STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL CHECKING OF NHS FIFE HOSTED STUDIES

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1. PURPOSE

This SOP describes the procedure for carrying out Quality Control Checking of studies hosted by NHS Fife and complies with the principles of Good Clinical Practice (GCP).

It is the responsibility of all researchers and R&D staff using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research). For guidance, contact the R&D Department via fife-uhb.randd@nhs.net

2. APPLICABILITY

This SOP applies to all NHS Fife R&D staff members, Investigators and research staff involved in the management of studies hosted by NHS Fife.

3. POLICY

ICH E6(R2) defines Quality Control (QC) as 'operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled'. As such, QC is a key activity used to verify compliance with the Clinical Trials Regulations (SI 2004/1031), as amended. It is an activity that involves the review of factors in a process as the process occurs.

QC activities must be documented and performed by a second individual who is independent of the initial activities being reviewed.

Whilst a number of NHS Fife studies are regularly monitored by external Sponsors, it is important that routine Quality Control Checking (QCC) is undertaken by NHS Fife R&D staff to ensure:

- The safety, rights and well-being of the study participants are protected
- The reported data are complete, accurate and verifiable from source documents
- The study complies with the currently approved protocol/amendment(s), GCP and the appropriate regulatory requirements
- Data collection and study-related procedures are completed by authorised members of staff.

The level and intensity of QCC required is study specific and dependent on a number of factors including the complexity and degree of risk associated with a study and the level of external monitoring planned by the Sponsor. Specific QCC requirements for a study must be agreed and documented within the approvals Risk Assessment, signed off by the Assistant R&D Director (see R&D SOP11).

4. RESPONSIBILITES

4.1 It is the Sponsor's responsibility to have a monitoring plan in place and to carry this out.

4.2 It is the responsibility of the R&D Approvals Team, in collaboration with the clinical team to perform a Risk Assessment as part of the Local Management Approvals Process (see R&D SOP 11).

4.3 It is the responsibility of the study personnel completing a study visit to ensure collected data and associated paperwork are made available for QCC checking by an appropriate member of staff.

4.4 It is the responsibility of the R&D Quality & Performance Lead/ R&D Quality & Performance Assistant to complete the QCC of data and paperwork and ensure any queries which arise are addressed/ resolved in a timely manner.

4.5 It is the responsibility of the R&D Quality & Performance Lead to feedback findings from the QCC to the R&D Approvals Team.

4.6 It is the responsibility of the R&D Approvals Team, in collaboration with the clinical team to Risk Assess all substantial amendments, material changes and outcomes of any QCC.

4.7 It is the responsibility of the Assistant R&D Director to review and implement any actions required to mitigate the increased risk or unacceptable QCC findings.

4.8 It is the responsibility of the R&D Quality & Performance Lead to maintain the Quality Control Check Log held in S:\Research\QUALITY ASSURANCE\QC CHECK LOG and to ensure oversight of the QCC process for all hosted studies and ensure QCC obligations are fulfilled.

5. PROCEDURE

5.1 Identifying Study Specific QCC Requirements

5.1.1 Study specific QCC requirements should be identified using the Risk Assessment process conducted as part of the Local Management Approvals process.

5.1.2 Once the appropriate level of QCC has been identified, this must be recorded on the Hosted Study Risk Assessment Form (Doc Ref 11-04) and highlighted in the Local Management Approval letter.

5.1.3 The Quality & Performance Lead must be advised by the R&D Approvals team via email that the Risk Assessment has been completed.

5.1.3 On receipt of the email from the R&D Approvals team, the R&D Quality & Performance Lead must add the QCC requirements to the QCC Log held in S:\Research\QUALITY ASSURANCE\QA LOGS.

5.2 QCC Templates

5.2.1 To ensure the appropriate documentation is checked as part of the QCC process, a Generic Participant Data QC Checklist (Doc Ref 48-01) and Generic Site File QC Checklist (Doc ref 48-02) must be modified by the R&D Quality & Performance Lead or the R&D Quality & Performance Assistant to ensure all documents associated with a specific study are included in the QCC process.

5.2.2 Once the template has been adapted for the study, it should be named appropriately [R&D Ref No.]-QC Checklist – [yyyy-mm-dd] and saved in S:\Research\QUALITY ASSURANCE\ STUDY SPECIFIC QC CHECKLISTS

5.3 Quality Control Checking

5.3.1 The R&D Quality & Performance Lead or the R&D Quality & Performance Assistant must contact the PI or delegate to arrange a convenient date to conduct any QC checks. A minimum of two weeks notice must be given.

5.3.2 All documentation generated during a study must be made available for the allocated member of staff to QC check.

5.3.3 The R&D Quality & Performance Lead or the R&D Quality & Performance Assistant undertaking the QC check should ensure that all documents listed on the study specific QC Checklist are present. Each of the documents should then be checked to ensure all criteria specified on the QC Checklist have been met.

5.3.4 Any data queries (e.g. missing/incomplete data) must be documented on the QC Checklist along with the date of the QC Check. Any queries not resolved immediately should be added to the summary table on the front of the form by the individual conducting the QC Check.

5.3.5 The draft completed QC Checklist must be reviewed by the R&D Quality & Performance Lead to assess whether any expedited actions are required or if the R&D Approvals Team should be alerted to undertake an updated Risk Assessment (see 5.4).

5.3.6 Following review by the R&D Quality & Performance Lead, the individual conducting the QC Check must submit the completed QC Checklist showing all outstanding queries, to the PI or delegate who must ensure these are answered / resolved in a timely manner.

5.3.7 Once addressed, the action taken by the PI or delegate must be documented on the QC Checklist. This can be completed and initialled/dated by either the QC Checker or the PI or Delegate.

5.3.8 The QC Checker must review the QC Checklist to ensure all queries have been resolved. Completed QC Checklists must be signed and dated on the front page by the QC Checker.

5.3.9 Any queries which are not resolved in a satisfactory way or in a timely manner must be escalated by the R&D Quality & Performance Lead to the Assistant R&D Director for action.

5.3.10 The R&D Quality & Performance Lead or delegate must document all QC Checking activity on the QCC Log.

5.4 Triggered Review of the Required Level of Quality Control Checking

5.4.1 Whilst the level of QCC is initially assessed during the Set-up phase of a study, this must be reviewed following an identified trigger to identify any grounds for increasing or decreasing the level of QC checking.

5.4.2 Potential triggers for reviewing the level of QCC may include:

- Substantial Amendment
- Changes in study personnel
- Substantial changes to the study protocol
- Increase in overall study recruitment number
- Increase in number of study visits
- Nature and number of QCC queries generated
- Increase / decrease in the number of QCC queries generated
- Restarting dormant or inactive studies
- Concerns raised about the conduct of the study

5.4.3 The R&D Approvals Team must review the trigger and carry out a revised Risk Assessment. Any proposed adjustment to the level of QCC must be documented on the Hosted Study Risk Assessment Form (Doc Ref 11-04) and discussed with the Assistant R&D Director, R&D Quality & Performance Lead and Lead R&D Research Nurse (where appropriate).

5.4.4 Any changes from the original level of QCC must be documented by the R&D Quality & Performance Lead in the QCC Log.

6. ASSOCIATED DOCUMENTS

Doc Ref 48-01 - Generic Participant Data QC Checklist
Doc Ref 48-02 – Generic Site File QC Checklist
Doc Ref 11-04 - Hosted Study Risk Assessment Form

7. REFERENCES

ICH E6 (R2) Good clinical practice
https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

8. ABBREVIATIONS

GCP - Good Clinical Practice
QC - Quality Control
QCC - Quality Control Checking
R&D - Research & Development
SOP - Standard Operating Procedure

9. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Quality & Performance Lead	03 March 2020	New

10. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	27 Feb 2020