add then they should be added into the iCT (Study level). Any items that are to be rejected, please let us know so that we can inform the escalating site.

Please remember that this is an escalation to the study level budget and once updated any site level iCTs will then need to be deleted and re-released for all sites that have not yet signed a contract.

The CRN will endeavour to let the escalating site know about the outcome of this escalation, but it is the sponsors responsibility to let all other sites know about the changes to the study budget as a result of this amendment.

Kind regards,
Lead CRN