Site specific information for NHS/ HSC sites – a call for comments

Background

UK competitiveness for health research is dependent on the competitiveness in each of the countries and collectively across the UK. The UK is committed to delivering streamlined and efficient processes for the regulation and governance of research within a framework of UK-wide compatibility. The UK has successfully operated within this commitment of compatibility for many years, for the benefit of the UK. The UK nations are working towards adoption of a combined form in the Integrated Research Application System (IRAS) to replace the Research Ethics Committee (REC) form and NHS Research & Development (R&D) form.

Current arrangements for delivering and confirming local management permission are organised differently within each country in recognition of the devolved nature of the health services across the UK, with agreed arrangements to support cross-border studies. A standard application form, the Site-Specific Information (SSI) Form, for NHS/ HSC permission is provided in IRAS to provide information relating to each site to allow sites to confirm their ability to conduct the study. The UK Four Nations Group, with representation from the UK Health Departments and the Health Research Authority (HRA), has heard feedback from both sponsors and sites that the requirement for the SSI form to be completed in its current format results in variable quality of the information provided to local sites, and the timing of submission is open to variation. This variability is a particular issue in England, and the HRA is already testing potential alternative options for agreeing local site information through the early cohorts of HRA Approval in England.

Call for comments

The four nations wish to seek views on options for future arrangements for site information. Each nation will have a process for provision of this information to R&D staff (which may be via the national coordinating centre) and local research teams. However, all four nations wish to achieve a common trigger for the sponsor to initiate formal site set-up.

Initial soundings suggest a number of options may be possible, but that the requirements may differ depending on whether the study is commercially or non-commercially sponsored. For all options further local documentation may need to be provided.

The following four options are proposed for comment:

1. Retain the existing SSI Form with a requirement for the applicant to provide a complete and valid form before the local site set-up process can commence
2. Use a revised shorter SSI Form, with a requirement for the applicant to provide a complete and valid form before the local site set-up process can commence
3. Use template document(s) with a minimum dataset of information for the sponsor or delegate to provide in order to initiate discussions with the site, and the remaining dataset completed jointly

For commercially sponsored studies:

4. No requirement for additional site information to be formally provided as relevant information available to sites via model agreement templates and costing templates, visit schedule of events and standard study documents e.g. protocol. Confirmation of the study team at each site would also need to be provided.

The above four options are not mutually exclusive, and may be applicable to particular situations or study types. We therefore welcome comments on potential benefits or implications on different scenarios such as commercial or non-commercial studies, clinical trials or non-trials and primary care or secondary care. We welcome comments on the content of any of the above options or any other options not yet considered.

Approach to consultation

The deadline for comments is Friday 18th December 2015

You may respond specifically to the questions below or respond in your own format.

1. What are your views on the current SSI form:
    - Are there any issues with completing and submitting the SSI form?
    - 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?
    - 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?
2. 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?
3. 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?
4. In your view, what is the minimum information essential to support effective and efficient site set-up?
5. 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?

Please send your comments to:

Wales: DSCHR@wales.gsi.gov.uk

Scotland: SSIcall@gov.scot

Northern Ireland: Michael.Cunningham@hscni.net

England: The HRA will seek feedback as part of ongoing listening and feedback during roll out of HRA Approval. HRA.approvalprogramme@nhs.net

In responding please let us know your role in research:

- Commercial sponsor
- Non-commercial sponsor
- NHS R&D
- Researcher
- Other