NHS
Research and Development Forum

NHS R&D Forum Response

CRN Study Support Service Effective Study Start-Up SOP.
Version Consultation Draft, 15 JUNE 2015

FINAL Version 1.0, July 22nd 2015

1. Introduction and Method

- The Forum working groups are extremely pleased to have the opportunity to comment on this Standard Operating Procedure for the new Study Support Services Effective Study Start-up, version Consultation in Draft. 15th June 2015

- The Forum hopes that the comments provided are useful in the development of a National Study Support Service (SSS) that will add value to researchers and Sponsors, and one that will compliment R&D support structures within NHS Trusts and Primary Care whilst mapping onto the new HRA approval processes.

- Three Forum working groups have reviewed and contributed; these are the Research Strategy Working Group, The Research Management Working Group and The Primary Care Working Group.

- The groups would very much welcome further opportunity to discuss and support the development of the Study Support Service and subsequent pieces of work, in particular any further policy development in this area.

KEY CONSIDERATIONS

- The SOP would benefit from more explicit statements on how each element of the SSS will add value; i.e. what the problems or risks currently are, how the Service will solve them and why the Service has to be mandatory (if indeed it is so).
- There is a lack of clarity in the roles and responsibilities of CRN SSS, Sponsors and Sites (at site and study-wide), and this should be addressed to enable the SOP and the Service to be most effective.
- The set up Service is considered to be offered too late in the process and as a result risk duplicating effort for NHS Sponsors in particular, and support activities should be considered pre-HRA approval.
- Timescales and metrics should be re-aligned with DoH and HRA (which could be an evolutionary process).
- It is unclear if all or parts of the service are optional or mandatory

2. Summary feedback

2.1. Service vs Core Site Activities

- The Forum working group members are encouraged that the value of local R&D support to researchers for study set up (including the assessment, arrangement and confirmation of capability and capacity in the NHS), has been acknowledged Nationally and that the activities undertaken by sites and networks to support researchers are better understood to include this service support function, that is different to final approval assurances or checks.

- The groups however felt that there is still much confusion with regards to roles and responsibilities for Portfolio studies and there is now the opportunity to make this much clearer for all the partners and stakeholders concerned. This is considered to be especially important when it comes to the ownership and responsibility for metrics, and might be best placed documented in a policy or other overarching paper to frame any subsequent SOPS as in other Quality Management Systems.

- The groups acknowledge that the Network has an aim and a mandate to make the researcher and the Sponsor experience consistent across the country, which is an aim that is shared and valued by the Forum working groups. However despite 'One NIHR', the distinctions between central CRN functions, local CRN functions, and local NHS 'site type' functions for portfolio studies are still not clear from reading this SOP. There is, for example, some confusion around what should be included in the following:

    - (a) Core 'site' activity (the term site is used in its broadest sense), where accountability for performance sits with the NHS/care organisation. This activity will be a site activity as part of HRA approval. These local activities have been articulated in the HRA paper "*Summary of the role and operations of research management offices in England*" (HRA, Oct 2013) but it has not been clear until this point how many of these activities will be funded by the Network or whether any of them will be considered to be mandatory. We assume (because local activity is within the scope of the SOP) that this activity will be funded by the Network through ABF for Portfolio studies, but that they may be performed by centralised Network staff under local agreement *on behalf of and at the request of those sites* according to local need.

      NB: Research Management teams at site are not identified as one of the professional groups belonging to the 'One NIHR' on the One NIHR website, although Research Nurses at site are included.Therefore although

teams maybe funded by the NIHR (as Research Nurses and Researchers are funded at site), it is not clear if the management teams are considered to be outside of the NIHR altogether or "working for" the NIHR as part of the CRN (many would not consider either to be an accurate position and so it would help to clarify what each of these means). Staff in NHS organisations can receive such mix of funding towards their posts such that they will often not know if they are considered to be network "staff" and their funding may also change from year to year. This in addition to the need for further clarity around the roles of Sponsor for study set up activities as the responsible organisation, creates confusion for a service and a process that needs to be followed.

- (b) Local network service activity where support for Portfolio studies will be undertaken by the Network (either through a centralised or devolved model). This activity will be funded by the Network and accountability for performance will sit with the Network. It is not yet clear whether this service will be offered at the request of the Sponsor or the Researcher (or the funder!) or whether it is mandatory for all Portfolio studies but it is assumed to be the case (see 2.2 below). These are the activities envisaged to be largely study-wide

- (c) The central CRN functions are those which support the National picture, for example the Central industry and Portfolio teams.

- The groups believe that clarity here is critical to ensuring a high quality lean and consistent service provision that avoids duplication of effort and unnecessary procedural layers. Currently however there is a risk of confusion around roles, responsibilities and metrics, and the groups believe this would not be helped by the current version of the SOP. The SOP may be easier to follow if this was broken down into smaller and clearer bite sized SOPS

- At present the groups understand that core activities are site responsibilities *and that sites are best placed to do them.* These activities may be eligible for Portfolio funding as network partners undertaking portfolio research and providers may join together to create centralised support functions via the network (most common for Primary Care). The network service provision responsibilities may be devolved or not to sites and some of them may be delivered centrally.

2.2.Monitoring and Metrics

- Although it is acknowledged that National policy change is not within the gift of the Network alone, there is both a need and an opportunity here to provide confirmation of all research management and service activities, including what the network will fund. As identified above, it is envisaged that the **core** NHS business activities for research set up and delivery are those that will be measured by the Department of Health, but funded by the CRN through to *sites (1)* for portfolio studies, (are they the activities for example on p27 of Appendix 1). For non-portfolio studies these activities will be costed and recovered from the Sponsor.

- However it is further acknowledged that if the Network are agreeing to provide funding then they will want to monitor performance against this core provision as other funders do. In which case the groups believe these metrics should be aligned to the HRA and DH metrics in order to assess whether sites are performing as agreed with the Sponsor, and delivering to time and target for example.

- The groups believe that the current metrics in the SOP are not in line with the HRA direction of travel and do not take into account that set up activity will be agreed with the Sponsor (not to be undertaken in a 30 day time window). The groups were also clear that reference to CSP, governance checks and the old metrics throughout the document is confusing and that we should be taking the opportunity to start anew unless it is to reference activities in CSP to be undertaken during phased roll out.

- Bench marks for study set up times may be identified eventually depending on study type but this will need to account for studies joining to set up at a later stage. Studies will need to be set up at various time points and where potential sites (and site types) are identified by the Sponsor in IRAS it might be another year before the Sponsor agrees to initiate them and the site is ready to recruit *(see section 2.4 below for more comments about portfolio support for additional sites).*

- The the activities that make up the Service offering provided by the network **in addition to** the core responsibilities could conversely be part of a local agreement where the Network decides to devolve activity to individual care organisations on *its* behalf, with the funding flow back to the site to perform the network service responsibilities. As above this agreement would be managed and monitored according to the quality of the services delivered.

- If the Network is not going to fund the capability and capacity assessment set up activities at site then the SOP should make no reference at all to this as a Net-

work function and all activities will need to be recovered from the Sponsor as a research cost.

2.3. Adding Value and a Mandatory Service

- The groups felt that there should be a much clearer focus and articulation on how the service element of the study support service (SSS) described in the SOP can really *add value* to the system and how this element of the support service function will bring positive change to research in addition to funding the core duties delivered at site. For example the SOP might specify what the problems currently are and how the service will solve them and that this should be more explicit.

- A service implies something that can be opted into and would be *chosen,* and the groups were clear that the service described in the SOP would not always be needed, perceiving it to be bureaucratic in places. For example it was difficult to see how NHS Sponsored studies and in particular those that are single site NHS Sponsored studies, would benefit from the study set up plan *at such a late stage* in the process. Therefore if it is mandatory activity then the SOP may need to be brought into the earlier part of the pathway, incorporated into NHS Sponsorship activities so that the R&D teams in NHS organisations are not being required to duplicate at a later stage.

- Added value might be provided through early engagement of HEI and commercial sponsors to support the feasibility and development of NHS focussed studies for roll out across many sites as this is something that individual organisations will not necessarily wish to absorb into their core workload and this could be a positive service offering from the CRN SSS. A second example might be the brokering of excess treatment costs for multi centre studies

- Currently this added value is explicit in the SOP and should be really articulated as something that can be sold to Sponsors, researchers, and funders as activity they would elect to be in receipt of that doesn't have the additional incentives of core funding provisions for sites, through ABF and accruals.

  NB: It is understood that an 'opt in' may not be appropriate perhaps where a policy decision has been taken that the risk to the NHS of not providing a central service is such that the support is mandated (perhaps for non-NHS sponsors for example) but again **this support needs to be provided at a much earlier stage than after HRA approval** in order to aide the development of an NHS ready study that will go through HRA approval to sites at the point it is ready to set up.

- Most group members believed that the SOP was written as if it is mandatory activity for all Portfolio studies regardless of need (i.e. this is the service that you get if your study is adopted onto the Portfolio). It should be noted that Clinical Research SOPS (as opposed to guidance) usually ***must*** be followed and therefore there are two functions to be considered here (1) whether it is a mandatory service offering (2) whether it is a mandatory set of instructions for providing that service.

- If the service is mandatory then NHS Chief Investigators and Sponsor who want to secure the accruals and service support cost funding for the delivery functions and nurse time etc, may be forced to accept a service that may not be in the interests of their study and this does not promote lean or pragmatic decision making. There is also the risk that an extra layer will be added for certain types of studies in particular and so **the challenge is perhaps to either articulate why the service is mandatory or to create a service that is smart and flexible to the needs of a locality and a project, but that *where it is selected* provides consistency of support through following of the SOP.** The separating of core activities from service activities and improved articulation of added value to support a defined need, would help this distinction.

- For the **core** responsibilities delivered at site level the Network might consider providing support for sites through funding to deliver their set up consistently at a local level as the groups agree local knowledge is needed to perform these functions. They might also provide those things to the sites that only a central function can do well on their behalf, for example facilitating the sharing of study level intelligence (and even resources) across a region or a patch to solve a problem.

- There was a strong feeling amongst the groups that the Network should be encouraged through their SOPS to ask the sites locally what they specifically needed to deliver their core duties and to also ask Sponsors, funders and researchers what they would want from any additional service support function; sites should also be offered flexibility and choice to deliver their duties in agreement with the Sponsor.

2.4.Additional Comments

- **Additional Sites & Portfolio Support:** The groups were concerned about the statement in Appendix 1 that "*any new sites added after NIHR CRN Portfolio inclusion are not automatically eligible for Network support and will need to be discussed and confirmed that they an be supported"*. This is not considered to be practical and seems to be a policy shift as service support costs should be met by the Network for Portfolio studies and sites will always be added in waves accord-

ing to the set up needs of the Sponsor? Again our understanding is that core activities should be funded regardless of the service offered and clarity here on the Network position would be welcome.

- **Ready to Recruit Status:** The group felt that a site can only declare that it is 'ready to recruit' after HRA (REC and regulatory approval). Therefore this should be either re-considered or re-worded in the SOP. Following HRA approval, site readiness will be confirmed to the Sponsor via agreeing the statement of activities and it is therefore critical that all Network processes to support site set up are joined up. Again the study support service for set up is considered to be too late in the process and may be better placed prior to HRA approval so that the only things remaining after HRA approval are the local site core capability and capacity 'assess, arrange and confirm' activities, which could of course include co-ordination across an LCRN patch.

- The proposed timelines do not account for sites that will be listed in the R&D form but where the sponsor and site both agree they will be in the second wave and as such should not be agreeing that they are ready to recruit at this point. Site assessment of target numbers will not be accurately known until this point.

- **References to CSP:** In Appendix 1 there is reference made to CSP for assess, arrange, confirm, and the group believes this should be removed to avoid the concept that individuals should still be undertaking CSP checks, although some of the local activities in appendix one are supportive, helping for example to confirm compliance at site, they are the statements of assurance and not the process of set up. The groups were not clear if the CRN expectation is that these activities would be collected centrally through a 'CSP-type' IT system or whether this would be better placed recorded as part of the statement of activities to avoid duplication of effort, and therefore further clarity on this is requested.

- **Duplication of Activities:** Some of the activities currently articulated in the Study recommendations section, were considered to still be either local core site activities or HRA activities (some of which were already identified in the document) and therefore may be duplicated as part of the centralised study-wide SSS provision (i.e. determine the study workload at the site including screening and follow-up; identify local support departments).

- If the SOP is incorporated earlier into the study development pathway as recommended by the groups, then activities (for example for the assessment of study site types) could perhaps be more aligned with the HRA approval process and not duplicated (site types will be recorded through completion of each statement of activities or could be incorporated into the Sponsor assessment for NHS spon-

sors?). Again for NHS organisations that are the Sponsor, the CI will have liaised in detail so would not be expecting to go through the additional pathway at this point therefore if the process is mandatory it will need to be much earlier in the process, joining up with Sponsors and funders.

- **IT support function:** The groups were unclear whether there would be any centralised IT support function to facilitate the sharing of documents.

- **Staff competencies:** The groups reflected a need to ensure that the Service elements are provided by staff who demonstrate competence to provide this service to Chief Investigators and Sponsors as it is a very different role to that of a Research Governance Officer.

2.5.In Summary

- In summary the feedback from the Forum working groups is clear that the Network is well placed to resolve some of the confusions that exist around network and site support functions, and that there is opportunity to really make explicit the Network service offering without duplicating effort. This may require further iterations of the SOP to get the provision right and the process map should reflect and make reference to where HRA approval comes in the scheme of things; some of the service provision may be brought forward to before HRA approval. The Forum would welcome closer involvement to support this where possible.
- As with all our consultation responses the Forum would very much welcome feedback if our understanding of the SOP is misplaced.