Health Research Authority

Guidance Document for HRA Statement of Activities for Participating NHS Organisations in England (version 4.2)

What is the HRA Statement of Activities?

The Statement of Activities is part of the application document set for non-commercial studies submitted for HRA Approval. The Statement has three main functions:

- The template completed by the sponsor provides key information to facilitate the HRA assessment component of HRA Approval;
- The information that is confirmed as part of HRA initial assessment, and provided by the sponsor to participating NHS organisations in England as part of the local document package, is intended to facilitate the assessing and arranging of capacity and capability (where applicable) to undertake the study[1];
- In certain cases, the completed and localised Statement of Activities (taken together with a HRA Schedule of Events), forms the agreement between the sponsor and participating organisation in England through which the organisation confirms that it is ready to commence the study (i.e. in place of any other form of site agreement/contract). Where this is the case, it is made clear in the HRA Initial Assessment letter (where one is issued) and in the HRA Approval letter. In all other cases, other agreements are to be put in place between sponsor and participating organisation, e.g. the model non-commercial agreement (mNCA). The HRA encourages use of the Statement of Activities as the agreement for studies that are not clinical trials or clinical interventions. For clinical trials and clinical interventions, the HRA encourages use of the appropriate model agreement (e.g. mNCA). The Statement of Activities should not be used as an agreement with participating organisations in Northern Ireland, Scotland or Wales.

Each template Statement of Activities for each 'site type' should be accompanied by a completed HRA Schedule of Events, as part of the submission for HRA Approval. The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity[2].

The Statement of Activities provides clarity on what funding the sponsor will be providing to cover Research Costs at participating organisations, as well as what Service Support and/or other resources are required locally. The Statement also provides the applicant with an opportunity to describe any NHS Treatment Cost savings that may accrue during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment will incur savings on treatment costs during the study). Even studies that incur Excess Treatment Costs in one

[1] For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

[2] See AcoRD for further information on cost attribution. At the current time, the HRA will not be assessing whether the cost attribution of the sponsor, as laid out in the HRA Schedule of Events, is correct or that the full local Research Costs of the study are covered. These additional assurances will be introduced in future cohorts, once the Statement of Activities and Schedule of Events have undergone robust testing in use.

aspect may accrue treatment cost savings in another (e.g. staffing for the experimental intervention may be more expensive than standard of care but the intervention itself may be provided free of charge, giving rise to an overall cost-saving). The Statement therefore helps participating organisations better understand the overall treatment cost/cost savings within their research portfolio and supports conversations with commissioners, where appropriate.

The Statement is intended to facilitate the conversation between sponsor and participating organisation that is required to effectively set up a study. The sponsor should provide the relevant template Statement of Activities, as assessed by the HRA, to each participating organisation as part of the information package sent following HRA initial assessment.

The Initial Assessment Letter (or HRA Approval Letter, where no Initial Assessment Letter needs to be issued) will confirm the version and date of the template/s assessed by the HRA and should also be included in the information package sent to participating organisations in England. The information package should be sent simultaneously to both the study delivery team and the research management support team for each participating organisation in England (including, where the study is on the NIHR Portfolio, the LCRN).

In many cases, arriving at a final Statement of Activities for a participating organisation will be a collaborative endeavour between the sponsor and that organisation, including local research team members, the research management function supporting them, and, where applicable, the LCRN. As such, the final statement for an organisation may require changes from the template version assessed by the HRA, in order to appropriately reflect the final understanding between parties. Changes should be made and agreed collaboratively.

What is a 'Site Type'?

Many research studies take place at more than one participating organisation. Where this is the case each participating organisation might be required to undertake the same research procedures, e.g. identify, consent, treat and follow-up research participants. In such cases the study has only one 'site type' and only one Statement of Activities and only one Schedule of Events should be submitted to the HRA.

In other cases, different participating organisations may be required to undertake different sub-sets of the overall set of research procedures that make up the study, e.g. some participating organisations may identify and consent participants whilst others treat and follow-up. In such a case there would be two 'site types', meaning that two Statements of Activities and two HRA Schedules of Events should be submitted to the HRA.

It is important to note that the number of Statements and Schedules to be submitted to the HRA for any one study is determined by the number of site types, not by the number of sites.

Confirmation of Capacity and Capability to Deliver Study

Where the Statement and Schedule form the agreement between the sponsor and participating organisation in England, with no additional agreement (e.g. a mNCA) to be put in place, agreement of the parties to the accuracy of the information in the two documents confirms that the

participating organisation has the capacity and capability to deliver the study and intends to commence the study locally on the date stated.

It is not intended that this confirmation involves wet-ink signatures, or the passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

Where additional information has been added to the Statement subsequent to application for HRA Approval (e.g. BACs details, name of PI, etc.), or information originally provided has been updated, such email confirmation should include copies of the final Statement and Schedule that form the agreement.

Where Initial Assessment and/or HRA Approval letter/s state that no local confirmation of capacity and capability is expected, the Statement will be assumed to have been confirmed by the participating organisation 35 days after sponsor submission for HRA approval (or potentially sooner, as detailed in the Initial Assessment and/or Approval letters), so long as HRA Approval is in place by that time and unless the organisation provides written explanation for a decision not to participate or explains that more time is needed to assess their participation.

How do I complete my Statement/s of Activities?

Parts of the Statement should be completed by the applicant before submission to the HRA. These questions appear in blue boxes and are further denoted with an asterisk*.
Other parts are for completion by the participating organisation and are intended for use primarily when the Statement is to form the agreement between the parties. These questions appear in green boxes and are further denoted with a caret^.
Finally, some parts of the Statement might be completed either by the applicant prior to submission to the HRA, or by the participating organisation once the local document pack has been shared with them (or collaboratively by both parties) – depending on the nature of the study and the activities to take place at the organisation. These questions appear in boxes without colour or shading.

Please read the question specific guidance where present.

Schedule 1 – Finance Schedule

Any funding, resources and/or equipment to be provided by the sponsor to the participating organisation should be detailed here. Where such transfer is to take place and the Statement is to be used in place of other agreements (e.g. the mNCA) this schedule should be partially completed by the sponsor before submitting the Statement as part of the application for HRA Approval. Remittance details should be completed by each organisation and shared directly with the sponsor, to facilitate payment. If funds, resources and/or equipment are to be provided by the sponsor to the participating organisation but the sponsor intends to use a separate agreement, this should be clearly stated.

Schedule 2 – Material Transfer Provisions

This schedule allows the sponsor and participating organisation to agree the transfer of human biological material, including relevant material under the Human Tissue Act 2004, and is in line with the guidance for sponsors and participating organisations in the UK-wide study-wide governance criteria on the use of material transfer agreements. The sponsor should use the options boxes at the top of the page to make clear whether or not it wishes these provision to form part of the agreement (where the Statement of Activities is being used as the agreement) and, if it does not, whether it has made alternative provisions for agreement for the transfer of any human biological material (any other agreements with participating organisations that are to be proposed by the sponsor, including material transfer agreements, should be submitted as templates to the HRA as part of the application for HRA Approval). The application for HRA Approval should also include the templates of any agreements to be proposed for use with NHS sites in the devolved administrations (where applicable).

Schedule 3 – Confidentiality, Data Protection and Freedom of Information Provisions

Where a study involves the transfer of Personal Data (as per the Data Protection Act 1998) from a participating organisation to the sponsor or its agents and/or there is transfer of confidential information between the parties, the sponsor may select to make use of these provisions for agreement with its participating organisation/s, where the Statement of Events is itself used as the study agreement. In such a study, should the sponsor elect to make use of an alternative agreement (or should the HRA expect an alternative agreement – i.e. if the study is a clinical trial or clinical investigation) the submission package to the HRA should include templates of the additional/alternative agreement/s. The application for HRA Approval should also include the templates of any agreements to be proposed for use with NHS sites in the devolved administrations (where applicable).

Appendix 1 – Staff Signature and Delegation Log

Appendix 1 is for use at the discretion of the participating organisation and sponsor, to record the delegated roles and responsibilities of the local research team (where applicable) and the authorisation of the Principal Investigator for this delegation. It is not intended that appendix 1 is completed for the submission to the HRA but is a matter between sponsor and their participating organisations. The document may serve to support assessing, arranging and confirming capacity and capability to undertake the study and may also serve (at participating organisation and sponsor discretion) to capture any changes in personnel and/or responsibilities during the course of the study (and to be held in the investigator site file).

How do I submit my Statement of Activities to the HRA?

All submissions for HRA Approval should be made electronically through IRAS. The Statement/s of Activities and Schedule/s of Events form part of the document set for non-commercial studies that should be uploaded to the IRAS Form checklist tab prior to submission. To upload your Statement/s and Schedule/s please select 'Add New Row' at the bottom of the checklist tab. Please attach one document per row labelled "'Other' (please specify)".

Accessing Help and Support Completing this Document

Please refer in the first instance to the question specific guidance. Additional queries may be addressed to hra.approval@nhs.net

User Feedback

The HRA wants to hear from you about the Statement of Activities and Schedule of Events. Whether you work for a sponsor or organisation hosting research, whether you have made an application for HRA Approval or not, we want your views. Formal feedback may be provided by completing the User Feedback form (attached to both the Statement and Schedule templates) and returning it to hra.approvalprogramme@nhs.net