

**WRITING AND REVIEWING STANDARD OPERATING PROCEDURES**

|  |  |
| --- | --- |
| Reference Number | MMU-RKE SOP 001 |
| Version | Draft version 0.1, 5th August 2015 |
| Effective Date |  |
| Review Date |  |
| Author | Zoe Lingard, Ethics and Research Governance Manager |
| Approved byDate  |  |

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Reason for Change** |
|  |  |  |

This is a controlled document. The master document is posted on the RKE website:

http://www2.mmu.ac.uk/research/research-governance/

Any print-off of this document will be classed as uncontrolled. Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking the RKE website for more recent versions.

1. **Background**

The Research Governance Framework for Health and Social Care and the Concordat to Support Research Integrity highlight the need for robust systems to ensure good governance and best practice is taking place in research. By accepting the role of ‘sponsor’ for NHS research Manchester Metropolitan University (MMU) is taking responsibility for the initiation, management, and quality of the research taking place. The development of clearly documented Standard Operating Procedures (SOPs) covering all aspects of conducting research studies enables MMU to fulfil these responsibilities.

1. **Purpose**

This Standard Operating Procedure (SOP) describes the process for writing, approving, implementing and reviewing MMU SOPs relating to studies that fall under the Research Governance Framework for Health and Social Care, 2nd Edition, Department of Health 2005, where the MMU is the sponsor.

1. **Procedure**
	1. **Writing SOPs**

When the need for a standard written procedure is identified, an author (a person with an in depth knowledge of the activity) will produce a draft SOP using the RKE SOP Template. The author will then send the draft SOP to the Ethics and Research Governance Manager (ERGM), who will issue a unique number to the SOP and register the SOP in the RKE SOP register.

* 1. **Authorising SOPs**

All SOPs require final approval and authorisation. Draft SOPs will be reviewed and approved by the Academic Ethics Committee. The Director of Research and Knowledge Exchange will authorise it by signing and dating the table on the cover page. Approval of a SOP will also authorise the associated forms, which should show an identical issue date to the SOP.

* 1. **SOP review**

All SOPs will have an effective date issued and a review date. SOP’s will be reviewed every two years. SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process or organisational change.

* 1. **Distribution of SOPs**

All SOPs will be added to the MMU Ethics and Governance website once authorised. It is the responsibility of all staff at MMU to check the website regularly to check if SOPs have been added or amended.

**3.6 Version Control**

Version control for SOPs will be managed according to SOP2: Document Control. The version history table on the front cover of the SOPs should be amended with each change to the SOP.

Final ‘master’ copies of SOPs will be accessed via the MMU Ethics and Governance website. Any printed copies of SOP’s will be classed as uncontrolled documents and readers will be referred to the online library for up-to-date versions.

1. **Associated Documents**

[RKE SOP Template.docx](Templates/RKE%20SOP%20Template.docx)

[RKE SOP Register.docx](RKE%20SOP%20Register.docx)

[SOP2 Document Control.docx](SOP2%20Document%20Control.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>