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# National Directive on Commercial Contract Research Studies

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# Introduction

The NHS Standard Contract requires that from 1 October 2018, all NHS providers in England will use the new commercial contract research set-up and reporting processes. This National Directive sets out what these processes involve. It will continue to be reviewed and revised throughout 2019 and onwards, building on learning gained during the introduction phase of the single/national contract value review process as discussed in section 4.

A commercial contract research study is a research project that is fully sponsored and fully funded by a commercial company, regardless of National Institute for Health Research Clinical Research Network (NIHR CRN) portfolio status. For the avoidance of doubt, this excludes Investigator-initiated Trials (defined as studies sponsored by a non-commercial entity e.g. University or NHS, with some level of funding being provided by a commercial organisation) and other industry collaborative studies not solely sponsored by a commercial entity, which are considered non-commercial studies.

NHS England's Twelve Actions to Support and Apply Research in the NHS<sup>1</sup> recognise that the NHS is a vibrant research environment but that more should be done to facilitate research and innovation in the NHS. In 2017 a public consultation set out joint options from NHS England and NHS Improvement, the National Institute for Health Research (NIHR) and the Health Research Authority (HRA) to simplify arrangements for research in the NHS in England and associated changes to the terms of the NHS Standard Contract in England. The response, which was published in May 2018, sets out specific actions to simplify and standardise processes for commercial contract research set up and reporting. The Standard Contract has been modified as a result, to place a contractual obligation on NHS providers in England to adhere to the new streamlined processes set out in this National Direction, specifically:

1 <https://www.england.nhs.uk/publication/12-actions-to-support-and-apply-research-in-the-nhs/>

- mandated use of an unmodified model agreement,
- mandated use of standard costing methodology,
- introduction of a national contract value review process.

The twelve actions are supported by both the Second Life Sciences Sector Deal, which was published in December 2018, and the NHS Long Term Plan, which was published in January 2019. Both reinforce a long-term commitment to creating the best environment for clinical research and making the UK one of the best places in the world to do biomedical, clinical and medical innovation research. The national contract value review is set out in Saving and Improving Lives; The future of UK

Clinical Delivery<sup>2</sup>, which was published 23 March 2021 and is overseen via the Research Recovery, Resilience and Growth (RRG) programme board.

<sup>2</sup><https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery#our-strategy-and-plans-for-delivery>

## 2 Mandated use of Unmodified Model Agreements **only**

All providers (and, by extension, commercial sponsors and Contract Research Organisations (CRO)) are required to comply with HRA expectations<sup>3</sup> to use of up-to-date model site agreement **for sponsor (and, where applicable, CRO) to site contracting** (e.g. Model Clinical Trial Agreement [mCTA] and CRO-mCTA) **including** as specified in the HRA and Health and Care Research Wales (HCRW) initial assessment letter and letter of HRA and HCRW Approval.

HRA and HCRW Approval to carry out commercial contract research studies in the NHS will be conditional upon use of **only** an unmodified model site agreement **to contract with the sites**, unless the HRA & HCRW Approval waives that requirement where appropriate (e.g. where no template relevant to the study design exists). More details on HRA and HCRW assessment and waiver process will be available on HRA's website.

<sup>3</sup> <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/model-agreements/>

## 3 Mandated use of Standard Costing Methodology

The Standard Contract requires providers (and thereby commercial sponsors and Contract Research Organisations) to use a standard “methodology for setting prices payable by research sponsors to NHS providers for their participation”. The standard methodology currently used is the NIHR **interactive Costing Tool (NIHR iCT)**.

This NIHR **iCT** provides for the **national contract value review**. The template reflects the latest financial year values for:

- national NIHR tariff elements for investigations,
- hourly rates for procedures, based upon NHS Employers costs,
- prescription charges based upon NHS England values,
- NHS inflator/deflator value for investigations,
- Market Forces Factor values,
- overhead components built from both indirect cost (for labour activities) and capacity building for both labour activities and investigations.

Operational guidance to support the use of the NIHR **iCT** is located on the NIHR costing template page

The NIHR iCT will continue to be subject to review and providers are encouraged to raise any issues with the template methodology.

#### 4 Introduction of the National Contract Value Review Process

The mandated use of the unmodified model site agreement and the standard costing methodology (iCT) were the next steps on the road to a national contract value review process. Providers using these templates and the process set out below will have the opportunity to provide feedback to NIHR and raise awareness of issues identified. NHS England and NHS Improvement and NIHR will work with key stakeholders to review the new process including its impact. The national contract value review process and its principles of upfront fixed costs and increased system transparency will become mandatory following the review of this introduction phase.

This national contract review process is a nationally co-ordinated contract value negotiation process. It builds on what has been achieved with the NIHR Industry Costing Template, to create a single contract value review with an assigned national co-ordinator for each commercial contract study.

Individual contracts will still be executed with each site, in line with nationally derived contract values, e.g. the NIHR iCT costing and hourly rates (modified as necessary for local circumstances, within the scope of the process) and HRA directions as to model contract clauses. Cost variations will be available to all parties at the outset of the costing process for a study via a costing list. Provider organisations are responsible for stipulating the variation in costing and will adhere to this costing list.

The initial proposed national contract value review process is set out on the NIHR website and will ensure efficiencies for the conduct of commercial contract research by:

- assigning a national co-ordinator who is empowered to work on behalf of all NHS providers and act as a single point of contact for negotiation with the sponsor on resource required,
- NHS providers publishing to commercial sponsors either a confirmation that they adhere to the national costs or setting out all the provider-specific adjustments to the national costs along with justifications,
- providing assurance that the NIHR Interactive Costing Tool captures all Sponsor and NHS requirements to deliver the study,
- capturing predefined NHS provider-specific adjustments to the national coordinator negotiated study template as part of the model agreement financial appendix.

NHS providers will not deviate from the published provider-specific costs in place at the time the commercial sponsor approached the site and will accept the requirements to deliver the study set out in the national coordinator-negotiated NIHR Interactive Costing Tool.

NHS providers will have the opportunity to nominate commercial research costing experts to act as the National Co-ordinators. These individuals will need to meet necessary criteria to ensure the successful and efficient costing and negotiations for

commercial contract research. It is acknowledged that NHS providers will have varying levels of expertise across location and/or therapy area which will mean that National Co-ordinators will not be equally dispersed across England. It is expected that providers work towards including the requirements of the national co-ordinator role in their local job descriptions for staff costing commercial contract research.

A peer-to-peer community of national coordinators, **will be developed to build** confidence and efficiencies in the role and process.

Information on progress will be available on **the AAC Website**.

#### **Annex A: NHS Standard Contract wording item Service Condition 26.4**

*If the Provider chooses to participate in any Commercial Contract Research Study which is submitted to the HRA for approval on or after 1 October 2018, the Provider must ensure that that participation will be in accordance with the National Directive on Commercial Contract Research Studies, at a price determined by NIHR for each Provider in accordance with the methodology prescribed in the Directive and under such other contractual terms and conditions as set out in the Directive.*

**Commercial Contract Research Study** a research project that is fully sponsored and fully funded by a commercial company

**National Directive on Commercial Contract Research Studies** the mandatory requirements governing participation by Providers in Commercial Research Studies, published jointly by NHS England and NHS Improvement, the National Institute for Health Research and the Health Research Authority from time to time, including;

- (i) a methodology for setting prices payable by research sponsors to Providers for their participation; and*
- (ii) other contractual terms and conditions to apply to Provider participation.*

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