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

Council for Allied Health Professions Research

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Introduction

The Council for Allied Health Professions Research (CAHPR) is the representative voice of 13 AHP professions on research matters. Our member organisations include:

- British and Irish Orthoptic Society
- British Association of Art Therapists
- British Association of Drama Therapists
- British Association for Music Therapy
- British Association of Prosthetists and Orthotists
- British Dietetic Association
- College of Paramedics
- College of Podiatry
- Chartered Society of Physiotherapy
- Institute of Osteopathy
- Royal College of Occupational Therapists
- Royal College of Speech & Language Therapists
- Society and College of Radiographers

For more information about CAHPR: http://cahpr.csp.org.uk/

Consultation Topic

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.

The responses below relate to the consultation document below:
https://www.engage.england.nhs.uk/consultation/simplifying-research-arrangements/user_uploads/supporting-research-consultation.pdf

Managing Excess Treatment Costs

1. Do you agree with the six design principles we have used to develop our proposals?

We agree with the design principles and welcome the plan to better manage excess treatment costs. We recommend amending proposal ii. Consistency to provide further clarity of the geographical scope/boundaries being referred to e.g. England only, or UK wide Further detail is required about how multi-site trials and those in more than one UK nation will be managed under these proposals.

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

2. 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?

We agree however, consideration needs to be given to whether the LCRNs have suitable expertise to manage this process. Further detail is required about how this proposal would work in practice, particularly to explain how applications across multiple LCRNs and sites would be managed.

3. Do you agree that pooling risk across the 15 LCRNs to manage annual variation in ETCs would be an appropriate approach?

We would welcome more detailed information in this area in order to make an informed decision. The following points need to be clarified: Would all CCGs contribute? Would the annual funding contribution vary each year? Could unused funds be carried forward? Would it be possible to exceed the annual funding allowance contribution? How would more funds be obtained? What would the priorities be for awarding funding?

4. Will the proposals outlined work for both single site and multi-site studies?

We support using a consistent approach. As stated above further consideration needs to be given to how applications across multiple LCRNs and sites would be managed. We recommend that a fast track option is developed for low risk projects (e.g. observational studies/survey methodologies).

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

5. Do you agree with the proposal to strengthen the process for specialised services?

A faster process in which decisions are made in 6 weeks is particularly welcome. Consideration needs to be given to specialist services that are not nationally commissioned (e.g. mental health).

6. Do you agree that applications that fall below the proposed minimum threshold would not be considered by NHS England?

We support this as it will result in a more efficient use of time and funding. As stated above we are in favour of developing a fast track option for low risk projects (e.g. observational studies/survey methodologies).

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

There are specific risks for small, allied health profession led departments. Such units can be asked to absorb additional patient visits and costs in order to provide the standardised care demanded and stated in a research protocol. This can be problematic and lead to pressures on service. One example shared with CAHPR is a study involving post-operative care for patients following joint replacement. The research required patient clinician contact for only those patients who were failing to progress. However, to maintain fidelity the protocol required all patients to receive “standard care”. The standardisation involved changes to local service provision, the need for additional patient contacts, and subsequently created a funding shortfall. When these additional costs were presented to the Trust there was a reluctance to provide support and the notion that the ‘NHS should be covering it’ was commonplace. On this occasion the arguments made that funding is provided at Trust level did not hold, perhaps due to the size of the department and perhaps because of less research ethos engagement. The reallocation of care to service research therefore can ultimately impact on patient care as there is only a finite amount of provision available. Furthermore, the seemingly unfair transfer of provision from non-research patients can be a disincentive to participate in research.

We recommend that consideration should be given to developing an appropriate mechanism to allow Trusts to facilitate and engage in research without disadvantage or increasing workload/pressure.

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

8. Please rank the options outlined in Table 2 in order of preference with your preferred option first and your least preferred last.

Option	**Rank (1 preferred to 4 least preferred)**
1	3
2	2
3	1
4	4

9. Why do you think your preferred option is the best one?

We support option 3 (ETC per Trust, per financial year, fixed sum) as this provides some balance for different sized Trusts).

10. Are there any other ways to set thresholds that would work better than those presented?

We believe using an alternative model to ETCs could simplify and standardise the process. A simple model would be to calculate research costs as follows: Normal spending minus commissioning tariff = research cost. Commissioning groups know how much an intervention / care package costs and thus anything over and above this must be a research cost. For example if the local physiotherapy service is costed at £40 per contact and the stated intervention requires 4 sessions then the NHS cost (as tariff) would be £160 and any other costs that are incurred are considered research costs.

This would be contingent on standard tariffs for treatment in all fields.

11. 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?

There is not enough information in the document to make an informed decision. Considering primary care as a whole is an over simplification. More detail is required.

Further improving clinical research set-up and reporting

Refer to section 4. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

12. Which do you think is the best option for costing NHS provider participation in commercial research? [Option 1,2,3?]

Option 1 (National, binding coordination of contract values)

13. If you have selected Option 3, what is your proposal and how does it meet the design criteria outlined, i.e. capability, consistency, transparency, speed and simplicity, single point of access and continuous improvement?

N/A

14. Why do you think the option you have selected is the best one?

This option follows the described design principles.

Ensuring National Coordinators have defined minimum training/experience will be vital to the success of the proposed process.

Please refer to section 4 and Annex B. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

15. 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?

We agree that this requirement should be reaffirmed through the NHS Standard Contract.

16. If you have answered "N" to the above, what are the concerns/objections we should consider? [free text]

N/A

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

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

We recommend producing step-by-step guidance for researchers. This would need to be suitable for novice researchers and researchers working with commercial partners in particular. Clear guidance on the following topics would be welcomed: intellectual property, effective use of data, how to calculate costing formulae.

Proposed National Variation to the NHS Standard Contract

18. Do you agree with our proposed wording for a future National Variation to the NHS Standard Contract?

Yes, the proposed wording is clearer.

This response was submitted on 31 January 2018. For further information please contact cahpr@csp.org.uk.