NHS
Research and Development Forum

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To whom it may concern.

RE: NHSE Commissioning Policies: Funding of treatment outside of clinical commissioning policy or mandated NICE guidance:

A: In year service development
B: Individual Funding Requests
C: Funding for experimental and unproven treatments
D: Continuing funding after clinical trials

- Thank you for providing an opportunity for comment on the above policy document.

- These comments are submitted on behalf of the NHS R&D Forum, which is a professional network and community of practice representing the health and care research management, support and leadership workforce. We are a non-profit organisation and have a clear interest in the implications of this policy on research, its management and delivery in the NHS.

- The Forum members and working groups would welcome further opportunity to feed into revised iterations of this policy. For further comment please contact kate.greenwood@rdforum.org.uk or info@rdforum.org.uk

- The consultation questions are found on **p13 & 14** of the guide. Whilst we have reviewed each question we have not responded to each individually. Our response therefore incorporates as many of the questions we have considered relevant to our area of interest, which is primarily the funding of clinical research treatments both during and after the research has ended. We have made some general comments on the overall layout and clarity of the policy, which we hope you will find helpful**.**

- **As always the Forum submits these comments in the spirit of constructive feedback, which we hope will be taken as such. Should we have misinterpreted the content in any way then please do let us know. This response will be published on our website www.rdforum.nhs.uk**

Summary of key points

- The Forum members welcome any attempt to clarify funding routes within NHSE for the funding of treatment costs in research however we have serious reservations about the inclusion of Excess Treatment Costs (ETCS) in this draft policy.

- We consider this draft policy to conflict with current guidance and duties to fund eligible non-commercial research treatment and excess treatment costs in the NHS. The policy does not allow for the complexities of ensuring excess treatment cost funding during multi-center studies and if implemented risks creating a gap in the timely provision of funds.

- The inclusion of specialised commissioning ETCS in the service development funding procedure means they are by definition unlikely to meet the acceptability criteria leaving an immediate gap in the funding of these difficult costs.

- The document is out of date in parts and NHSE should now work closely with the Health Research Authority, the Department of Health, the NHS R&D Forum working groups, NIHR, Charities and other non-commercial partners to ensure a revised version that is in line with existing guidance and a whole system approach.

- As this policy relates only to specialised commissioning procedures links to other processes and information would be welcomed.

Forum Response:

Comments on Clarity

- We have taken from the guidance that the scope of this policy is only for those treatment costs, which fall within the remit of specialised commissioning and that treatment costs to be funded via other commissioning routes are not within scope. If correct then this is not clear from the policy itself and should be made explicit, in lay terms, from the outset. It would be useful to have a reference then to the additional policies where other commissioning funding procedures that are the responsibility of NHS England and Clinical Commissioning Groups (e.g. for the clinical research treatment costs incurred in Primary Care) can be found.

- The use of the term 'generic commissioning policies' to describe central

commissioning of specialised services is quite confusing.

- In general the document is challenging to read. It is lengthy and complex and the lay sections use terminology that is arguably not easily or widely understood outside of those who work directly in a commissioning setting. The first two paragraphs of section **3.1** are an example of this. It would be a good idea to provide an explanation of what commissioning and direct commissioning means for the lay reader.

- The policy is reasonably clear on the principles upon which funding decisions will be made, however we believe there are considerable risks to the inclusion of Excess Treatment Costs within the scope of in-service development funding (see risks and gaps below). Otherwise we recommend the use of graphics and text boxes to highlight those key-founding principles upon which decisions will be made to make them more prominent.

- The policy makes statements about the nature of clinical research that we consider to be untrue and out of date, namely that "*the majority, are industry-sponsored*" (p.30). This is not the case and a cause for concern if policy decisions are predicated on this assumption, (please see latest NIHR portfolio figures www.nihr.ac.uk)

- The NHS in England currently has a statutory duty to promote research and has a critical part to play in the funding of treatment interventions for non-commercial research, including the assessment of interventions that are more than 1st line treatments.

- Our experience suggests the following statements concerning non-commercial trials of first line treatment and trials comparing existing and established treatments are not accurate. Although we acknowledge that *requests for funding* treatment costs in these trials may be rare, we argue this might be due to difficulty accessing funding routes for these costs rather than the number of patients receiving treatment in these types of studies per se?

  "This type of trial is rare, as most funding requests for experimental treatments are for second, third and fourth line treatments for the seriously ill, as a last resort. Equally rare are requests to fund patients in trials which address specific questions for an existing and established treatment…" (P.30)

- We advise avoiding use of the word 'sponsor' when describing a 'funder' (p.30). A research Sponsor has particular meaning and specific responsibilities in the context of clinical research and although they may sometimes be one and the same organisation they can very often separate for any given study.

- The detailed information required for making applications to NHSE is missing

from the policy, which we accept is a high level document however it would be helpful to include references to a website or other operational documents where the information can be found.

Comments on Risks and Gaps

- **We consider the inclusion of Excess Treatment Costs (ETCS) within the service development funding procedure to be inappropriate and of concern.** This process is lengthy and requires considerations that are not in-line with current NHS England guidance for the management of ETCS NHS England guidance. This guidance explicitly states:

  "Commissioners cannot [therefore] expect to be consulted, in every single case, on the development of all research studies for which they are subsequently asked to fund Excess Treatment Costs. Commissioners and their providers cannot refuse to meet Excess Treatment Costs, on the sole basis of affordability or prioritisation, where a legitimate funding request for these costs is submitted for a research project that has been awarded research funding by NIHR or one of its research partners."

- The principles for funding agreement described on **p12** of the policy are such that ETCs would be unlikely to meet them. **This means there is a serious gap in provision for ETCS that are to be funded through the specialised commissioning route.**

  For an example please see the first principle for funding:

  "NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness".

  Treatment interventions that are part of a clinical research study are by definition under evidence review and are part of the process for generating the evidence to confirm their effectiveness in a clinical situation. Therefore although many clinical research interventions will of course have some evidence base for their use, the evidence for clinical effectiveness will likely still be under review and without the funding to study the treatment the evidence will not become available.

  ETCS are also by their nature in excess of normal cost (despite savings that can be offset elsewhere), and are for study participants only and therefore not "*available to all patients within the same patient group*"

- Funding procedures for ETCS continue to be raised by Forum members as complex, difficult to access, and a block to research set-up and delivery. Therefore whilst we are pleased to see efforts to ensure clarity around specialised commissioning routes for ETC funding, these routes must ensure

that funding decisions are made speedily and effectively.

- ETCs can be calculated at study level in discussion with commissioners and funders, however ultimately sites require funding for their costs at a local level when they are approached to assess their capacity and capability to take on the study. Research sites very often join a study at a much later date to the first site recruited, and treatment pathways can change in this time. A large study that is multi-centre may have different ETCS at its sites with different arrangements for accessing funding. Therefore if the process for specialised commissioning costs is lengthy and onerous they will not succeed, the site will not be able to join, and the study can fail.

- There appears to be a conflict between this policy, which is based upon fair access to treatment for all, and that of the existing statutory duty to promote clinical research, which one might argue, is not. This could be resolved by removing clinical research from this policy altogether.

- If NHSE only intend to fund the treatment costs for clinical research that *"is of direct relevance to the goals and priorities of NHS England"* (p30), then a whole systems change to the current funding arrangements would be required for all studies eligible now for NHS treatment cost funding support, (i.e. research funded by the National Institute of Health Research (NIHR), other areas of central Government including Research Councils, NIHR partners and also investigator-initiated, commercial-collaborative studies). Whilst we recognize there is added value and a potential reduction in waste from involving commissioners upfront in research priority setting and co-design, we argue this is a separate issue to the current duty of NHS England to meet NHS treatment costs for eligible studies, and any change would require alternative funding channels for treatment cost support to be urgently established, agreed and written into UK policy.

- We are therefore concerned by the proposed review process required by NHSE for funding experimental treatment costs in research, and whilst accepting that research should take strategic relevance and ultimate commissioning decisions into account to avoid waste, we argue that this should be made part of the research funding process in agreement with partners and not part of the research approval process once a study is up and running. It would be in conflict with the current guidance (as quoted above) to conduct a second review after a study that is eligible for treatment cost funding has received research grant funding from the NIHR or partner organization and approval from the Health Research Authority.

- **Section 6** refers in detail to the ongoing provision of funds for treatments in clinical research. This is a complex area and we recommend the document is shortened by including only the information relevant to NHS England policy

decisions thus steering clear of issuing guidance on how research should be conducted (this is not the remit of this policy and may become out of date)

- Current guidance from the Health Research Authority on the provision of care after research can be found here:

  http://www.hra.nhs.uk/resources/during-and-after-your-study/care-after-research/

- As above, it would be of benefit to researchers and Sponsors of NHS research to understand *how* to seek input from NHSE on these matters early in research development and reference to this operational detail (website or operating procedures) should be made.

- Thank you for opportunity to comment. Please do not hesitate to contact the Forum management team if you have any questions about our feedback.