Quarterly Study Review Form for Trust Sponsored Studies

This Form is to be used when submitting a quarterly progress report to the sponsor

Refer also to R&D/S06

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS FORM TO ENSURE THAT THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit’s website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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| Form Reference: | R&D/F22 |
| Version Number: | 6.0 |
| Author: | Monica Haritakis |
| Implementation date of current version: | 14th February 2023 |

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| Approved by: | Name/Position: | Deborah Phillips, Research Advisor  |
| Date: | 17th January 2023 |
|  | Name/Position: | Sarah Sheath, SOP Controller |
|  | Date: | 17th January 2023 |

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| This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise |

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

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| Version | **Date Implemented** | **Reviewers** | **Details of significant changes** |
| 1.0 | 12th October 2009 |  |  |
| 2.0 | 21st November 2011 |  | Scheduled review. Minor changes to layout. DSUR included. |
| 3.0 | 15th August 2017 |  | Removal of references to the North and East Yorkshire Alliance. Change of fax number. |
| 4.0 | 20th March 2019 |  | Change in procedure for quarterly reporting. Form amended to ensure appropriate for Quarterly QA meetings. Update to link for R&D website |
| 5.0 | 11th April 2019 |  | One column removed from section 5 |
| 6.0 | 14th February 2023 | Monica HaritakisGreg ForshawTom SzczerbickiJonathan Hawker | Change of Trust name. Change of author. Reformatted to make it easier to complete. Fewer fields to complete so that it is easier to identify any concerns. |
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**QUARTERLY STUDY REVIEW – TRUST SPONSORED STUDIES**

**STUDY DETAILS**

**1. CHIEF INVESTIGATOR**

|  |  |  |  |
| --- | --- | --- | --- |
| Name: |   | Email: |   |

**2. STUDY**

|  |  |  |  |
| --- | --- | --- | --- |
| Short title of study: |   | REC Number: |  |
| IRAS number: |  | EudraCT Number (if applicable): |  |
| Study design: |  |
| Recruitment target: |  |
| Proposed number of sites: |  |

**3. DATES**

|  |  |
| --- | --- |
| Date of Sponsorship: |  |
| Date of REC approval: |  |
| Date of MHRA approval/notification (if applicable): |  |
| Date of HRA approval: |  |
| Planned study end date: |   |

**4. STUDY UPDATE**

|  |
| --- |
| **Regulatory reporting requirements** |
| Date most recent REC progress report submitted? | Date sent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_N/A[ ]  |
| Date most recent DSUR been submitted? | Date sent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_N/A[ ]  |
| Have any other reports / abstracts / publications been submitted? | Yes[ ]  No[ ] If ‘yes’ please provide further information below: |
| Have copies of reports been sent to the R&D unit? | Yes[ ]  No[ ]  N/A[ ]  |
| **Recruitment and Withdrawals** |
| Number of sites open: |  |
| Are there any issues with opening sites? | Yes[ ]  No[ ]  If ‘**yes**’ please provide further information below: |
| Total Recruitment: |  |
| Have there been any difficulties with recruitment? | Yes[ ]  No[ ]  If ‘**yes**’ please provide further information below: |
| Total Withdrawals: |  |
| Are there any concerns about the number and/or reason for withdrawals? | Yes[ ]  No[ ]  If ‘**yes**’ please provide further information below: |
| **Safety Reporting- SAEs/SUSARs** |
| Is safety reporting a requirement of the study?  | Yes[ ]  No[ ]  (if ‘**no**’ move to ‘safety reporting section’)  |
| Does the RSI need to be reviewed?  | Yes[ ]  No[ ]  |
| Have any SAEs or SUSARS been reported?  | Yes[ ]  (please provide SAE log) No[ ]  (if ‘**no**’ move to ‘safety reporting section’)  |
| Have all SAEs and SUSARS been reported and recorded as per Trust SOPs and regulatory Requirements? | Yes[ ]  No[ ] If ‘**no**’ please provide further information below: |
| Are there any concerns about the number or reporting of SAEs? | Yes[ ]  No[ ]  If ‘**yes**’ please provide further information below: |
| **Safety Reporting- Breaches** |
| Have there been any breaches to study protocol or GCP since last report? | Yes[ ] (please provide Breaches log)No[ ]  (if ‘**no**’ move to ‘amendments’ section) |
| Have there been any **serious breaches** to study protocol or GCP since last report? | Yes[ ]  No[ ] If ‘yes’ please provide further information below: |
| Have these been reported and recorded as per Trust SOPs and regulatory Requirements? | Yes[ ]  No [ ] If ‘no’ please provide further information below: |
| Are there any concerns regarding number of breaches at any Site | Yes[ ]  No [ ] If ‘**yes**’ please provide further information below: |
| **Amendments** |  |
| Have there been any amendments been made to the study since the previous report? | Yes[ ]  (please provide amendment log)No[ ]  |
| **Study Oversight** |  |
| Is there sufficient CI oversight for the study | Yes[ ]  No[ ]  If ‘**no**’ please provide further information below: |
| Is CI oversight adequately recorded | Yes[ ]  No[ ]  If ‘**no**’ please provide further information below: |
| **Study Team** |
| Has there been a change to Study management team? | Yes[ ]  (please provide delegation log)No[ ]  |
| **Monitoring** |
| Is there a risk assessment for the study? | Yes[ ]  Date of risk assessment\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]   |
| Is there a monitoring plan for the study? | Yes[ ]  Date of monitoring plan\_\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]  If ‘no’ please provide further information below: |
| Are monitoring visits being conducted as per the monitoring plan?  | Yes[ ]  No[ ]  If ‘no’ please provide further information below: |
| Have any significant issues been identified at monitoring? | Yes[ ]  No[ ]  If ‘yes’ please provide further information below: |
| Are there any issues with sites addressing monitoring findings in a timely manner? | Yes[ ]  No[ ]  If ‘yes’ please provide further information below: |
| Are there any other quality control concerns? (include for example, CRF completion/missing data/source data records/ follow up data/PI oversight). | Yes[ ]  No[ ]  If ‘yes’ please provide further information below |
| **Study Analysis** |
| Is there a Data Management Plan for the study? | Yes[ ]  Date of DMP\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]  |
| Is there a Statistical Analysis Plan for the study? | Yes[ ]  Date of SAP\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]  |
| **Checking Study Procedures** |
| Is an out of hours procedure in place? | Yes[ ]  Date last checked\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]  |
| Are Unblinding procedures in place? | Yes [ ]  Date last checked\_\_\_\_\_\_\_\_\_\_\_\_\_No[ ]   |
| **Finance/Contract** |
| Is there a contract or agreement in place for this study? | Yes [ ]  No[ ]   |
| Have all payments due from the funder been made in line with payment schedule? | Yes [ ]  No[ ]  If ‘no’ please provide further information below: |
| Are outgoing payments being made in line with expected expenditure? | Yes[ ]  No[ ]  If ‘no’ please provide further information below: |
| Are there sufficient funds/supplies/equipment/staff to continue the study? | Yes [ ]  No[ ]  If ‘no’ please provide further information below: |
| **New Findings** |
| Are there any new findings that may have impact on the study? Consider changes in routine clinical practice, recent research findings etc. | Yes [ ]  No[ ] If ‘yes’ please provide further information below: |
| **Any other issues** |
| Are there any other issues you wish to report to the Sponsor?(Please consider all sites, support departments, study equipment, external vendors) | Yes[ ]  No[ ] If ‘yes’ please provide further information below: |

**6. DECLARATION**

|  |  |
| --- | --- |
| Signature of person completing report |  |
| Print name: |   | Date: |   |

|  |  |
| --- | --- |
| Signature of CI / PI  |  |
| Print name: |   | Date: |   |

SUBMIT TO Research.QA@york.nhs.uk

WITHIN 7 WORKING DAYS OF THE QUARTERLY QA MEETING

**REPORT MUST BE SIGNED BY CI / PI TO BE VALID**

**7. REPORT REVIEW (R&D QA Use only)**

|  |  |
| --- | --- |
| *Report received on :*  | *DD/MMM/YY* |
| *Report reviewed on :* | *By :* |
| *Feedback communicated to :* | *By :* |