NHS England

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National Directive on Commercial Contract Research Studies

NHS England in partnership with the National Institute for Health Research and the Health Research Authority

NHS Health Research Authority

NHS National Institute for Health Research

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Contents

1 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 be reviewed and revised in 2019.

A commercial contract 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 sponsored by a commercial entity, which are considered non-commercial studies.

NHS England's Twelve Actions to Support and Apply Research in the NHS[1] 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, 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 Directive, specifically:

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

This national directive will be reviewed and updated in April 2019 building on learning gained during the introduction phase of the single contract review process as discussed in section 4.

2 Mandated use of Unmodified Model Site Agreements

All providers (and, by extension, commercial sponsors and Contract Research Organisations) are required to comply with HRA expectations on the use of up-to-date model site agreements 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 trials in the NHS will be conditional upon use of an unmodified model site agreement (e.g. the model Clinical Trial Agreement [mCTA]), unless the HRA & HCRW approval waives that requirement where appropriate (e.g. where no template relevant to the study design exists). More details on the HRA and HRCW assessment and waiver process are available on HRA's website.

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

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 CRN Industry costing template, which is specifically referenced in the Department of Health's Attributing the costs of health and social care Research and Development (AcoRD)[2] in the context of simplified full cost recovery for NHS providers.

This NIHR Industry Costing template provides the standard pricing function for the single contract 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,
- NHS England 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 Industry Costing Template, is located on the NIHR costing template page.

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

4 Introduction of the Single Contract Value Review Process

The mandated use of the unmodified model site agreement and the standard costing methodology are the next steps on the road to a single 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 NHIR will work with key stakeholders to review the new process including its impact. The single contract value review process will become mandatory following the review of this introduction phase.

This single 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 process with 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 tariff and hourly rates (modified as necessary for local circumstances, within the scope of the process) and HRA directions as to model contract clauses.

[2] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

The initial proposed single 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 acting as a single point of contact for negotiation with the sponsor on resource required,
- providing assurance that the NIHR Industry Costing Template captures all Sponsor and NHS requirements to deliver the study,
- capturing predefined NHS provider-specific adjustments to the national co-ordinator negotiated study template as part of the model agreement financial appendix.

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 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 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 commercial research costing staff.

CRN will support development of a peer-to-peer community to build confidence and efficiencies in the role and process.

Information on progress is available on the NIHR 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, 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.