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

1. What is your name? (Optional)

Name

Lisa Hevey

2. What is your email address? (Optional)

Lisa.hevey@bps.ac.uk

3. What is the name of your organisation? (Optional)

Name of organisation

British Pharmacol

4. What is your predominant role in research?

What is your predominant role in research?

Other

If you have selected 'Other', please specify

Membership orga

5. What type of organisation do you work for?

What type of organisation do you work for?(Required)

Charity

If you have selected 'Other', please specify.

6. Are you responding on behalf of your organisation?

(•) Yes ( ) No

7. Which section of the consultation do you want to respond to?

(Required) ( ) Manage excess treatment costs better (non commercial research) ( ) Further improve commercial clinical research set-up and reporting (•) Both

Managing Excess Treatment Costs in non-commercial research

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

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

YES

The society agrees with most of the design principles and strongly agrees with a single point of access, which would help provide a consistent approach.

The BPS agrees that changes are urgently required. The current arrangements are inconsistent between providers and, although delays have been reduced by recent governance changes, the current delay from application to first patient recruited is extremely long (142 days). The process for performing multicentre research in particular, which is essential for development of new drugs for example, remains very burdensome for researchers and creates unreasonable delays before studies are started and completed. There is inconsistency in the processes utilised by different R&D Departments, often duplicating HRA processes, and excusing these processes on the basis that legal liability lies with individual NHS Trusts. This has resulted in the UK becoming a less attractive and more expensive place for research. The Society believes that the NHS has the potential for finding and including patients in high quality clinical research perhaps more efficiently than any other country in the world but due to the 'red tape', this has become more difficult.

The arrangements for excess treatment costs are opaque and difficult for researchers and clinicians to understand. The sums involved are often small compared to the overall costs of the research and in many cases may be lower than the administrative costs involved in dealing with them. Provider hospital trusts often haggle over very small excess treatment costs, but the potential financial benefits of research participation should also be considered. For example, some funded research saves treatment costs for

the NHS and this should be taken into consideration.

To deal with the administration of research, NHS Trusts have had to invest substantially in staff and it is not clear that this investment has saved money overall or indeed provided worthwhile improvement in the safety or quality of clinical research. It has become a self-sustaining document-driven cottage industry.

9. 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?

(•) Yes ( ) No

Please provide any comments:

The Society considers that coordination of a standard process for determining ETCs for non-commercial research would be better managed by 15 sub-regional LCRNs rather than by 200-plus CCGs.

However, there is risk that the proposed system will remain overcomplicated, with potential for duplication by the 15 LCRNs. The proposal to have coordination where applications fall across multiple LCRNs could work but would need to be very well thought through and managed.

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

( ) Yes (•) No

Please provide any comments:

Overall, the Society does not believe that this would be the most appropriate approach without further supporting data. The risks appear to be very unevenly distributed, as judged by the data in Figure 1 of the consultation, being between £0/annum and £88k/annum. We suppose that factors such as the distribution of research-active hospitals and the extent of non-commercial research within them determines this unevenness. However, as indicated, without more information, it is not possible to know whether the burden should fall evenly on the 15 LCRNs.

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

(•) Yes ( ) No

Please provide any comments:

The Society believes that in principle, the proposals outlined should work for both single site and multi-site studies. It is extremely important to have consistent policies for these two types of study, to avoid over-complexity and confusion amongst researchers.

Managing Excess Treatment Costs in non-commercial research

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

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

(•) Yes ( ) No

The Society believes that it is unfortunate that a separate system is needed for this due to the separate arrangements for specialist commissioning. However, provided the processes are identical to those proposed for the LCRNs, it is of the opinion that this could work. It is also clear that NHS England Specialised Commissioning requires a responsive research network to ensure that appropriate decisions are taken on the basis of information collected within the NHS. A 'rapid, standardised process for ETCs relating to specialised services' will help do to this. It must however be noted that details of the process are not provided in this document.

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

(•) Yes ( ) No

Please provide any comments:

The Society would like to add that this should be an appropriate amount and not too low.

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

The Society does not wish to add any additional comments to the specialised services proposals.

Managing Excess Treatment Costs in non-commercial research

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

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

Option 2

Option 4

Option 1

Option 3

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

It is clear to the Society that each option has its individual problems, some of which have been outlined in the table. On balance, we believe that option 2 would be the best option as we are of the opinion that this would be the most equitable. We are particularly concerned about fixed thresholds, which do not take into account activity and the size of Trusts. We believe that this this would act as a disincentive for some Trusts to take part in research, particularly where the ETCs are at the lower end.

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

○ Yes ◉ No

Please provide any comments:

18. 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?

◉ Yes ○ No

Please provide any comments:

The Society believes that this would be logical.

19. Would you like to continue and respond to the second part of the consultation 'Further improve commercial clinical research'?

(Required) ◉ Yes ○ No

Further improve commercial clinical research set-up and reporting

Please refer to section 4.3 of the consultation document. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK.

20. Which do you think is the best option for costing NHS provider participation in commercial research?

(•) Option 1 ( ) Option 2 ( ) Option 3

21. If you have selected Option 3, what is your proposal and how does it meet the design criteria outlined?

For example; capability, consistency, transparency, speed and simplicity, single point of access and continuous improvement.

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

The Society believes that option 1 has the virtues of simplicity, and we would favour this option. We believe that this should be engineered to consider both the commercial and non-commercial trials.

Further improve commercial clinical research set-up and reporting

Please refer to section 4.3 of the consultation document and Annex B. Considering our broader national interest in making it as attractive as possible to conduct clinical research in the UK:

23. 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?

(•) Yes ( ) No ( ) Not sure

If you have selected 'No', what are the concerns/objections we should consider?

Further improve commercial clinical research set-up and reporting

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

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

Prospective registration of trial protocols should be required for all trials, as should payment to all investigators.

NHS Standard Contract

Please refer to section 5 of the consultation document.

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

( ) Yes ( ) No

Please provide any comments:

The Society does not believe that it is best placed to answer this question and wishes to defer to contract lawyers on this topic.