

**MONITORING AND AUDIT**

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| Approved byDate  | Prof David Raper, Director of Research and Knowledge Exchange1st February 2016 |

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| **Version** | **Date** | **Reason for Change** |
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http://www2.mmu.ac.uk/research/research-governance/

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1. **Background**

Under the Research Governance Framework for Health and Social Care, MMU has a responsibility to monitor research studies for which it acts as a sponsor. Additionally, the Concordat for Research Integrity expects that all research will be conducted according to the highest standards of rigour and integrity, and that organisations will have procedures in place to ensure that research is conducted in accordance with standards of best practice. Adequate monitoring of research studies ensures that the wellbeing of participants and quality of data are maintained throughout the study. The type of monitoring and audit performed will depend upon the nature and complexity of the study.

1. **Purpose**

This Standard Operating Procedure (SOP) describes the process for monitoring and auditing research studies. It applies to all studies involving human participants.

1. **Procedure**
	1. **Routine Monitoring and Audit**

The frequency, style, and persons performing monitoring will vary depending on the study. For student research, monitoring should be performed by the academic supervisor. All research studies should monitor and/or audit the following:

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| Monitoring | To confirm that: |
| Consent Process | * Participants are being consented appropriately
* A consent form has been completed for all participants
* All consent forms have been completed correctly
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| Protocol adherence | * Eligibility criteria have been met for all participants
* Study procedures have been followed as per the protocol
* Withdrawals have been recorded as per the protocol
* Randomisation procedures have been followed (where applicable)
* AEs/SAE as recorded as per the protocol (where applicable)
* Protocol Violations are recorded as per the protocol (where applicable)
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| Data Quality | * CRFs have been completed fully (where applicable)
* Data has been recorded accurately
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For research requiring NHS or SCREC approval, an audit of Study Master File (SMF) / Investigator Site File (ISF) contents ([Study Master File Audit](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Study-Master-File-Audit.docx)), staff training records and data security should take place before the start of a study.

For interventional research projects, the CI for each study should also complete an [Issue Log](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Issue-Log.docx) throughout the study recording any problems encountered (excluding those already recorded as protocol violations, protocol deviations, or adverse events). This should be forwarded to the Ethics and Research Governance Manager at the end of the study as per SOP14 Study Closure.

* 1. **Recording of Monitoring/Audit**

For research requiring NHS or SCREC approval, a written record of all monitoring/audit activities along with documentation of any remedial action taken should be filed within the SMF (See [SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx))

* 1. **For cause audit**

On receipt of a protocol violation form and or SAE Form, the RKE Office may audit areas of the research study to assess the extent of the problem and its relation to any other compliance issues.

* 1. **Audit by external bodies**

Research studies may be subject to audit by external organisations involved in the research (e.g. NHS Research governance departments, regulatory bodies). Reports from such audits should be filed in the SMF where applicable. A copy of the audit report should be forwarded to the RKE Office.

1. **Related Documents**

[SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx)

SOP9 Site Set-up

SOP14 Study Closure

[Study Master File Audit](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Study-Master-File-Audit.docx)

[Issue Log](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Issue-Log.docx)

1. **References**

Research Governance Framework for Health and Social Care

<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf>

The Concordat to Support Research Integrity

<http://www.universitiesuk.ac.uk/highereducation/Documents/2012/TheConcordatToSupportResearchIntegrity.pdf>