**Statement of Activities (SoA) – Guidance**

The form is colour-coded:

* The blue portions must be completed before being submitted to the Health Research Authority (HRA) and Health Research Authority Wales (HCRW) with initial application. This is the template copy.
* White portions contain details about individual sites; the copy sent to a site contains its details.
* The green portions are completed by the site to confirm agreement.

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| *Blue shaded fields (also marked with an asterisk\*) should be completed by the sponsor/applicant prior to submission to the HRA,and HCRW.* |
| Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor. |
| Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate. |

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| **Contact details** | Please enter **researcher** contact details |
| **Site Type** | One of these statements must be completed for each site type: if the study has PICs as well as a research site, this would entail two statements; one to be a template for research sites, one to be used for PICs.  |

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| **Name of Participating Organisation** | This will be customised on each copy to be sent to a specific site. For the template to be submitted to the HRA, leave blank or indicate that the statement will be used for multiple sites. |

1. **Does the sponsor intend that this document (SoA) forms the agreement between itself and the participating organisation/s in England and / or Wales?**
* For studies in the top four IRAS categories, regulations require a contract. In those instances, tick ‘no’. Please contact your departmental research contracts specialist with details of your study for further guidance.
* For all other studies, tick ‘yes’
1. **Date statement of Activities Confirmed** and
2. **Confirmation on behalf of participating organisation**
* This confirmation follows receipt of HRA approval and marks the point at which activity can begin at a site.
* Green portion to be completed by R&D at individual site.
1. **If this Statement is not intended to form the agreement with the participating organisation/s in England and / or Wales, will the sponsor be using an unmodified non-commercial agreement?**

This question follows on from Q1. If answer to 1 is *yes*, leave this blank; if answer to 1 is *no*, the Research Services contract team will advise whether a model *non-commercial site agreement* (mNCA)is necessary.

**6. Predicted Participant Recruitment, if applicable.**

* This is a white portion, to be completed per site, as negotiated with them.
* If there are multiple sites state, in the template to be submitted:

*The study has multiple sites and recruitment rates may vary.*

**7. Proposed start date … at participating organisation**

* Proposed start date to be negotiated with individual sites – if multi-site study indicate that this date may vary between sites/leave blank for template submission.
* Activity to which this date refers should be the same for all sites: this will typically be screening or patient identification.
1. **Predicted end date … at participating organisation**
* As with question 7, date may vary with site, but concluding activity should be the same for all sites.
1. **Projected NHS Treatment Cost savings at this site type, if applicable**

This would apply, for instance, if drugs or devices are being provided that would otherwise be a cost to the Trust. Seek advice from finance.

1. **The following training for local staff will be provided by sponsor.**

This could include protocol training (site initiation) by central research team and

access to online and face to face GCP training.

**In addition to the above training… the sponsor also expects that the following local research team members will undertake the following training.**

Please add the following statement:

*The Sponsor expects individuals involved in a study to be trained appropriately for their function.*

**Schedules:**

1. Finance, 2. Material Transfer Provisions, 3. Data Processing, 4. Data Sharing

Each Schedule has three options:

* Not applicable;
* Separate agreement is being used; tick this box if as per question 4 a *non-commercial template site agreement* is being used
* This statement of activities is intended to form the agreement; tick this box if as per question 1 *this document (SoA)*is being used.

**Appendix 1**: Staff Signature and Delegation Log

This log is not currently compliant with regulations. Please do not use it. Tick the second box.