

SOP-QA-37 V5

Title: Management Review

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GRAMPIAN CLINICAL RESEARCH OFFICE



Document History

Version	Description of update	Date Effective
3	Scheduled review at three years; no changes identified.	01-08-20
4	Scheduled review at three years; no changes identified.	09-08-23
5	Scheduled review at three years; no changes identified.	15-09-26

1. Scope

- 1.1 This SOP applies to University of Aberdeen (UoA) and NHS Grampian (NHSG) staff involved in the preparation or performance of Management Review of the Quality Management System (QMS).
- 1.2 UoA and NHSG are jointly responsible for implementing and maintaining a QMS. The QMS (comprising a Quality Manual, Quality Statement and SOPs) shall be used for research projects, sponsored or co-sponsored by either organisation, to ensure that they are conducted and that data generated, documented and reported, is in compliance with the principles of Good Clinical Practice (GCP) and the applicable regulatory requirements. The QMS may also be used for hosted studies.

2. Responsibilities

Quality Assurance Manager Managing the QMS on behalf of Sponsor.
Ensuring a Management Review occurs at least annually.

3. Procedure

- 3.1 The Quality Assurance Manager (QAM) shall arrange regular Management Reviews. These shall ideally take place at least annually but may occur more frequently if deemed appropriate by the QAM, Clinical Research Operational Group (CROG) or R&D Director.
- 3.2 The Management Review shall be attended by the R&D Director, QAM, Research Governance Manager (RGM) and Senior R&D Manager. Other persons may attend as deemed appropriate.
- 3.3 The QAM, or delegate, shall issue an agenda, minutes of previous Management Review and any relevant papers and reports, at least one week prior to the agreed date.

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Key to symbols = Important point to note = Warning

3.4 The Management Review shall include:

- Any feedback from researchers, CIs, PIs and any other interested parties on the functioning of the QMS.
- Review of findings from any regulatory inspections.
- Review of non-conformances and observations raised during internal audits.
- Review of non-conformances and observations raised during monitoring.
- Systematic findings and trends noted in audit and monitoring.
- Effectiveness of Corrections and CAPA.
- Possible areas of improvement and future development of the QMS.
- Review of Quality Manual for effectiveness.
- Review of Quality Statement for effectiveness.
- Staff training.
- Resource issues concerning the QMS.
- Review of stakeholder feedback and satisfaction surveys.
- Planned assessment and regulatory inspections.

3.5 The QAM shall ensure minutes and an action table are generated. Action points shall have a timescale assigned (one month, unless exceptional circumstances).

4. Abbreviations and definitions

CAPA	Correction, Corrective Action and Preventive Action
CI	Chief Investigator
CROG	Clinical Research Operational Group
GCP	Good Clinical Practice
PI	Principal Investigator
QAM	Quality Assurance Manager
QMS	Quality Management System
R&D	Research and Development
RGM	Research Governance Manager

5. Related documentation and references

TMP-QA-63	Management review agenda
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