

| <b>Stage 1 of NCVR – Implementation steps</b>  | <b>Change from current process</b>  |
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| Commercial companies will be able to see declaration of adherence to the costs generated by the standard costing methodology for each NHS organisation. This will inform site identification.  | Provides system wide intelligence – Currently sponsors only find out if individual sites adhere to iCT generated costs when the site has been selected and negotiations are underway. |
| A commercial company will complete and iterate the iCT to reflect the study requirements outlined in the study documentation and information to be submitted for approval. National resources and Local CRN support based on the location of the lead site is available as necessary for using the tool.   | No change.  |
| Submission of the iCT to the CRN will enable identification of the chief investigator site UK national contract value review coordinator.  | Combines Local CRN/DA validation (quality check for all protocol items listed) with a site level review.  |
| The UK national contract value review coordinator and commercial representative will work in partnership to undertake a national review to confirm the study requirements in the iCT are reflective of the study to be submitted for approvals. The allocated UK national contract value review coordinator will work with the relevant NHS staff, such as the chief investigator, study team or allied professionals (for example pharmacy or radiology), and the commercial representative to ensure the iCT reflects the NHS resource requirements to undertake all the activities contained within the study protocol and supporting study documentation that will form the approval submission. | This approach expands scope of chief investigator site responsibilities i.e. ensure resource is appropriately defined to enable delivery of study.                                    |
| Once the study level iCT has been agreed, the site-specific versions will be created to embed in the model agreement for each selected site.   | Site specific versions created following NCVR, rather than after CRN/DA validation.   |

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| <p>The finance schedule in the relevant model agreement for each NHS organisation participating in the study will reflect the finalised study values in the iCT and any NHS organisation-specific price as relevant, in line with the declaration</p>  | <p>No change.</p>   |
| <p>Where organisations have declared adherence to the costs generated by the Standard Costing Methodology, there will be no local site re-negotiation on price or activity. There will be an escalation process in the event of a site having concern that there is an error in the iCT. Emerging concerns will be captured to refine the operational process for the contract value review.</p> | <p>Defined escalation for working outside national directive.</p> |
| <p>Local site level adjustments for inclusion of activities dependent on-site type or local delivery mechanisms (e.g., use of clinical research facility) will be reflected in the site level iCT agreed between the sponsor and that individual site.</p>   | <p>No change.</p>   |
| <p>The study model agreement and finance schedule will be signed by NHS organisations in England or Wales when local capacity and capability can be confirmed, subsequent to the conclusion of the NCVR contract review process.</p>   | <p>No change.</p>   |
| <p>Executing the model agreement is confirmation of the site specific costs:</p> <ul style="list-style-type: none"> <li>• Protocol amendments impacting costs are reflected at site level</li> <li>• An escalation process (to act as a dispute resolution pathway) is defined for use as required by the NHS or commercial sponsor.</li> </ul>  | <p>No change.</p>   |