NHS England

Supporting Research in the NHS:

A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract

NHS England INFORMATION READER BOX		
Directorate		
Medical	Operations and Information	Specialised Commissioning
Nursing	Trans. & Corp. Ops.	**Strategy & Innovation**
Finance		

Publications Gateway Reference:	**07459**
Document Purpose	Consultations
Document Name	Supporting Research in the NHS: A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract
Author	NHS England
Publication Date	30 November 2017
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, CSU Managing Directors, Foundation Trust CEs , Directors of Finance, GPs, NHS Trust CEs, Researchers, Research funders, Research sponsors, Industry Stakeholders in clinical trials
Additional Circulation List	
Description	This consultation sets out proposals for how NHS England, The Department of Health and the Health Research Authority, working together, will implement changes to simplify NHS research proposals to: Manage excess treatment costs better. Further improve commercial clinical research set-up and reporting. This consultation also sets out specific proposals for changes to the terms of the NHS Standard Contract to support implementation of these new arrangements.
Cross Reference	Guidance on Excess Treatment Costs, NHS England, 2015
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	**Deadline for responses 01/02/2018**
Contact Details for further information	Lindsey Hughes Innovation and Research Unit 4N04, Quarry House Leeds LS2 7UE (44) 07918368455 https://www.engage.england.nhs.uk/consultation/simplifying-research-arrangements/

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

Supporting Research in the NHS: A Consultation

Version number: 1.0

First published: 30/11/2017

Prepared by: Strategy and Innovation Directorate.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact Hussein Dharma at England.Research@nhs.net

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;
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.

1 Contents

1 Introduction

Since its inception 70 years ago, the NHS has worked at the leading edge of scientific development. It has helped to confirm the link between smoking and cancer; achieve the first full hip replacement; develop the CT scanner, and gene therapy; and successfully trial an artificial pancreas. The UK's 34 Nobel Prize winners for medical research place us second only to the USA.

Our comparative global strength is derived from outstanding capabilities and partnerships. These include the National Institute for Health Research (NIHR) in England and the emerging UK Research and Innovation, which brings together the Research Councils and Innovate UK. We benefit from a large and diverse medical charity sector, including major research charities such as the Wellcome Trust and Cancer Research UK, as well as world-leading university partners and our six designated Academic Health Sciences Centres. Industry is a huge contributor, investing over £5bn annually on UK health research. The National Institute for Health and Care Excellence (NICE) provides internationally-respected health technology assessments and advice.

Supported by these organisations, the NHS in England is undertaking more research than ever before – despite wider pressures on clinical workforce supply. In 2016/17, we saw 65% of NHS trusts increase their research activity. This enabled more than 665,000 people to participate in clinical research through the NIHR Clinical Research Network, increasing access to novel treatments and care, up 10%. We saw 2,055 new studies on the NIHR Clinical Research Network portfolio, up 15%.

Research offers a range of benefits to the NHS. There is evidence that research active organisations have better outcomes than those undertaking less research, such as lower rates of mortality following emergency admissions[1,2]. Additionally, a 2016 NIHR-commissioned report[3] found that, for commercial studies[4], NHS Trusts received an average of £6,658 in revenue per patient from sponsor companies. This equated to estimated totals of £176 million of commercial income across the commercial NIHR Clinical Research Network Portfolio for FY 2014/15.

[1] Ozdemir B et al, (2015) Research Activity and the Association with Mortality.. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4342017/

[2] Dowling A et al (2016) High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. Available at: High hospital research participation and improved colorectal cancer survival outcomes: a population-based study

[3] KPMG, 2016 *NIHR Clinical Research Network: Impact and Value Assessment*; Available at: https://www.nihr.ac.uk/life-sciences-industry/documents/NIHR%20CRN%20Impact%20and%20Value%20FINAL%20REPORT_vSTC_160908_FOR%20EXTERNAL%20USE.pdf

[4] Commercial research is funded by industry and private companies (national and international). Non-commercial research is typically funded by charities, government and Research Councils

Section 13L of the Health and Social Care Act 2012[5] places a legal duty on NHS England to promote research and the use of research evidence in the NHS, and the NHS Constitution[6] highlights our "*commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population*". The Government's mandate[7] to NHS England for 2017-18 also asks the NHS to support research innovation and growth.

Next Steps on the Five Year Forward View[8] confirmed NHS England's commitment to creating a more fertile environment for clinical trials. The August 2017 *Life Sciences Industrial Strategy*[9] also set out an ambition to further improve UK clinical trial capabilities and continue to attract world-class scientists to the UK, so that we continue to act as a global leader in healthcare research.

In November 2017, NHS England and NIHR set out a joint statement on how we will go further to support and apply research within the NHS. The first set of actions within the statement aim to simplify NHS research processes. This includes improving how we **manage excess treatment costs better** and **eliminate delays in confirming multi-site trials**. This consultation sets out our proposals on both of these actions and invites views on how we can best implement the proposed changes.

2 Consultation details

2.1 What we are consulting on

This consultation sets out proposals for how NHS England, The Department of Health and the Health Research Authority (HRA), working together, will implement changes to simplify NHS research proposals to:

- Manage excess treatment costs better
- Further improve commercial clinical research set-up and reporting

This consultation also sets out specific proposals for changes to the terms of the NHS Standard Contract to support implementation of these new arrangements. (See section 5 below for further detail on the specific proposals we are making and how they relate to the recent separate consultation on other changes to the Contract, which concluded on 10 November 2017.)

The Department of Health, NHS England, NHS Improvement, the Health Research Authority, the National Institute for Health Research and the Office for Life Sciences have a shared ambition for the NHS to offer a simple, coordinated and cost-effective

[5] http://www.legislation.gov.uk/ukpga/2012/7/section/23/enacted
[6] https://www.gov.uk/government/publications/the-nhs-constitution-for-england
[7] https://www.gov.uk/government/publications/the-nhs-constitution-for-england
[8] NHS England, 2017, *Next Steps on the Five Year Forward View*; https://www.england.nhs.uk/publication/next-steps-on-the-nhs-five-year-forward-view/
[9] Office for Life Sciences, 2017, *Life Sciences: Industrial* Strategy; https://www.gov.uk/government/publications/life-sciences-industrial-strategy

process for contracting research – and we are committed to working together to agree the way forward, taking into account the responses to this consultation.

2.1.1 Managing Excess Treatment Costs in non-commercial research

NHS England and the Department of Health have heard continued frustration about the complexity and variation in processes for commissioners and providers agreeing excess treatment costs (ETCs).

We are proposing three changes that will overcome some of the long standing issues with ETCs:

1. Partnering with the 15 Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local Clinical Commissioning Groups (CCGs)

2. Establishing a more rapid, standardised process for ETCs associated with specialised commissioning, which are the responsibility of NHS England

3. Setting a minimum threshold under which ETCs will need to be absorbed by providers participating in studies.

2.1.2 Further improving clinical research set-up and reporting

A second practical way we can cut the NHS bureaucracy of research set-up is to cut delays in establishing multi-site trials. The HRA has successfully established a single research ethics and regulatory approval process. This has contributed to reducing the median time from trial application to first patient recruitment from 231 days (Q3 2015/16) to 142 days (Q3 2016/17).

However, sponsors of multi-site trials (including clinical investigations of medtech) still face frequent uncertainties and delays in site set-up. Each participating provider currently issues its own confirmation of participation, and can seek to vary contract terms and prices for exactly the same study. In some cases, we are seeing differences of up to nine months in confirmation of the fastest and slowest sites. It should be possible to eliminate these delays, making the NHS in England a more attractive base for research. This would serve to benefit patients, NHS providers and the wider UK economy.

Further standardisation could also introduce greater certainty and fairness; and cut transaction costs for NHS providers, and industry and charities alike. Provider R&D offices would be empowered to focus on patient recruitment, rather than having to haggle over terms that have already been agreed elsewhere in the NHS.

To unlock these benefits, NHS England, NIHR and the HRA have joined forces. We are proposing to mandate standard arrangements, to apply right across the NHS in

England. These would be given effect through amendments to the NHS Standard Contract.

Specifically, we are proposing to amend the NHS Standard Contract to require providers to comply with updated national guidance:

- mandating a standardised process for assessing and determining contract values for commercial contract research.

- requiring providers to use a standard research contract; and

- publishing a common, simple set of performance data on research initiation and delivery.

We are also seeking views on what further steps would be helpful on the part of commercial research sponsors and/or their representatives.

2.2 Who should read this

Individuals or organisations that may be directly affected by the proposals being consulted on or that have a particular interest in the policy scope and health objectives. Specifically, this includes patients (and their representatives), NHS staff, NHS organisations, researchers and research funders, and research sponsors.

You may have an interest in several areas of this consultation, or just one. You can respond to any parts of the consultation depending on your area of interest.

2.3 Duration

The consultation will run for 9 weeks, starting on 30 November 2017 and ending on 1 February 2018.

NHS England will also convene a number of listening and engagement events during the consultation period to ensure that all stakeholders are given a chance to provide their views.

2.4 How to respond or enquire about this consultation

You can respond via the online survey at https://www.engage.england.nhs.uk/consultation/simplifying-research-arrangements/

We encourage you to read the full consultation document before completing the questionnaire.

If you have any questions about the consultation you can email us at England.Research@nhs.net

Alternatively, if you can't respond online you can post your response(s) to **Supporting Research in the NHS Consultation, NHS England, 4N04, Quarry House, Leeds, LS2 7UE.**

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

2.5 After the consultation

Responses will be taken into account and considered fully before deciding the final policy and modalities for implementation.

Subject to the outcome of this consultation, changes to the Contract will be enacted by NHS England through a National Variation at a future date to be determined.

3 Managing Excess Treatment Costs

3.1 What are Excess Treatment Costs?

In England, the costs of non-commercial research are met from a number of sources depending on the type of cost, in line with the principles of Attributing the Costs of Health and Social Care Research and Development (AcoRD) (Department of Health 2012)[10].

Researchers wishing to access funding for their research must therefore attribute its costs across three broad categories described in the table below:

Table 1: Attribution of costs for non-commercial research

Category	Description	Funding mechanism
Research Costs	Research costs are the costs of the research and development itself that end when the research ends. They relate to activities that are being undertaken to answer the research question.	Research costs are met by the research funder.
NHS Support Costs	Support costs are the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided.	For studies that meet the eligibility criteria for NIHR Clinical Research Network (CRN) Support, resources are provided primarily via NIHR Clinical Research Network. For studies that do not meet the NIHR criteria, these costs must be met by the study funder or sponsor.
NHS Treatment Costs	NHS treatment costs are the costs of patient care, which would be incurred if the care/treatment under review became standard care. For the purpose of attributing costs during a research study, an assumption is made that the care/treatment under review will become standard, but whether this happens in practice is dependent on the results of the research and on the NHS' desire to commission it.	NHS treatment costs are funded by the NHS through normal commissioning arrangements for patient care.

[10] Attributing the Cost of Health and Social Care Research (Department of Health (2012) https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

A research study may result in care that differs from standard treatment, or is delivered in a different location from where it would normally be given. The associated NHS Treatment Costs may be less, or may be greater, than the cost of standard treatment. If greater, the difference between the NHS Treatment Costs and the cost of the standard treatment is referred to as the **NHS Excess Treatment Costs**.

These costs should be met as part of the normal commissioning process. Funding to pay for ETCs is contained within national tariff for those services for which there is a tariff price. In making a request for additional funding for ETCs providers should demonstrate that tariff or contractual payments for activity are insufficient to cover the cost of the excess treatment cost.

3.2 Why is change needed?

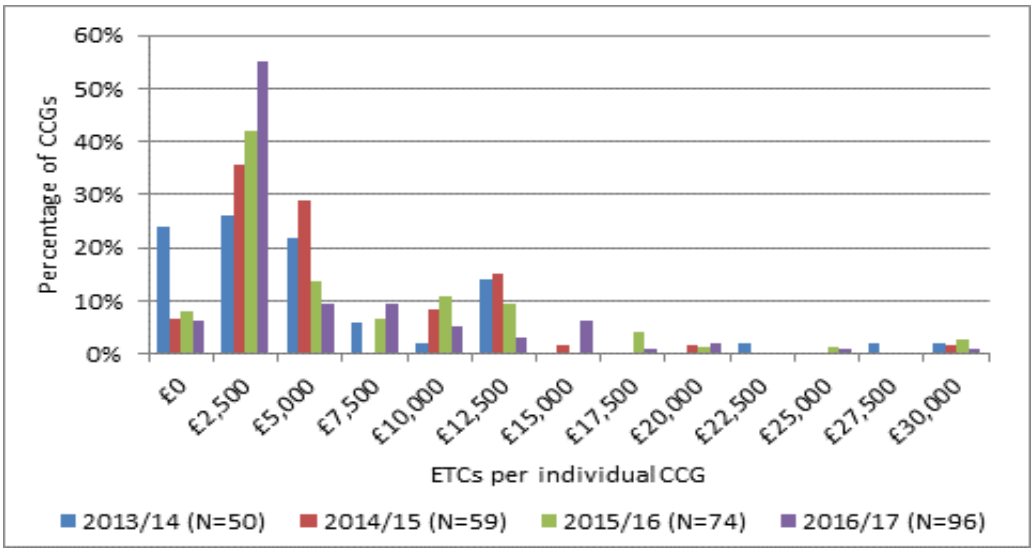
NHS England and Clinical Commissioning Groups (CCGs) have a responsibility via the Government's mandate to NHS England to meet the costs of ETCs through normal commissioning arrangements. There have been a number of attempts to clarify and improve the process for managing ETCs, including the 2015 NHS England guidance for commissioners, researchers and providers[11]. However, ETCs are still causing friction between researchers, commissioners and providers and remain one of a number of barriers to timely execution of research in the NHS.

Processes based on the 2015 NHS England guidance are helping some local systems to manage their ETC obligations effectively. For example, in Wessex, Kent Surrey and Sussex, Thames Valley and North East and North Cumbria defined sub regional processes are in operation. However, stakeholder engagement tells us that in many areas ETC processes are not working effectively.

In May 2017 NHS England, the Department of Health (DH) and Public Health England (PHE) set up a joint project team to review current ETC policy and propose solutions to overcome the issues encountered in the system.

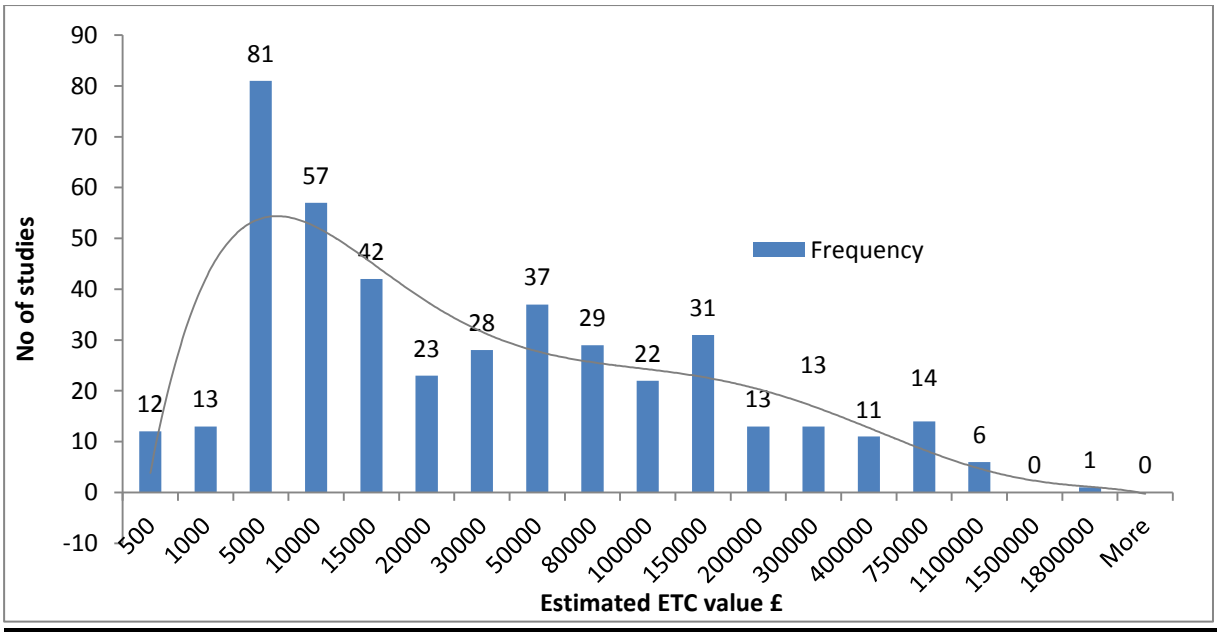
To better understand the costs associated with ETCs and gain insights into how the ETC system is functioning in local areas, we commissioned the Policy Research Unit in Economic Evaluation in Health and Care Interventions (EEPRU) at the University of Sheffield to undertake a qualitative and quantitative data collection. This took place between May and September 2017. We are extremely grateful to those organisations who responded to EEPRU requests for data and who took part in interviews to inform this work. A summary of the data we received on CCG expenditure and estimated ETCs given at NIHR funding application stage are shown in Figures 1 and 2 respectively. Further information on the data collection is available at Annex A.

[11] Guidance on Excess Treatment Costs, NHS England (2015) https://www.england.nhs.uk/commissioning/research/etc/



Data excludes 2 CCGs where annual ETC is greater than £30,000: 1 CCG ETC=£37,293 in 2015/16 and ETC=£55,050 2016/17; 1 CCG ETC=£88,050 in 2016/17.

▲Figure 1: distribution of annual ETCs by individual CCG



▲Figure 2: The distribution of ETCs estimated at the point of funding application for NIHR studies over four years (2013/14-2016/17).

Alongside this, we gathered views on possible policy options, testing them with stakeholders at an engagement day on 5 September 2017. This group included members of the DH Non Commercial Costing and Attribution Group and additional stakeholders known to us who represented researchers, commissioners, funders, providers, National Institute for Health Research (NIHR) organisations, Health Research Authority (HRA) and Academic Health Science Networks (AHSNs).

Insights from the data collected by EEPRU were limited. This is, in the most part, because the data that is required to understand the current cost of ETCs is not collected outside general contracting information, or at all. Recognising that we do not have truly reliable data, we have used what we do have to gain as much insight as possible into ETC requests and investments over the last four years.

This information, along with the insights from our engagement, has informed the policy options presented in this consultation. We recognise that without accurate data we may not get to the right answer at the first time of asking, however, we are keen to implement improvements as soon as possible in order to begin data collection through the new arrangements. This will enable us to refine and improve the process in future years.

3.3 Our proposals

We have developed our proposals for the future management of ETCs based on the following design principles:

(i) **Capability.** It is unrealistic to expect 200-plus individual CCGs all to have the expertise to navigate the complexity of ETCs equally well. Instead we should better utilise existing sub regional expertise.

(ii) **Consistency.** The whole country should follow the same process.

(iii) **Cost neutrality**, compared with the current position. Any solution cannot afford to create an additional unfunded NHS cost pressure. Nor should it seek to reduce existing commissioner expenditure. In this we are hindered by poor existing data collection. Our best estimate of the total national cost to commissioners of ETCs is in excess of £7m, but not more than £30m, per annum.

(iv) **Simplicity**. We are moving towards creating accountable care systems in the NHS, with reduced transaction costs between commissioners and providers. In this context, the friction over what can sometimes be very small amounts of money looks increasingly anomalous.

(v) **Single point of access.** It should be clear who to approach for help or to manage applications

(vi) **Transparency.** Researchers and providers tell us that decisions are made behind closed doors, with criteria for decision-making not made available. In future decisions should be open and transparent to all stakeholders.

With these principles in mind, we are proposing a number of inter-related changes to the way we manage ETCs.

1. **Partnering with the 15 NIHR Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local CCGs**
   NIHR LCRNs are already a critical part of the research infrastructure and have the skills and expertise to manage an ETC process as part of the existing

support and AcoRD specialist community. We are therefore proposing that they manage ETC process for the CCGs within their local CRN regions. Each LCRN will manage a pre-identified local annual funding pot provided by, and on behalf of, it's contributing CCGs.

LCRNs will administer a standard process across the country, with a single point of contact in each sub region and coordination where applications fall across multiple LCRNs. They will ensure that applicants understand requirements regarding the proposed minimum threshold, specialised commissioning, subvention funding, and, with the support of a named lead CCG finance officer per CRN, requirements around tariff, so that applications for ETCs are submitted through the right route and with the right information. They will also collect all relevant data about applications and payments within their sub region, enabling us to collate accurate data on ETCs during 2018/19 to inform further improvements in future years.

Through this approach we will utilise the research capability within LCRNs, rather than spread requirements across multiple CCGs. We will also align the process as much as possible to the existing funding allocations for support costs, which the LCRNs manage.

We will ask CCGs to confirm an annual funding allocation to their sub regional LCRN. This will give the LCRNs a defined budget which they will manage on an annual basis. Given the high apparent variability of excess treatment costs, we will examine how best to coordinate across and pool risk, for example across the 15 LCRNs.

We will begin work with LCRNs and CCGs to establish the sub regional funding allocations during the early part of 2018 in order to be in a position to begin implementation as early as is practicably possible in 2018/19, subject to responses to this consultation.

2. Establishing a more rapid, standardised process for specialised commissioning ETCs, which are the responsibility of NHS England

Specialised services are commissioned by NHS England, not CCGs. We are therefore proposing to establish a rapid, standardised process for ETCs relating to specialised services. This process will be based on the successful cost attribution pilot for the Efficacy and Mechanism Evaluation (EME) programme and will align closely to the process within LCRNs. We will ensure coordination with the LCRNs so that applications are directed without delay to the correct system.

Establishing this process will enable us to run the process rapidly, enabling a decision on most applications within six weeks. We will also ensure early engagement between NIHR and specialised commissioners in the funding process, allowing high cost/low value proposals to be challenged and potentially rejected earlier in the process. As with the CCG process, applications that fall below the proposed minimum threshold would not be

considered by NHS England and will need to be met from existing provider resources.

3. **Setting a minimum threshold under which ETCs will need to be absorbed by providers participating in studies and a maximum threshold over which cases will be challenged early in the process.**

Many of our stakeholders have told us that there are often protracted negotiations for ETCs that are relatively small sums and the administrative costs to providers and commissioners related to agreeing payments outweighs the cost of the ETC itself. From the available data we estimate that 25% of study ETCs at NIHR funding application are below £5000.

We will remove this issue by operating a minimum threshold, under which ETCs will be absorbed by providers participating in research studies. We know that some established local processes already successfully operate a minimum threshold of this type[12,13]. See case study below. To date we have had broad support for this approach, but understand that primary care providers would not be able to absorb costs under a minimum threshold as outlined below. They would therefore be exempt from this rule but we are considering if there would still need to be a nominal payment cap to discourage applications for ETCs from primary care where the cost of processing will significantly out-weigh the cost of the ETCs.

As with our proposal for Specialised Commissioning, we will also ensure early engagement in the funding process, allowing high cost/low value proposals to be challenged and potentially rejected earlier in the process.

Case Study – Wessex Local Clinical Research Network

Wessex LCRN manages a local ETC process on behalf of the commissioners in the CRN region. The process operates a minimum threshold for applications of £1000 per study per organisation under which Trusts are expected to meet the cost of the ETCs. Guidance for applications, application form and invoicing form are all available on the Wessex LCRN website.

There are a number of mechanisms by which the minimum threshold for each application could be set, each of which has differing implications for providers and commissioners. These include:

- ETC per patient, per financial year, per Trust
- ETC per Trust, per financial year, based on income
- ETC per Trust, per financial year, fixed sum
- ETC per study, per Trust (over the lifetime of the study)

[12] https://www.nihr.ac.uk/nihr-in-your-area/wessex/nhs-excess-treatment-costs.htm
[13] Some CCGs have arrangements with their provider organisations that they will absorb costs in relation to ETCs up to a certain value before requesting separate funding

The potential implications of these options are set out in the table below:

Table 2: Options for setting minimum ETC threshold for CCG funding

Option	Limit calculation	Example limit	Potential Implications	Benefits	Risks
1	ETC per patient, per financial year for Trust.	£60	Applications for ETCs worth less than £60 per patient per financial year for Trusts are not accepted. Costs must be absorbed by the participating Trusts.	Recognises that costs per patient may be low.	Studies with high volumes would incur high costs that Trusts must absorb.
2	Total (cumulative) ETC per Trust, per financial year, based on Trust income which would be banded to offer stability around the threshold year on year.	Variable	Trusts required to absorb the first £X,000 ETCs per financial year. this amount would vary based on Trust income, This could be up to a maximum per Trust per year.	Allows variable investment based on Trust income which may be more equitable.	Could be seen as an inconsistent approach as varies by Trust, Different implications across different Trusts.
3	ETC per Trust, per financial year, fixed sum.	£10,000	Trusts required to absorb the first £10,000 of ETCs per financial year before being eligible for separate funding. The threshold would be the same for all Trusts. This could be up to a maximum per year.	Clarity in process.	Equal costs applied to all Trusts, which may be unaffordable for some and may be significantly less than some Trusts absorb currently.
4	ETC per study per Trust (over lifetime of the study).	£2,000	Trusts are expected to absorb ETCs for studies where the total ETC per	Clarity in process.	Equal cost pressure applied to all Trusts, which may be

			study cost is <= £2,000 to the Trust. Applications for ETCs under the threshold are not accepted.		unaffordable for some. Could act as disincentive for Trusts to participate in low cost studies.

As well as collecting prospective data in the first year of the new arrangements we will review and evaluate the operation of the new arrangements and use our learning to improve and amend where necessary.

3.4 Our consultation questions

We would welcome comments on the following questions:

- Do you agree with the six design principles we have used to develop our proposals? Y/N please comment

Partnering with 15 NIHR Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local CCGs

- Do you agree that ETCs will be better coordinated by LCRNs at sub regional level with a single point of contact rather than managed by CCGs individually? (Y/N/ Please comment)

- Do you agree that pooling risk across the 15 LCRNs to manage annual variation in ETCs would be an appropriate approach? (Y/N/ Please comment)

- Will the proposals outlined work for both single site and multi-site studies? (Y/N/Please comment)

Establishing a more rapid, standardised process for ETCs associated with specialised commissioning

- Do you agree with the proposal to strengthen the process for specialised services? (Y/N/Please comment)

- Do you agree that applications that fall below the proposed minimum threshold would not be considered by NHS England? (Y/N/Please comment)

- Are there any additional comments to add to the specialised services proposals?

Setting a minimum threshold under which ETCs will need to be absorbed by providers participating in studies.

- Please rank the options outlined in Table 2 in order of preference with your

preferred option first and your least preferred last.

- Why do you think your preferred option is the best one?
- Are there any other ways to set thresholds that would work better than those presented? (Y/N/ Please comment)
- Do you think there should be a nominal payment cap for primary care to discourage applications for ETCs where the cost of processing will significantly out-weigh the cost of the ETCs? (Y/N/Please comment)

4 Further improving clinical research set-up and reporting

4.1 What is required for research set-up and reporting

In March 2010, the Government asked the Academy of Medical Sciences to undertake an independent review of the regulation and governance of health research. The review was commissioned due to '*widespread and increasing concern that the process of medical research is being jeopardised by a regulatory and governance framework that has become unnecessarily complex and burdensome*.' In January 2011, the Academy of Medical Sciences published a report, 'A new pathway for the regulation and governance of health research', produced under the chairmanship of Professor Sir Michael Rawlins FMedSci.

In March 2011, the Government responded with a series of commitments in its Plan for Growth, leading to the creation of the Health Research Authority (HRA) to streamline regulation and improve the cost effectiveness of clinical research.

The HRA now operates a single approval process for all project-based research that involves NHS organisations in England. It brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC).[14]

For some categories of study, the HRA sets out an expectation that NHS organisations will participate without any separate confirmation. In most cases, however, the HRA approval process recognises that participating NHS organisations will need to arrange and/or confirm their capacity and capability to deliver a study, taking account of local circumstances.[15]

[14] https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

[15] https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/

To reach confirmation, an agreement on prices for the defined research activities between the Sponsor and research site(s) is required. Providers in England operate as individual entities thus the cost of undertaking these research activities across providers can vary.

4.2 Why is change needed

The Health Research Authority's new approval process has contributed to reducing the median time from trial application to first patient recruitment from 231 days (Q3 2015/16) to 142 days (Q3 2016/17).

However, sponsors of multi-site trials (including clinical investigations of medtech) still face frequent uncertainties and delays in site set-up. Each participating provider currently issues its own confirmation of participation, and can seek to vary contract terms and prices for exactly the same study. In some cases, we are seeing differences of up to nine months in confirmation of the fastest and slowest sites.

Reasons for delays vary from study to study and site to site, but include:

- Failure by sponsors to provide the necessary documentation, to allow the set up process to start; and/or use of non-standard templates;
- Lengthy negotiation of contracts and costings by each provider, creating a complex set up process for multi-site studies; and
- Lack of national end-to-end oversight of the necessary approval and confirmation processes to allow multi-site studies to set up at efficiently as possible.

It should be possible to eliminate these delays, making the NHS in England a more attractive base for research. This would serve to benefit patients, NHS providers, and the wider UK economy.

Further standardisation could also introduce greater certainty and fairness; and cut transaction for NHS providers, and industry and charities alike. Provider R&D offices would be empowered to focus on patient recruitment, rather than having to haggle over terms that have already been agreed elsewhere in the NHS.

4.3 Our proposals

To unlock these benefits, NHS England, NIHR and the HRA have joined forces. We are proposing to mandate standard arrangements, to apply right across the NHS in England. These would be given effect through amendments to the NHS Standard Contract.

We have developed our proposals for the future management of clinical trials based on the following design principles:

(i) **Speed.** We want to eliminate all avoidable delays

(ii) **Predictability.** The whole country should follow standardised processes.

(iii) **Simplicity.** Our aim is to make agreement on terms for conducting clinical trials as simple as possible for both research sponsors and provider alike, reducing transaction costs.

(iv) **Consistency**. The same rules should apply throughout England.

(v) **Fairness.** Clinical trial prices should be fair to the NHS and sponsors alike. They are not intended to allow the NHS to "profit" from research.

(vi) **Credibility**. System should command the confidence of the NHS and sponsors.

With these principles in mind, we are proposing to amend the NHS Standard Contract for 2018/19 to require providers to comply with updated national guidance:

(i) mandating a nationally coordinated process for assessing and determining contract values

Option #1 – National, binding coordination of contract values

The simplest option would be to establish a single process for assessing and determining contract values for commercial contract studies[16], regardless of NIHR Portfolio status. This would be delivered through a new coordination and pricing function, hosted by the National Institute for Health Research. Expert assessors would apply a standard costing methodology, to make a fair and binding determination of prices.

[16] A commercial contract study is a research project that is fully sponsored and fully funded by a commercial company, regardless of 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.

In spring 2018, NIHR would consult on its updated methodology. In broad terms, it is envisaged that NIHR CRN would allocate a National Coordinator for each clinical research proposal[17], with defined minimum standards of training/experience. The National Coordinator would liaise with the commercial research sponsor on behalf of all interested providers to establish a single contract value for the clinical research study. This coordinator would be responsible for:

- Supporting the commercial Sponsor in understanding the NHS study set-up process and costing methodology as necessary;
- Ensuring clinical staff input as required;
- Negotiating with the Sponsor prior to, or in parallel with, submission of the study for HRA Approval, to ensure all activities are appropriately costed to secure an accurate and transparent level of cost recovery, and defined element of capacity building
- Making a binding an fair determination of contract values, leaving only appropriate adjustments for market forces (Market Forces Factor) and/or specialist facilities (for example Clinical Research Facility) for individual sites
- Maintaining responsibility throughout the study life cycle including review of any study amendments with potential impact on the cost.
- Escalating unresolved issues in a timely manner including to the NIHR CRN Coordinating Centre, as required

Also, under this option:

- The existing CRN Industry Costing Group would provide a governance group for ongoing review of the NIHR industry costing template, providing reassurance to industry that the implementation of the model will not result in unwarranted price inflation, and to providers that implementation will broadly reflect actual costs incurred.
- NHS England would support ongoing review and development of current costing schedule within the NIHR CRN Industry Costing template to maintain up-to-date, robust baseline values for all departments involved in research activities and credibility of the template.
- Providers would be required to accept the stipulated contract value without further negotiation.
- Where an NHS Organisation may work with their Clinical Research Facility or a Higher Education Institution to participate in a study, the internal distribution of income of the single contract value negotiated should be based on a pre-agreed Memorandum of Understanding outlining principles and expectations for distribution.
- NIHR would establish regular audits to assess any variation in costs across departments involved in research activities and identify issues impacting single agreement, providing reassurance that the model does not significantly disadvantage any specific or individual providers

[17] The initial focus will be on multi-centre research proposals, but could be extended to single-site research, if necessary

NHS England, NIHR and the HRA would work with industry, charity and NHS partners to ensure that the revised approach commands the confidence of all parties.

Option #2 – First/lead site setting of contract values, with MFF adjustment

An alternative option would be to require trusts to operate a 'lead provider' model, whereby the approach taken for the first site becomes binding for all subsequent participating providers, with MFF adjustment. This would be simple, but it risks gaming and inconsistent approaches across similar trials.

Option #3 - Alternative options

We are also open to alternative options, that meet the design criteria outlined earlier, ie capability, consistency, transparency, speed and simplicity, single point of access and continuous improvement

(ii) requiring providers to use a standard research contract;

We propose to require all providers (and, by extension, sponsors) to use updated, model contract terms and conditions, developed in partnership by the ABPI, HRA and other NHS partners. The relevant updated model clinical trial/ investigation agreements and the associated guidance will be published by the HRA on the IRAS website. The model agreements will be reviewed periodically on a UK-wide basis with the relevant industry groups.

(iii) publishing a common, simple set of performance data on research initiation and delivery.

We propose to require all providers to comply with reporting guidance issued by the HRA, NIHR, DH and/or NHSE. Initially, this would codify existing requirements. However, in due course this would be updated to reflect the outcome of discussions currently underway to determine more effective and streamlined ways to generate, report and publish collective clinical research performance data and to ensure that the data is transparent, accessible and helpful for all, including to inform appropriate site selection. More detail is provided in **Annex B**.

Noting that many delays are also linked to failure by sponsors to provide the necessary documentation, to allow the set up process to start; and/or use of non-standard templates, we are also seeking views on what further steps would be helpful on the part of commercial research sponsors and/or their representatives.

4.4 Our consultation questions

We would welcome comments on the following questions:

Please refer to the preceding section. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

- Which do you think is the best option for costing NHS provider participation in commercial research? [Option 1,2,3?]
- If you have selected Option 3, what is your proposal and how does it meet the design criteria outlined, ie capability, consistency, transparency, speed and simplicity, single point of access and continuous improvement?
- Why do you think the option you have selected is the best one?

Please refer to the preceding section and Annex B. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

- Do you agree that we should reaffirm, through the NHS Standard Contract, the requirement for NHS providers to report and publish a standard dataset for performance in clinical research initiation and delivery? [Y/N/Not sure]
- If you have answered “N” to the above, what are the concerns/objections we should consider? [free text]

Thinking about commercial research generally, and noting that responsibility for delays sometimes lies with research sponsors:

- Are there any additional steps that you think would be helpful on the part of commercial research sponsors and/or their representatives?

5 Proposed National Variation to the NHS Standard Contract

The NHS Standard Contract is published by NHS England and is mandated for use by NHS commissioners when commissioning healthcare services, other than primary care, from providers (whether NHS Trusts, Foundations Trusts or other organisations). Inclusion of new requirements on providers or commissioners in the Contract can be an effective means for NHS England to ensure implementation of national policy initiatives.

The Standing Rules regulations require NHS England to consult with specific stakeholders when proposing substantial changes to the terms of the NHS Standard Contract.

The current version of the Contract was published in November 2016 (available at https://www.england.nhs.uk/nhs-standard-contract/17-18/). It contains brief provisions relating to research at Service Condition 26.

(The Contract is published in two versions – a full-length version, typically used for high-value services, and a shorter-form version used with contracts of lower financial values, typically with smaller (often Non-NHS providers). The research provisions are only included in the full-length version.)

Consultation on changes

In October 2017, NHS England launched a consultation on National Variation to the Contract to introduce a range of proposed changes (details at https://www.england.nhs.uk/nhs-standard-contract/17-19-updated/). This consultation included proposed changes to the existing Contract wording in Service Condition 26 relating to Excess Treatment Costs. The consultation closed on Friday 10 November 2017.

Given that we are now in a position to consult on further changes to the Contract wording relating to research, NHS England does not propose to proceed with the changes proposed in the October consultation in isolation. Rather, through this new research-specific consultation, we are now seeking views on a further updated version of Service Condition 26, amended to reflect the proposals set out in this document.

Wording in the existing NHS Standard Contract, published in November 2016

The research-related wording in Service Condition 26 of the existing Contract says this:

26.3	*The Provider must put arrangements in place to facilitate recruitment of Service Users and Staff as appropriate into Approved Research Studies.*	*All*
26.4	*In respect of any Approved Research Study the Parties must have regard, as applicable, to NHS Treatment Costs Guidance.*	*All*

(The third column in the table above denotes the applicability of each Contract provision to particular types of service or provider. So these provisions apply to all services (acute, mental health community etc) and regardless of the type of provider (NHS Trust, NHS Foundation Trust, non-NHS organisation).

The capitalised terms above are 'defined terms' in the Contract, with the definitions being as follows:

Approved Research Study *a clinical research study:*
(i) which is of clear value to the NHS;
(ii) which is subject to high quality peer review (commensurate with the size and complexity of the study);
(iii) which is subject to NHS research ethics committee approval where relevant;
(iv) which meets all the requirements of any relevant Regulatory or Supervisory Body; and
(v) in respect of which research funding is in place compliant with NHS Treatment Costs Guidance

NHS Treatment Costs Guidance *Attributing the costs of health and social care Research & Development (AcoRD), available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140054/dh_133883.pdf and HSG (97) 32, available at: http://www.nihr.ac.uk/documents/policy-and-standards/Health-Service-Guidance-Patient-Care-Costs-97_32.pdf*

Service User *a patient or service user for whom a Commissioner has statutory responsibility and who receives Services under this Contract*

Staff *all persons (whether clinical or non-clinical) employed or engaged by the Provider or by any Sub-Contractor (including volunteers, agency, locums, casual or seconded personnel) in the provision of the Services or any activity related to or connected with the provision of the Services, including Consultants*

Revised wording now proposed for inclusion in a National Variation to the Contract

The wording we now propose – to be enacted through a National Variation to the Contract once the research consultation has concluded, and taking effect from 1 October 2018 – is as follows:

With effect from [date to be confirmed], Service Condition 26.3 and 26.4 are deleted and replaced by the following:

26.3	*Where, from 1 October 2018, the Provider commences participation in a Commercial Research Study, it must do so at the NIHR Research Price, on the terms of the NHS Commercial Research Contract, and otherwise in accordance with National Guidance on Conducting Commercial Research Studies*	***All***
26.4	*The Provider must comply with HRA/NIHR Research Reporting Guidance, as applicable.*	
26.5	*The Parties must comply with NHS Treatment Costs Guidance, as applicable.*	***All***
26.6	*The Provider must put arrangements in place to facilitate recruitment of Service Users and Staff as appropriate into Approved Research Studies.*	***All***

and the definition of NHS Treatment Costs Guidance in the General Conditions is deleted and replaced by the following:

NHS Treatment Costs Guidance
Attributing the costs of health and social care Research & Development (AcoRD), available at
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140054/dh_133883.pdf
HSG (97) 32, available at
http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353
Guidance on excess treatment costs, available at https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf
and any subsequent guidance to be published by NHS England and/or the Department of Health

and the definitions in the General Conditions are varied to include the following additional definitions:

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

Health Research Authority *the executive non-departmental public body (NDPB) sponsored by the Department of Health which protects and promotes the interests of patients and the public in health and social care research*

HRA/NIHR Research Reporting Guidance *the guidance published by the Health Research Authority and the National Institute for Health Research regarding publication by any Provider of data showing the progress of research studies in which that Provider is participating, available at https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm*

National Guidance on Conducting Commercial Research Studies *the guidance for the operation of Commercial Research Studies, to be published at [weblink] by NHS England, the Health Research Authority and/or the National Institute for Health Research*

National Institute for Health Research *the organisation established by the Department of Health to transform research in the NHS*

NHS Commercial Research Contract *the mandatory terms and conditions under which NHS Trusts and NHS Foundation Trusts must carry out Commercial Research Studies, to be published by NHS England, the Health Research Authority and/or the National Institute for Health Research at [weblink]*

NIHR Research Price *the mandatory price, determined by the National Institute for Health Research in accordance with the National Guidance on Conducting Commercial Research Studies, to be paid to the Provider under the terms of the NHS Commercial Research Contract to cover the Provider's costs for participation in a Commercial Research Study*

5.1 Our consultation questions

We would welcome comments on the following question:

- **Do you agree with our proposed wording for a future National Variation to the NHS Standard Contract? (Y/N/Please comment)**

Annex A

Summary of results from EEPRU data collection

- Evidence from funders indicates total ETCs at funding application range from £10.9m to £32.5m (2016/17)
- Extrapolating the total ETC reported by CCGs and Trusts using the patient population covered by the returns to the population of England gives an estimate of £7.1m for a population of 55.3m.
- Data was requested from a range of sources, but we had limited and poor quality data:
    - Many partial returns or estimated data
    - Significant geographical gaps in coverage
    - Data provided is not all comparable
- The vast majority of respondents for CCGs and Trusts who did not provide the information requested reported that these data were not routinely collected.

Stakeholder (number of returns)	2016/17(£)
ETCs reported by funders of clinical studies at point of grant application	
ETCs from NIHR	8,627,057
ETCs from CRUK	23,749,890
ETCs from MS-UK	150,000
Total ETCs reported by funders	***32,526,947***
ETCs reported to be incurred by commissioners and providers in clinical practice	
ETC reported by DH Subvention	400,000
ETC funded by Specialised Commissioning~ (0)	15,000
ETC reported by PHE (1)	98,870
ETC reported by Local Authorities (02/154)	5,535
ETC reported by Wessex LCRN	113,643
ETC reported by CCGs (max 107/199)	575,530
ETC reported by Providers (max 37/221)	719,828
Total ETC reported by commissioners and providers	*1,928,406*
ETC extrapolated from returns by CCGs and Trusts	*6,547,845*
Total ETC reported by all commissioners and providers (including ETC extrapolated from CCGs and Trusts)	***7,067,250***

Number of CCGs that responded to the survey by local CRN region

(Quantitative data)

LCRN	Total CCGs (N)	CCGs represented by responses (N)	Percentage (%)
East Midlands	19	13	68
Eastern	11	10	91
Greater Manchester	11	4	36
Kent, Surrey and Sussex	20	20	100
North East and North Cumbria	11	11	100
North Thames	20	0	0
North West Coast	20	0	0
North West London	8	0	0
South London	12	1	8
South West Peninsula	4	2	50
Thames Valley and South Midlands	11	11	100
Wessex	Handled separately		
West Midlands	22	12	55
West of England	7	7	100
Yorkshire and Humber	23	20	87
TOTAL	199	111	56

Number of Trusts that responded to the Survey by Local CRN region (Quantitative data)

	Invites (N)	Responses with values for ETC (N)	Blank or zero returns for ETC (N)	Total responses	
				N	%
East Midlands	16	2	8	10	63
Eastern	17	1	6	7	41
Greater Manchester	15	3	4	7	47
Kent, Surrey and Sussex	18	1	2	3	17
North East and North Cumbria	13	0	1	1	8
North Thames	22	2	5	7	32
North West Coast	22	2	2	4	18
North West London	9	1	1	2	22
South London	12	3	5	8	67
South West Peninsula	11	4	2	6	55
Thames Valley and South Midlands Wessex	6	0	1	1	17
West Midlands	28	0	11	11	39
West of England	10	2	4	6	60
Yorkshire and Humber	22	4	12	16	73
Total	221	25	64	89	40

Local Processes

The responses indicate that 96 CCGs have a very clear process, 18 a reasonably clear process and 8 have a less clear process. However, having a clear process, does not necessarily infer that ETC applications will necessarily be funded. Evidence from the interviews and the trust online survey responses suggest that some of these CCGs classed as having a good process may then decide to decline support on the basis of little money or research not being a priority in area. Similarly, CCGs with less clear processes may have never rejected an application requesting ETC funding.

Summary details of interviewees (qualitative data)

Stakeholder representing the following perspectives	Number of interviews	Geographical area
LCRN	2	South West Peninsula, Wessex
CCG	7	East Midlands, Eastern, Greater Manchester, North East North Cumbria, Thames Valley and South Midlands, West Midlands, West of England
Trusts	7	East Midlands, Greater Manchester, North Thames, South London, South West Peninsula, Wessex , Yorkshire and Humber
Researchers (CI, trial management team)	11	Mix of single-site and multi-site studies
Public Health	3	Across England, Yorkshire and Humber

Funders of clinical studies	1	Across England
Welsh Government	1	Wales

Annex B

Proposals for reaffirming and developing transparency of clinical research performance data

NHS England supports the transparency of clinical research performance data, and therefore proposes to reaffirm the requirement for providers to report and publish (on a publicly available part of their website) clinical trial initiation and delivery data for all clinical trials in line with the HRA-NIHR Minimum Data Set and the requirements specified in the NIHR contract and reiterated in the DH/Local CRN Host and Partner organisation contracts.

Current position

Since 2013, the Department of Health has required, via National Institute for Health Research (NIHR) contracts with providers of NHS services, the publication on a quarterly basis of information regarding clinical trial initiation and the recruitment to time and target for commercial contract clinical trials.

Providers of NHS services are required to publish the following information for Initiating Clinical Research on a publicly available part of their website:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- The date the site was invited
- The date the site was selected
- The HRA Approval date
- The date the site was confirmed by the sponsor
- The date the site was confirmed
- The date when the site is ready to start
- The date of the recruitment of first patient, and
- The source of the delay in recruiting the first patient into a trial (NHS Provider/ Sponsor/ Both/ Neither).

Plus, in the event that a trial initiation did not proceed to confirmation:

- The non-confirmation status.

Providers of NHS services are also required to publish the following information regarding commercial contract clinical trials, to meet the transparency commitment for delivering clinical research to time and target on a publicly available part of their website:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- Whether or not a target number of patients was agreed

- The minimum number of patients agreed to be recruited (if a range has been agreed; this will be the same as the maximum if a fixed number has been agreed)
- The maximum number of patients agreed to be recruited (if a range has been agreed; this will be the same as the minimum if a fixed number has been agreed)
- Whether or not a target date to recruit patients was agreed
- The date agreed to recruit the target number of patients
- The total number of patients recruited at the agreed target date
- The total number of study participants recruited
- The date that the trial closed to recruitment
- The reason for the closure of the trial.

A list of Trusts' website pages where this information is published is available on the NIHR website[18].

A definition of clinical trials for the purpose of this reporting is outlined in Annex 1 to the current Performance in Initiating and Delivering Guidelines[19]. A collaborative project between the NIHR and HRA has developed a single 'minimum data set' that reflects the new HRA Approval processes[20] and will simplify the reporting system.

Proposed changes

Active discussions are underway to determine more effective and streamlined ways to generate, report and publish collective clinical research performance data and to ensure that the data is transparent, accessible and helpful for all, including to inform appropriate site selection.

The discussions include: which data items are now appropriate to collect and publish on a publicly available part of the provider's website; whether the scope of the data collected and published should be extended beyond clinical trials; how duplication of data collection could be reduced through use of CRN Local Portfolio Management Systems for operational activity management, connected to the Central Portfolio Management System, to enable centralised reporting and access to the resulting performance intelligence for multiple stakeholders in a single digital solution; and how research activity and performance information can be better used to raise the profile and importance of research in an NHS organisation.

Providers will be expected to comply with any guidance that is issued by the Department of Health, NHS England, NIHR and HRA following these discussions and support a move towards a digitally enabled 'measure, report and improve' approach

[18] Performance information on the initiation and delivery of clinical research; https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/performance-in-initiating-and-delivering-research/performance-information-on-the-initiation-and-delivery-of-clinical-research.htm
[19] https://www.nihr.ac.uk/research-and-impact/documents/PID%20Documents/Guidance%20Documents/Performance%20in%20Initiating%20and%20Delivering%20Guidelines%20Published.pdf
[20] HRA Approvals and NIHR Metrics; https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm

for performance in initiation and delivery of clinical research to increase research opportunities and benefits for NHS patients.