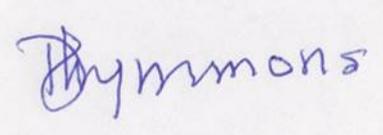


**Standard Operating Procedure**

<b>Number:</b>	UM/UoM Data Management/SOP17/5.0		
<b>Title:</b>	Data Management		
<b>Version:</b>	<b>5.0 (March 2018)</b>	<b>Effective Date</b>	<b>March 2018</b>
<b>Author:</b>	Steve McCall / Victoria Sheard	<b>Review Date</b>	<b>March 2020</b>
<b>Reviewed by :</b> Dr Mohammed Zubair		<b>Approved By:</b> Prof Deborah Symmons	
<b>Position:</b> Research Governance, Ethics and Integrity Manager		<b>Position:</b> Chair of the Clinical Trials Management Group	
<b>Signature:</b>	<b>Signature:</b>		
			

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 weblinks and office details
5.0	March 2018	Review and update

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## 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 and medical devices must have clearly documented Standard Operating Procedures 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.

## 2.0 Purpose

The purpose of this document is to provide guidance for managing Clinical Trial data (by definition to include electronic data) and ensuring that all data is collected, stored, verified and analysed appropriately.

This SOP applies to all data relating to Trials which come under the CTIMP 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.

As the Sponsor the University of Manchester is responsible for ensuring that appropriately qualified individuals are responsible for data management. Responsibility for data management would normally be delegated to the Chief Investigator of the trial or a UKCRC registered clinical trials unit.

## 3.0 Procedure

### 3.1 Definitions

**Source data:** original records (or certified copies) of clinical findings/observations e.g. laboratory tests, scans. Source data are contained in source documents.

**Source documents:** original documents (e.g. hospital records, laboratory notes, subjects' diaries, x-rays) essential to the Clinical Trial. Source documents are classified as "essential documents" that allow evaluation of the Trial and ensure the quality of data. They are essential for the purposes of ensuring compliance with GCP and regulatory requirements.

**Case Report Form (CRF):** a form (printed or electronic) designed to record all of the protocol-required information. Usually each trial participant will have a single CRF.

**Sensitive information:** any patient identifiable data received from the NHS; or any information that could cause harm or distress to an identifiable individual if generally released.

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### 3.2 Data management process

The data management process refers to the substantive process by which data is: (i) collected via a data collection tool; (ii) transferred to a Case Report Form (CRF); (iii) transferred to a data management system (usually an electronic system); (iv) analysed via an appropriate statistical analysis tool; (v) backed-up to an appropriate data backup system; (vi) archived to an appropriate data archiving system.

Only data that is essential for the purposes of the study should be collected. The advice of a statistician should be sought during the trial design process.

All data management risks, including mitigation, should be incorporated into the study specific risk management plan.

### 3.3 Data management system, software or database

A data management system (DMS) is designed to store the clinical trial data captured via the CRF. This might simply be paper-based, but, more usually, is electronic (software or database). The type, size and complexity of the system will reflect the needs of the trial and could range from a single spreadsheet to a custom-designed and built database system.

*Chief Investigators (or their designated delegate with responsibility for data management), unless appropriately experienced or qualified, are advised to seek expert advice on the design, build, testing and deployment of an appropriate DMS well before the trial is due to start.*

The following fundamental points (not an exhaustive list) should be addressed in the development:

- data collection tools (including recording what will be used for the trial)
- user requirements for data input, processing and reporting
- ensuring data integrity (all associated risks should be detailed in the study risk assessment)
- system and data auditing to log access and track changes/corrections
- security of the DMS and the trial data, especially if network connected
- access control (authentication) and appropriate levels of access (authorisation)
- change control (for patches, upgrades, modifications)
- data storage (paper/electronic)
- database lock (including requirements before database lock)
- backup policy, system procedure and system and plan, including regular testing
- archiving policy, system and procedure, including digital preservation issues

In addition, the University of Manchester Library policy states that it is mandatory for all research studies to have a Data Management Plan. The data management plan should be developed by the CI/Trial team/CTU and will be checked by the Sponsor prior to submission to Ethics/Health

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Research Authority. A detailed plan containing all elements of data flow will be required and reviewed before Sponsor greenlight to recruit participants is given.

### **3.4 Data entry, data processing and data validation**

GCP dictates that quality control should be maintained at each stage of data handling (entry, processing and validation) to ensure data are reliable and processed correctly.

A trial specific SOP should be written for data entry, processing and validation. The trial specific data handling SOP should, as a minimum, have the following in place:

- map of the data flows from data collection through to archiving
- procedures for completing CRFs
- data monitoring plans/procedures (e.g. frequency and validation points)
- procedure for data entry and edit checks
- procedure for post data entry validation
- data protection
- backup

#### **3.4.1 Data Entry**

The Data Manager (an individual with delegated responsibility for data management) should be responsible for ensuring a process is in place to: receive data (via CRFs); review the data to identify missing data, incomplete data and data outside of range; code and enter the data in the DMS. Discrepancies should be raised with the CI/PI (or delegate) and any queries recorded and corrected. On paper-based CRFs, correction fluid should not be used as this will obscure the original data. Amendments should be initialled and dated by the PI (or delegate).

Coding and entry of data into the DMS should be undertaken by a delegated member of the research team working to a defined data entry process. Good practice dictates that a 'double entry' process should be adopted to ensure data verification.

#### **3.4.2 Data Processing**

The following key points should be followed when processing clinical trial data:

- all transactions (insert, change, delete) must have a clear and complete audit trail (less sophisticated electronic systems (e.g. spreadsheets) may require printing/dating of previous versions of the data);
- only authorised staff should be able to process the data;
- authorised data processors are responsible for maintaining data security and confidentiality;
- if data are transformed during processing, it should be possible to compare the original data and observations with the processed data (reconciliation).
- manual coding of data must be done through appropriate coding lists

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All points must be fully documented in a Data Monitoring Plan.

### **3.4.3 Data Validation**

This process aims to ensure the validity of the data before statistical analysis. Data validation should take place at three stages:

- when CRFs are completed: source data validation is performed through cross-referencing the data entered into the CRF against source documents (e.g. patient records);
- data entry: the DMS may enable automatic data entry checks; otherwise manual data checks should be specified and tested;
- post-entry: queries are run to detect (for example) all missing values and all values outside a defined range.

When algorithms/apps are being used as part of the study, these must also have adequate validation steps with regular reviews.

Validation checks should continue until all missing values and inconsistencies are identified and corrected.

### **3.5 Data backup**

The DMS should always have a back-up system in place to guard against loss or disaster.

The University provides a range of storage facilities that provide a reliable means of automatically backing up data. A twin data centre operation is in place to provide resilience and disaster recovery.

*Customisable backup and recovery plans can be specified as part of the service design process. CIs should seek advice from University IT services.*

### **3.6 Data archiving**

It is a requirement that data from Clinical Trials is maintained for a significant period of time after the trial has closed. This is usually a minimum of five years and can be longer. Consideration of appropriate archiving for trial data should take place during the trial design and costing phase (see: SOP on Archiving).

*For more detailed advice and guidance Principal Investigators should consult the University's Records Management Office and, in respect of archiving electronic data, University IT Services.*

### **3.7 Data monitoring**

For large, complex trials it is recommended that an Independent Data Monitoring Committee (IDMC) be set up to periodically carry out reviews of trial data at staged intervals during the study (Please see SOP14: Data Monitoring Committee and Trial Steering Committee).

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The IDMC should have terms of reference and include experienced investigators, clinicians and statisticians, all of whom should be independent of the study team.

The IDMC can perform both a quality role (to ensure data management processes are being followed) and a monitoring role to determine whether or not the study should continue (e.g. if interim results indicate strongly that the treatment is superior or inferior to the control). The IDMC should report recommendations for action to the Trial Steering Committee, if there is one, or the CI.

### **3.8 Data protection**

Throughout the data management process it is essential that data are kept in accordance with the eight principles of Data Protection. It is a legal requirement that all data are kept in compliance with the Data Protection Act 1998.

All sensitive information (within the University's definition of the term) on paper should be kept physically secure. All electronic data should be kept secure on systems that comply with the University's IT Security Policies.

*It is essential that the Chief Investigator (or delegated individual) seeks advice, well before the trial is due to start, from both University Estates and University IT Services on physical and IT security respectively.*

*Remote access to data in a DMS and transfers of data from the DMS (e.g. via email) should not be performed until a full risk assessment has been undertaken and professional advice from University IT Services has been sought on recommended procedures and technologies.*

See: SOP18 on IT Security and Encryption for more information:

<http://www.staffnet.manchester.ac.uk/services/rbess/governance/clinicaltrials/policiesandprocedures/> .

### **4.0 Related Procedures and references**

- International Conference on Harmonisation (ICH) of Good Clinical Practice (URL required)
- University of Manchester Cyber Security website:  
<http://www.itservices.manchester.ac.uk/cybersecurity/>
- University of Manchester Guide to Data Handling:  
<http://documents.manchester.ac.uk/display.aspx?DocID=19941>
- Imperial College London: Data Management SOP (CRGO/SOP/020)
- Cardiff University: Data Management SOP (CU/08/S20/1.0)

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## Contact list

- MHS Faculty Research Office

<http://www.staffnet.manchester.ac.uk/bmh/about-fbmh/our-structure/pss-functions/rbss/research-support/>

- Research Governance and Integrity Team

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