NHS
Research and Development Forum

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To whom it may concern,

Re: Four Nations Group site-specific information for NHS/ HSC sites – a call for comments

Please find below a response to the above call for consultation, on behalf of the NHS R&D Forum working groups. The Forum is a professional network for people working in the management and leadership of Health and Care research, and is a not-for-profit organisation. One working group (the Research Management Working Group) provides this response, which would fall under the category of 'NHS R&D'. We have chosen to respond to the questions directly asked.

Forum Response

1. **What are your views on the current SSI form?**

- In general the group were clear that that SSI form had served a valuable purpose but that it was no longer comprehensive enough to do the job it was originally intended to do (namely to *provide* site specific information), and that its role had also changed over time to be more of a tool for *recording* of site specific information by local teams.

- The group was clear that many R&D teams have reconfigured to be more facilitative to research teams and will often use the SSIF to work with Sponsors to build a local picture of how the study will run at site. In this regard the SSI does not provide the means for a comprehensive local assessment: information is only a snapshot in time, it is not the means by which sites can really establish or record how a study will run, or indeed whether it can run well locally. However it *is* something that sites can use to start the conversation with research teams and to record recruitment targets, planned timelines and intent.

- The group liked the current ability for Principal Investigators to sign up to their responsibilities via the SSIF but acknowledged that this could be done through other means (such as PI agreements or a new template). Another positive was that it could be generated from one data set in IRAS and is a national form, which supports R&D offices to approach research teams and help them with their assessments – it can effectively start the conversation with a PI. It was however widely accepted that much of the

additional information in the form was considered to be meaningless, a snap shot in time and usually cut and paste from other SSI submissions.

2. **Are there any issues with completing and submitting the SSI form?**

   There were no perceived difficulties with completing the form as such however it might be submitted at different times along the set-up pathway. The form currently requires local knowledge and depending on the nature of the R&D support function within each organisation may be either the start, or the end, of the local review process.

3. **Does the SSI form effectively capture all the information required by sites at an appropriate time, or is there still information exchange after submission? Or is submission delayed pending confirmation of information?**

   The group was clear that the current SSIF form does not effectively capture all information required by sites at an appropriate time and that many questions (such as for example, Sponsor training requirements and SIV) are not included and are often asked for separately. Laboratory and pharmacy manuals are often submitted after the SSI and costing and contracting information can be submitted at different time points too.

4. **Are there fields on the SSI form that add little value, or that could legitimately be determined later in the set up process for NHS sites?**

   There are some fields the group considered to add little value for sites as they were considered to either be part of that site's local policy (for example, where the patients can go within the organisation for support). There was not consensus amongst the group with regards to WTE, as this currently provides a means by which sites can start the conversation about resource requirements with the Principal Investigator (particular research nurse support), but this will not reflect the nature of the research team over time as it will change and can be difficult to meaningfully estimate. Again clarity over the purpose of each dataset should helps this process (for example – the new agreed form could provide an assessment of the activity, how long the Sponsor might expect it to take and the level of expertise they need to undertake that particular task. The site would then be able to confirm if that is possible for them given resources and capability).

5. **What are your views on a revised shorter SSI form, maintaining the approach to require all fields to be accurately completed by the applicant before submission?**

   It is not clear who the applicant would be? If it is the Sponsor providing information to sites then the form is not long enough. If it is sites performing site -specific assessment/capacity and capability assessment, then a shorter form may not be enough to record the whole assessment, although a much

shorter form might prompt that assessment to be made. In principle a short form generated from a single IRAS data set might be helpful to kick start a local process of assessment, particularly for the larger Trusts who still operate local team submissions to the R&D Office but this does feel like a lot of forms, which can be confusing for researchers.

The group would need further information to make a more informed decision on this question but a clear distinction should be now made between provision of information to sites (rather than sites collecting information from the Sponsor), and sites assessing this information and their ability to comply and deliver against it. A national form is beneficial for the former but the question remains whether another separate national form is really required for the latter.

6. **What are your views on replacing the SSI form with a template where a sub-set of the template items are mandatory for the sponsor or delegate to provide, but that the other information can be provided by the appropriate person at an appropriate point of time?**

The group understood this to be the principles behind the current Statement of Activities. In general this was the preferred option as long as the template produced is a comprehensive set of all the information required by the site (submitted from the Sponsor or applicant) to enable the site to (a) understand all the activities required and agreed by HRA/central approval or assurance (b) to assess local capacity and capability and make the arrangements required. The process should be iterative but there does need to be a minimum level of information required by the Sponsor to submit to site and if some of that information is going to be provided later by the Sponsor (as opposed to the information agreed by the Site) then there should be early decision as to what this might reasonably be and how that might impact on site set up.

7. **In your view, what is the minimum information essential to support effective and efficient site set-up**?

- We have not provided our list here but are very willing to work with the Four Nations Group to identify a minimum data set. It should however include all the generic information about a study that a site needs to assess its ability to deliver it (the '*what*'). The local specific information (the '*who*' and the '*how*') can then be established by the Site and recorded somewhere, although it is accepted that some R&D teams may wish for elements of the 'who' to be provided on a local SSI-type form.

- The group was extremely keen to make the point that <u>follow-up</u> activity requirements should be made explicit on any provision of information to sites.

8. Are there any unintended consequences the four nations should be mindful of if we were to move away from an SSI form to a new approach?

- The only unintended consequence we can foresee is losing the ability to co-ordinate from a single IRAS dataset that researchers understand, therefore in any decision the communication to researchers should be considered at all times and a clear distinction made between the purposes of each form/dataset (for example – '*this is the information required by sites in order for them to assess their ability to deliver Sponsor requirements*').

- There should be a common definition of a minimum dataset required to start any 'clocks' used for metrics and if the means of signing off PI responsibilities via the SSIF is removed it would be helpful to endorse the use of local agreements UK-wide to be clear they are a requirement for all studies (or at least certain study types) and not local nuance. Primary care implications should also be considered as study set-up is very much more complicated.

- Finally the removal of a nationally endorsed form *may* mean local PIs (as opposed to local R&D offices) misunderstand the national requirement to assess capability and capacity and we do not want lose the gains we have made in ensuring this facilitated activity happens meaningfully (and that local research teams expect it to happen). This however can be managed through good communications, local SOPS and policy requirements, but may be an unforeseen consequence if alternatives are not carefully considered (it is not in itself a reason to keep an additional form).

We hope that you find this information useful but please do not hesitate to come back to us should you require further support, particularly with regards to Primary Care.

With best wishes

Research Management Working Group
On behalf of the NHS R&D Forum working groups