Standard Operating Procedure:  Management Review

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This SOP will be reviewed at least every 3 years from initial and subsequent issue dates.

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1. PURPOSE/INTRODUCTION

1.1 This Standard Operating Procedure (SOP) describes the process for the performance of Management Reviews of the joint University of Aberdeen (UoA) and NHS Grampian (NHSG) Quality Management System (QMS).

2. SCOPE

2.1 This SOP applies to UoA and NHSG staff involved in the preparation or performance of Management Review of the QMS.

2.2 This SOP may also be used by staff from other NHS areas, or organisations, with prior agreement.

3. RELATED DOCUMENTATION

3.1 None

4. REFERENCES

▪ UK Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No. 1031) as amended.

Current versions of these documents can be accessed via the Clinical Research Governance and Quality Assurance Website: http://www.abdn.ac.uk/clinicalresearchgovernance/

It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

4.2 ABBREVIATIONS AND DEFINITIONS

CAPA  Corrective And Preventive Action
CROG  Clinical Research Operational Group
CTIMP  Clinical Trial of Investigational Medicinal Product
GCP  Good Clinical Practice
NHSG  NHS Grampian
QAM  Quality Assurance Manager
QMS  Quality Management System
R&D  Research and Development
R&I  Research and Innovation
UoA  University of Aberdeen

5. RESPONSIBILITIES

5.1 UoA and NHSG are jointly responsible for implementing and maintaining a QMS. The

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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 research projects are conducted and data generated, documented and reported in compliance with the principles of Good Clinical Practice (GCP) and the applicable regulatory requirements. The QMS may also be used for hosted studies.

5.2 The Clinical Research Operational Group (CROG) as Sponsors or Co-Sponsors delegate, are responsible for ensuring there is a regular Management Review of the QMS. This shall take place at least annually.

5.4 The Quality Assurance Manager (QAM) has overall responsibility for ensuring that the Management Review occurs.

6. **PROCEDURE**

6.1 The QAM shall arrange an annual Management Review Meeting. This shall take place at least annually but may occur more frequently if deemed appropriate by the QAM, CROG or R&D Director.

6.2 The Management Review shall be attended by the R&D Director, QAM, Research Governance Manager (RGM) and Senior R&D Manager.

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.

6.3 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 CAPA.
- Possible areas of improvement and future development of the QMS.
- Review of Quality Statement for effectiveness.
- Staff training.
- Resource issues concerning the QMS.
- Review of feedback and satisfaction surveys.
- Planned assessment and regulatory inspections.

6.4 The QAM shall ensure minutes and an action table are generated. Action points shall have a timescale assigned (one month, unless exceptional circumstances).
SOP-QA-37 Appendix 1

Management Review Meeting

Date
Time
Location
AGENDA

1. Apologies

2. Minutes of previous Management Review Meeting

3. Matters arising

4. Regulatory inspection reports from MHRA

5. Quality Manager Report including:
   - Review of internal audits.
   - Review of monitoring.
   - Review of systematic issues identified.
   - Opportunities for improvement.
   - Review of Corrections and CAPA.
   - Feedback.


7. Review of SOPs.

8. Regulatory inspections due in the coming year.

9. Any other business.

10. Date of next Management Review Meeting.

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