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**STUDY MASTER FILE AND SITE FILE SET-UP**

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| **Version** | **Date** | **Reason for Change** |
| 2 | 15th October 2020 | References to Research Governance Framework updated to UK Policy Framework for Health and Social Care Research |

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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**

A Study Master File (SMF) is a standard filing system that allows the effective storage and location of essential documents needed for clinical research. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate.

It is a legal requirement to maintain a SMF for all clinical trials of Investigational Medicinal Products (CTIMPs). It is also required for any project conducted within the NHS, which has to meet the UK Policy Framework for Health and Social Care Research, and other clinical investigations that may have an impact on the safety and well-being of human participants. Not all documents will be of relevance to every project. For example, for clinical trials of IMPs, most of the essential documents must legally be maintained whereas, for solely observational studies, certain documents will not be applicable.

Where the research is taking place at more than one site, each site should also maintain an Investigator Site File (ISF). This should contain the essential documents that permit an evaluation of the conduct of a research project. The contents of the ISF serve to demonstrate the compliance of the Investigator and the research team with the requirements of the UK Policy Framework for Health and Social Care Research.

The documents contained in the ISF may be audited by the host organisation as part of the Research Governance process.

1. **Purpose**

This SOP describes the preparation, maintenance, storage and archiving of a SMF and an ISF.

1. **Procedure** 
   1. **Essential Documents and SMF Initiation and Maintenance**

The Chief Investigator (CI) should establish a SMF as soon as possible after an outline protocol/proposal is available and/or first contact is made with a research sponsor. The CI is responsible for maintaining and updating the essential documents within the SMF from this time until the project is formally closed. If responsibility for setting up/maintaining the site file is delegated to another member of the research team, this must be recorded in the [Delegation Log](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Delegation-log-Template.docx).

The [Study Master File Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Study-Master-File-Template.docx) lists the essential documents that should be maintained within a SMF. As noted above, the specific documents filed will differ according to the nature of a study. The list is not exhaustive, and it is strongly recommended that any approvals and communication not listed here should also be retained. A [Study Master File Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/Study-Master-File-Template.docx) should be completed and included at the front of each project file.

* 1. **Amended Documents**

Documents often need to be amended during the course of a project. Previous versions must be retained in the SMF alongside the new amended version(s). Most recent versions should be stored at the front, and previous versions should be scored through and marked as superseded on the front page to ensure they are not mistaken for current documents.

Any substantial amendments to documents, such as the protocol or informed consent forms, should be approved by the relevant authorities (the research Sponsor, RECs, MHRA etc.), as appropriate, **prior** to implementing any changes to the project/trial.

* 1. **Storage**

The SMF should be held at the lead investigation site. If any documents are filed separately from the SMF, a File Note should be kept in the SMF detailing where the document is filed, e.g. Copy consent forms are held in locked filing cabinet in room x.

As some of the documents within a SMF will be originals and/or contain confidential data, it is important that they are retained in a secure place, with restricted access. All members of the research team should have access to the SMF. It is recognised as best practice to store documents within a locked cupboard within a locked room. Documents should be maintained in a legible condition, with prompt retrieval possible.

* 1. **Archiving**

It may be necessary for the results of a clinical research project/trial to be examined and checked after it has finished. Study documents should be archived according to SOP15 Archiving.

* 1. **Site Files**

Where there is more than one research site, the CI must provide each site with a site file prior to starting recruitment. This should be set up using the [ISF Template](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/linked-documents/ISF-Template.docx) and should be kept securely in a locked room with restricted access.

The PI is responsible for updating the ISF with relevant and applicable documentation as the study progresses. All filing must be done in a timely manner and documents must be filed in date sequential order with the most recent at the front of each section. Correspondence which is necessary to construct key activities and decisions must be retained. The ISF must be made available to Sponsor and auditing personnel in host organisations upon request.

Once the study is finished, the PI is responsible for reviewing the ISF to ensure that all the required documents are present. The site agreement will determine whether the ISF is archived on site or at the sponsors archive facilities.

1. **Related Documents**

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

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

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

SOP15 Archiving

1. **References**

[UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)