STANDARD OPERATING PROCEDURE FOR QUALITY ASSURANCE AUDITS

SOP NUMBER:	**Fife R&D SOP12**
AUTHOR:	**Julie Aitken**
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1. PURPOSE

The purpose of this SOP is to describe the procedure for carrying out internal audit within NHS Fife and also audit of external service providers to NHS Fife (vendors) who are involved with clinical research.

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 personnel associated with and managing clinical research studies sponsored or co-sponsored by NHS Fife. It also applies where an internal audit is deemed necessary for a study which is hosted by NHS Fife.

3. POLICY

3.1 Sponsors of clinical research must have Quality Assurance (QA) mechanisms in place to ensure that studies are conducted in accordance with Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP) guidelines, current regulations and relevant Policies, SOPs and Work Instructions (WI). The NHS Fife R&D Department does this through a programme of audits.

3.2 A variety of functional groups and facilities within NHS Fife and external service providers/facilities may be involved with research. Any of these may be subject to audit by QA staff nominated through the Research and Development (R&D) office.

3.3 The individual carrying out the audit must be appropriately trained and qualified and this must be demonstrated in their training records.

3.4 External companies may be employed to carry out audits on behalf of NHS Fife. Such a transfer of responsibilities must be formally agreed with the external party in writing.

4. PROCEDURE

4.1 The type of audit that will be performed will vary in nature and be dependent on the process, facility, study or service provider that is to be audited.

4.2 A date for the audit must be agreed in advance with all the individual(s) concerned.

4.3 A proposed audit plan must be documented and agreed between the auditor and auditee and retained by the NHS Fife R&D Quality & Performance Lead in the Quality Assurance Folder (S:\Research\QUALITY ASSURANCE).

4.4 The frequency of audits will vary and be dependent on a risk based decision. Where audits are required to be undertaken at regular intervals the schedule of the audit must be documented by the R&D Quality & Performance Lead. Additional or unscheduled audits may be carried out at the request of NHS Fife R&D Senior Management, any other person involved with the study (e.g. the CI or PI) or as new studies/processes arise.

4.5 The Audit Report must document non-compliant findings.

4.6 Findings must be rectified by a suitable delegated member of staff within an agreed timescale and any Corrective Actions/Preventative Actions (CAPA) must be recorded in the CAPA log (S:\Research\QUALITY ASSURANCE\QA LOGS) by the R&D Quality & Performance Lead (or delegate).

4.7 Persistent failure to rectify findings will be reported by the R&D Quality & Performance Lead to the NHS Fife Assistant R&D Director and/or R&D Director.

4.8 Serious and significant findings detected at audit must be documented and escalated by the R&D Quality & Performance Lead to the NHS Fife Assistant R&D Director and/or R&D Director within 48 hours.

4.9 The R&D Quality & Performance Lead or delegate must agree a timescale for implementing any Corrective Actions/Preventative Actions (CAPA) with the research team and must ensure that all actions are followed to completion, closed off and that Audit Reports and any associated documents are securely filed in the Quality Assurance Folder (S:\Research\QUALITY ASSURANCE).

4.10 Failure of the auditee to respond to findings identified in the Audit Report within the agreed timescale must be reported by the R&D Quality & Performance Lead to the Assistant R&D Director.

4.11 For Study Specific Audits of NHS Fife Sponsored studies, a copy of the Audit Statement should be filed in the Study Master File and the Sponsor File.

5. ASSOCIATED DOCUMENTS

6. DEFINITIONS

CAPA	Corrective Actions & Preventative Actions
CTIMP	Clinical Trial of Investigational Medicinal Product
GCP	Good Clinical Practice
QA	Quality Assurance
R&D	Research and Development

7. REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004.
(*http://www.opsi.gov.uk/si/si2004/20041031.htm*).
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

9. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Dr David Chinn Senior R&D Advisor	31 Oct 2014	New - Adapted from TASC SOP20, v 3.0
2	Julie Aitken R&D Quality & Performance Lead	29 Apr 2020	Reformatted in line with current SOP template. Text refreshed throughout for clarity

10. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	29 April 2020