MANCHESTER 1824

The University of Manchester

Standard Operating Procedure

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Position: Chair of Clinical Trials Management Group		**Position:** Associate Vice President for Research Integrity	
Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**January 2013**	**Update of weblinks and office details**

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Office 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

The European Clinical Trials Directive 2001/20/EC ("the Directive") was introduced to establish a standardised framework for good practice in the management of Clinical Trials throughout the European Community. The Directive sets out how clinical trials investigating the safety or efficacy of a medicinal product for use in humans must be conducted, and includes clinical trials involving healthy volunteers as well as small scale or pilot studies. The Directive also requires It also requires clinical trials to be conducted in compliance with the principles of Good Clinical Practice (GCP), with detailed standards subsequently published as the European Directive 2005/28/EC (usually referred to as "the GCP Directive").

The Directive was transposed into UK law as the Medicines for Human Use (Clinical Trial) Regulations 2004, statutory instrument SI 2004/1031, which came into force on 1 May 2004. This statutory instrument and all its subsequent Amendments (including SI 2006/1928, which transposed into UK law the GCP Directive), will be referred to as "the Regulations" in the rest of the document.

The Regulations are intended to protect the rights, safety and well-being of research participants in Clinical Trials of Investigational Medicinal Products (CTIMPs) and to harmonise, and make transparent, regulatory processes relating to clinical trials of medicines for human use.

In order to be compliant with the law, organisations conducting CTIMPs must have clearly documented Standard Operating Procedures (SOPs) covering all aspects of conducting Clinical Trials.

This document should be read in conjunction with the University's 'Policy on Clinical Trials'. The procedures outlined in associated SOPs represent good practice for those involved in CTIMPs and the outlined procedures in the SOPs must be followed by all the University researchers.

All documentation related to CTIMPs which fall under the Regulations has to be produced and controlled in a specified way. This is to ensure all staff are working to the approved and active version of all documents.

2.0 Purpose

This SOP relates to guidance for the creation, amendment, retention and destruction of documentation related to the CTIMPs where the University is the named sponsor. This SOP covers all documentation including, standard operating procedures and policy documents.

3.0 Roles and responsibilities

The University of Manchester's lead on operational Clinical Trials matters is the Associate Vice President for Research Integrity under the auspices of the Research Conduct and Accountability Committee.

The Chair of the University Clinical Trials Management Group (CTMG) will be the Person Responsible for CTIMPs. The Chair of CTMG will be responsible for implementing overarching policies (to be ratified by the Research Compliance Committee (RCC) relating to CTIMPs (including SOPs), approve sponsorship arrangements for CTIMPs (including undertaking a risk assessment) and will receive monitoring, annual, and safety reports. CTMG will meet regularly and will involve a representative from each trial that the University sponsors.

The Research Policy Officer (Clinical Trials) is accountable to the Chair of the CTMG and will act on his/her behalf to oversee adherence to this policy.

Principal Investigators are responsible for ensuring that this policy is observed for any CTIMPs for which s/he is the Principal Investigator, and to abide by the relevant University wide and/or local standard operating procedures (SOPs). (In this document, the term Principal Investigator refers to the person responsible for conducting the research project).

All University members of staff working on CTIMPs are accountable to the Principal Investigator for undertaking activity in adherence with this policy.

4.0 Procedures

4.1 Document control

4.1.1 All University-wide documentation related to the CTIMPs is created centrally and controlled by the Research Policy Officer (Clinical Trials).

4.1.2 All documents are given a unique document number, title, version number, author, effective date, review date and page numbers.

4.1.3 Revision numbers, dates and reasons for change are logged centrally.

4.1.4 The active version of the document is available on the University intranet. Chief Investigators are notified by email when a new document or revision is available.

4.1.5 Centrally produced/controlled documents include (but are not restricted to):

- **Policy for Compliance with The Medicines for Human use (Clinical Trials) Regulations 2004 and subsequent amendments (Investigational Medicinal Products) and other Clinical Research**.
- All CTIMP related SOPs

4.1.6 Where locally produced documents are required (e.g. SOPs specific for the CTIMP trial), these are controlled by the Chief Investigator or relevant member of staff according to local document control policy for their trial team.

4.1.7 As a minimum all locally produced documents should have a unique ID number, title, version number, author, effective date, review date and page number.

4.2 Creation of documents

4.2.1 All University-wide documentation related to the HTA Licence is created centrally.

4.2.2 Documents will follow a standard layout as defined by University Policy.

In summary:

- Printed single-sided on plain white paper.
- In Arial 11 point, fully justified type
- The front page will be the University document control page
- Sections must be numbered, and section headings will be in 11-point bold.
- Paragraphs within sections will be numbered in legal style (e.g. within section 2, the paragraphs will be numbered 2.1, 2.2, 2.3, etc.)
- There must be footnote on each page, including any appendices, which includes the title of the policy, the version of the policy, the date of approval, the page number, total number of pages and a prompt to check the Intranet for the latest version.
- Where possible use job titles to describe roles and responsibilities as opposed to names. This will negate the need for policy / document revision when post holders change.
- Draft procedural documents must be clearly marked as such using a 'watermark'.
- All procedural documents must be written in a style that is concise and clear using unambiguous terms and language.
- All abbreviations must be expanded on their first use in the document.

4.3 Approval

All University-wide CTIMP documents are circulated to the chair of the CTMG for review and comments. They are then approved by the AVP for Research Integrity. In the case of policies, after approval by the AVP for Research Integrity, they are then ratified by the Research Compliance Committee.

4.3.2 Where ratification of a policy by the Research Compliance Committee is inappropriate (e.g. where urgent sign off is required) the document can be signed off by the Associate Vice President for Research Integrity.

4.4 Amendment

4.4.1 When amendment of centrally drafted documentation is necessary, an email notifying all staff of the new version number(s) and reminding them to access the amended document, via the University intranet, will be circulated.

4.4.2 Any amendments are recorded on the University document control page.

4.5 Retention

4.5.1 The Research Policy Officer (Clinical Trials) will hold a working file of all current documentation. All active documents will be uploaded to the University intranet for access by all staff.

4.6 Destruction

4.6.1 The Research Policy Officer (Clinical Trials) will keep an archive file with all superseded documentation for reference.

4.6.2 The intranet will only contain the current version and local sites should shred all outdated versions of documents and replace with the current version as soon as it is available. Chief Investigators will be notified by email when a new document is available.

5 Consultation, Approval and Ratification Process

5.1 Consultation and Communication with Stakeholders

5.1.1 All University-wide CTIMP related documents are written by a member of staff with relevant expertise and experience. Additional advice is sought from members of the research community within the University or external advisors, as necessary.

5.2 Document Approval Process

5.2.1 Standard Operating Procedures are approved by the Chair of the CTMG and/or Associate Vice President for Research Integrity.

5.2.2 Policies are ratified by the Research Conduct and Accountability Committee.

6 Dissemination and Implementation

6.1 Dissemination

6.1.1 When approved, this document will be posted on the Clinical Trials pages of the University's Research Office website. Only the current version will be available.

6.1.2 All Chief Investigators will be notified by email when the latest version of the document is available.

6.2 Implementation of Procedural Documents

6.2.1 Support and advice on the implementation of this document can be obtained via the Research Policy Officer (Clinical Trials) or the Chair of the CTMG.

7 Review, Monitoring Compliance With and the Effectiveness of Procedural Documents

7.1 Process for Monitoring Compliance and Effectiveness

7.1.1 The Chair of the CTMG/Research Policy Officer (Clinical Trials) will monitor compliance through regular audits of tissue holdings including audit of tissue transferred on/off site.

7.1.2 Document contents will be reviewed against any changes to the applicable guidelines and regulations and taking into account any feedback received from Chief Investigators.

7.1.3 The outcome of the review – and any resulting amendments - will be reported to the Research Conduct and Accountability Committee.

7.2 Standards and Key Performance Indicators 'KPIs'

7.2.1 This document will be available on the University intranet.

7.2.2 This document must be reviewed at least every two years or when there are significant changes.

7.2.3 Awareness of the document will be delivered at the CTMG meeting involving all Chief Investigators.

References:

- Directive 2001/20/EC
- Directive 2005/28/EC
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 1928)
  The above can be accessed via/ downloaded from the MHRA website:
  http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/ImplementationoftheClinicalTrialsDirectiveintheUK/index.htm

- Clinical Trials Toolkit information on 'Substantial Protocol Amendments', which can be accessed via/downloaded from
  http://www.ct-toolkit.ac.uk/_db/_documents/Protocol_Amendments.pdf
- Research Governance Framework 2nd Edition