The University of Manchester

Standard Operating Procedure

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Title:	Archiving		
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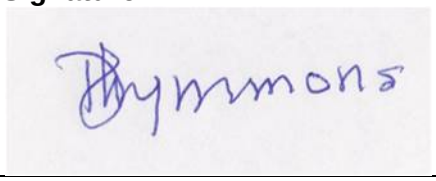
Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**January 2013**	**Update of weblinks and office details**
2.1	**May 2014**	**Addition of version control statement for SOP**
3.0	**October 2015**	**Update of weblinks and office details**
4.0	**August 2016**	**Update of information, weblinks and office details**
5.0	**March 2018**	**Interim review and update**

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Governance, Ethics and Integrity Team website (http://www.staffnet.manchester.ac.uk/services/rbess/ governance/) for any new versions or contacting the author to confirm the current version.

1.0 Background

In order to be compliant with the European Directive on Good Clinical Practice in Clinical Trials (2001/20/EC) organisations conducting Clinical Trials of Investigational Medicinal Products must have clearly documented Standard Operating Procedures (SOPs) covering all aspects of conducting Clinical Trials. The SOPs also apply to all other projects that fall under the UK Policy Framework for Health and Social Care Research.

The European Clinical Trials Directive is translated into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) ("the Regulations"). These regulations define the legal requirements for archiving arrangements for both trial data and documentation.

2.0 Purpose

This Standard Operating Procedure (SOP) applies to Clinical Trials of Investigational Medicinal Products (CTIMP) and trials of medical devices – i.e. all Trials which come under the Regulations, where the University of Manchester is the Sponsor. The requirements of this SOP should be applied as a minimum to such trials and in conjunction with all applicable University policies and procedures and the policies and procedures of the relevant NHS Trust.

This SOP should be interpreted with regard to local existing archiving arrangements, but any variations should aim to provide an equivalent standard of provision to the procedures outlined below.

The purpose of this SOP is to define those procedures which apply to the archiving of essential records of relevant clinical trials at the end of a trial.

3.0 Procedures

Roles and responsibilities

Sponsor

The trial Sponsor is responsible for ensuring that trial data is retained and maintained in appropriate conditions with regard to integrity and accessibility, and that appropriate retention policies are applied to such records

Test facility and site management

Local management is responsible for providing appropriate archive facilities. They should ensure that supporting records such as SOPs, personnel records and equipment maintenance records for storage facilities are available and retained.

Chief Investigator
The Chief Investigator (CI) is responsible for ensuring that all appropriate documentation is available for archiving and is transferred for archiving at the appropriate time.

Archivist
Each trial should have an appropriate, named archivist. The archivist should, where possible, be a person who is independent of the trial and the line management of that trial to avoid conflict of interest. The named archivist at the University of Manchester is responsible for making the necessary arrangements with the archiving facility.

Retention periods
All archived material should be given a fixed retention period, taking into account legal and regulatory obligations and any retention periods defined by the funding body or Sponsor.

CTIMP Trials
For trials involving investigational medicinal products, records must be kept for 25 years after the conclusion of the trial.

Devices
For medical device trials, archiving duration will be determined on a risk based approach, in line with HRA and GCP Expectations.

Advanced therapy trials (ATIMPs)
For trials involving advanced therapy investigational medicinal product (ATIMP), the sponsor of the trial, manufacturer, and chief investigator/institution must keep their records related to the traceability of the ATIMP (including essential documents and medical files of trial subjects) for a minimum of 30 years. The retention period must be stated in any study contract the University has agreed to contractually.

Non CTIMP Trials
Essential documents and medical files of trial subjects must be retained for a minimum of five years after the completion of the trial.

Forward planning
Archiving provision should be included at the grant application stage, particularly if costs for commercial storage will need to be met. Staff resources for undertaking archiving work also need to be taken account of at this stage. The archiving arrangements for a trial should be stated in the protocol at the trial outset.

Boxing archives

On completion of the trial, the trial master file should be checked against the trial master file template to ensure that all required documents are present and in the correct order.
Trial master files and any other essential documentation should be boxed in appropriate archive boxes with sealed lids. Lids should be placed on boxes when the documents are not in use to protect the contents. Archiving material is currently stored at Iron Mountain (see below) following local processes and procedures.

Content lists for each box should be produced, and each file within a box should be assigned a unique reference number. A copy of the box list should be kept inside the box, and all box lists should be drawn together into a global list for the trial, which should be kept electronically. A location index should also be kept recording the physical whereabouts of each box. This list will be kept by the Office of the named archivist.

Boxes should be labelled in accordance with the global list.

Boxes should be stored in an appropriate location.

Storage conditions

The storage area should have suitable and stable environmental conditions. Temperature should be constant and between 13^{o} and 18°C, humidity should be constant and between 45% and 65% Relative Humidity.

The storage area should be secure, and should not be accessible to unauthorized personnel.

The storage area should be appropriately protected against fire and flood. Rooms with water pipes running through them should not be used, and in general basements should be avoided due to the risk of flooding.

Storage provisions should be made with regard to the ease of retrieval of documents where necessary.

It should be noted that the University of Manchester uses an external contractor (Iron Mountain) to provide an off-site storage facility which meets the requirements listed above, and which can be utilised if no alternative suitable archive storage is available. It should be noted however that space within this facility is limited and those responsible for archiving arrangements should enquire as far in advance as possible as to likely provision before assuming that this will be the final destination of archived records. The contract with Iron Mountain ensures Iron Mountain must liaise with Records Management at the University of Manchester if files are to be moved to another facility.

For further information on the onsite storage facility please contact the Records Management Office at the University.

For on-site archiving, please refer to appendix I.

Access to archives
Access to archived trial records should be restricted to authorised personnel only. Any retrieval of documents should be properly recorded. Retrieved files should be returned to storage as soon as possible.

Destruction of records
When archived records reach the end of their retention period they should be securely destroyed, with the appropriate Dean of the Faculty informed in advance by the named archivist. A record of this destruction and the reasons for it should be created and retained for a period of 7 years from the date of destruction. The record of destruction should clearly list which records have been destroyed. This list will be shared with the appropriate Dean of the Faculty by the named archivist.

Scanning
It is not recommended that paper records be scanned and the originals destroyed, as this can lead to problems surrounding the authenticity of records.

Electronic records
Where trials create electronic records, consideration should be given to the method of preservation and storage of this data. Any media used to store electronic information should be assessed for longevity. Stored electronic data should be regularly checked for integrity and accessibility. Arrangements should be made for regular transfer of data to new media if necessary.

Software and hardware manuals relating to storage media used should be retained for the life of that media.

File formats should be considered in terms of long term access and support, and files should be translated to non-proprietary formats if necessary.

4.0 Appendices

Appendix I: Storage Template Example

Appendix I

STORAGE TEMPLATE

UNIVERSITY OF MANCHESTER

RECORDS MANAGEMENT PROGRAMME

ON-SITE RECORDS STORAGE

TEL: 58111 / 55782 / 58400 / 58401

FAX: 58402

EMAIL: foi@manchester.ac.uk

FILE REFERENCE	DESCRIPTION OF DOCUMENTS	DATE RANGE OF DOCUMENTS	DATE STORED ON SITE	DATE RETRIEVED FROM STORAGE	DATE RETURNED TO STORAGE

Retrieval Template

UNIVERSITY OF MANCHESTER
RECORDS MANAGEMENT PROGRAMME
ON-SITE RECORDS STORAGE
TEL: 58111 / 55782 / 58400 / 58401
FAX: 58402
EMAIL: foi@manchester.ac.uk

REQUEST FOR THE RETRIEVAL OF ON-SITE STORED RECORDS

NAME:	
ROOM NUMBER:	
BUILDING:	
TEL:	

PLEASE RETURN THE FOLLOWING RECORDS TO THE ABOVE ADDRESS:

FILE REFERENCE:				
DATE REQUESTED:				
URGENT (SAME DAY DELIVERY)	**YES**		**NO**	
NEXT DAY DELIVERY:	**YES**		**NO**	

Please tick the relevant box

SIGNED:	**DATED:**

PLEASE FAX THIS REQUEST TO THE ABOVE FAX NUMBER.

IF YOU HAVE ANY QUERIES, PLEASE DO NOT HESITATE TO CONTACT ANY OF THE ABOVE TELEPHONE NUMBERS. A MEMBER OF THE RECORDS MANAGEMENT OFFICE WILL BE ONLY TO HAPPY TO ASSIST YOU WITH YOUR ENQUIRY.

RETURN TEMPLATE

UNIVERSITY OF MANCHESTER
RECORDS MANAGEMENT PROGRAMME
ON-SITE RECORDS STORAGE
TEL: 58111 / 55782 / 58400 / 58401
FAX: 58402
EMAIL: foi@manchester.ac.uk

REQUEST FOR THE RETURN OF ON-SITE STORED RECORDS

NAME:	
ROOM NUMBER:	
BUILDING:	
TEL:	

PLEASE RETURN THE FOLLOWING RECORDS TO ON-SITE STORAGE

FILE REFERENCE:	
DATE RETURNED:	

SIGNED:	**DATED:**

PLEASE FAX THIS REQUEST TO THE ABOVE FAX NUMBER.

IF YOU HAVE ANY QUERIES, PLEASE DO NOT HESITATE TO CONTACT ANY OF THE ABOVE TELEPHONE NUMBERS. A MEMBER OF THE RECORDS MANAGEMENT OFFICE WILL BE ONLY TO HAPPY TO ASSIST YOU WITH YOUR ENQUIRY.

UNIVERSITY OF MANCHESTER
RECORDS MANAGEMENT PROGRAMME
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TEL: 58111 / 55782 / 58400 / 58401
FAX: 58402
EMAIL: foi@manchester.ac.uk

PROCEDURES FOR ON-SITE STORAGE

1 Use storage boxes from Lyreco. You may order these on the 'General Requisition Form' as follows:

Product Code	Description	Pack Size	Number Required
122 898	Impega Storage Box	10 per pack	Any number

2 Use 'Record Storage Form' to list all the files / records being put into storage

3 When files are listed, boxed and ready for collection telephone General Services Porters on extension 52708 to arrange for a porter to collect the boxes from your office and deliver them to The Archive and Records Centre in the John Rylands Library. Telephone the Records Management Office when the porters leave with your boxes. A member of staff from the Records Management Office will meet the boxes in the entrance of the Library and organise for them to be brought up to the fourth floor.

4 Provide a copy of the 'Record Storage Form' to the Records Management Office so that we have a complete list of all files / records in storage

5 If you require a file / record to be retrieved from storage please complete the 'Record Retrieval Form' and fax it to the Records Management Office

6 When you require a file / record to be returned to storage please complete the 'Return Form and fax it to the Records Management Office

7 Please note for in order to make the most economical use of storage space, we do not accept files in a lever arch file or similar type file. They must be taken out and placed in manila envelopes and labelled accordingly. This method will also reduce the weight of the file

8 The weight of the boxes should not exceed 8kg for Health and Safety reasons and this is the recommended weight for the shelves installed in the Archive and Record Centre