

**DOCUMENT CONTROL**

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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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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**

Research Ethics Committees (RECs) and The Medicine and Healthcare Regulatory products Agency (MHRA) require that documents submitted to them be version controlled. Controlled documents include:

* Study protocols
* Participant information sheets
* Informed consent forms
* Advertisements
* GP letters
* Case report forms
* Subject diaries
* Departmental and study specific SOPs

For other research involving human participants, it is good practice to have procedures in place to ensure the accountability, traceability, and consistency of these documents.

1. **Purpose**

This Standard Operating Procedure (SOP) describes the management of controlled documents required for research involving human participants.

1. **Procedure**
	1. **Version control and naming convention**

All controlled documents must be allocated a version number and dated.

* Draft versions of documents should be clearly labelled DRAFT
* File names should include the project title, version and date
* The version number and date should be visible on printed versions of the document (e.g. on the front page or in the footer)

For NHS submissions, version numbering should use the following format:

* Final versions are indicated using whole numbers (e.g. Final version 1.0, 2nd June 2015), with version 1.0 being the one submitted for external approval.
* Any subsequent amendments should be numbered using decimals whilst in draft version (e.g. Draft version 1.1, 3rd June 2015), moving to the next whole number when submitted for approval (e.g. Final Version 2.0, 4th June 2015).
	1. **Other considerations**

Where appropriate the following information should be on the document:

* Pagination – It is recommended that pages are numbered as “Page X of Y”
* Confidential – If the document is confidential, mark “Confidential”
* Copyright of {Insert as appropriate} – Insert copyright information if necessary
* Effective date and expiry date or next review date (if applicable)
* Approvals (e.g. Include signature and date of Author, Reviewer and Authoriser for SOPs, protocols)
* Reason for Change - If it is a revision of the control document, state reason for change and list changes
	1. **Circulation of study documents to research sites**

When a new version of a document is issued, the researcher should obtain written confirmation from the principal investigator at each site that:

* the updated document has been placed in the site file
* the previous version of the document is retained in the site file but is marked as ‘SUPERCEDED’ on the front page
* all staff working on the study are aware of the changes to the document
* all stocks of previous versions of paperwork held at site have been destroyed (if applicable)
	1. **Storage and archiving**

Controlled documents should be stored in an area or room restricted to authorised individuals only. For research that requires NHS or SCREC approval, documents should be filed appropriately in the Study Master File (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)) and following study closure archived according to SOP15 Archiving. All previous final versions of controlled documents must be archived.

1. **Associated 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)

SOP15 Archiving