Statement of Activities – Guidance

The form is colour-coded:

- The blue portions must be completed before being submitted to the HRA 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.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*
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.

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.

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 forms the agreement between itself and the participating organisation/s in England?**
   - For studies in the top four IRAS categories, regulations require a contract. In those instances, tick 'no' .
   - For all other studies, the OUH contracts team will advise the R&D team.

2. **Date statement of Activities Confirmed** and
3. **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.

4. **If this Statement is not intended to form the agreement with the participating organisation/s in England, 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*, contracts will advise whether this will be sufficient or a modified agreement is necessary

5. **If no, please provide details…**

The Trust's template site agreement is based on the non-commercial template site agreement and follows its general principles.

- A template of the site agreement will need to accompany the application

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.

8. **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.

13. **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.

14. **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.

15. **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. Confidentiality, Data Protection and Freedom of Information

Each Schedule has three options:

- Not applicable;
- Separate agreement is being used;
- This statement of activities is intended to form the agreement

Where a schedule is applicable, selection of second or third option will correlate with answers to questions 1, 4 and 5.

Appendix 1: Staff Signature and Delegation Log

This log is not currently compliant with regulations. Please do not use it.