Standard Operating Procedure

Number:	UM/UoM Registering non-UoM Clinical Trial/SOP04/6.0		
Title:	**Registration of a non-University sponsored Clinical Trial/Investigation**		
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Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**January 2013**	**Update of web links and office details**
2.1	**May 2014**	**Addition of version control statement for SOP**
3.0	**October 2015**	**Update of web links and office details**
4.0	**October 2016**	**Update of web links and office details**
5.0	**March 2018**	**Review and update of content**
6.0	**January 2023**	**Review, update of content, name and links**

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. The document is part of Sponsor QMS system, designed to manage best practice throughout clinical research and study management.

1.0 Background

The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union. It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document.

Regulation 3, as amended by Statutory Instrument 2006/1928, requires that research which falls under the regulation has a "Sponsor". As stated in the Regulations, the Sponsor "in relation to a clinical trial, [is] the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial". Therefore, all proposed research which falls within the scope of the Regulations must have a confirmed Sponsor.

University of Manchester employees are required to register proposed research projects which are Clinical Trial/Investigations with the Research Governance, Ethics and Integrity Team, whether or not the University of Manchester is being requested to act as Sponsor. If the University is being requested or may be requested to act as Sponsor or co-sponsor for a Clinical Trial/Investigations please follow the University Sponsorship of a Clinical trial SOP05 (Processing requests for confirmation of sponsorship for funding applications for Clinical Trials of an Investigational Medicinal Product or Device).

The Medicines and Healthcare products Regulatory Authority (MHRA) expects the University to be aware of all Clinical Trial/Investigation, which are being led by its employees whether or not the University is acting as Sponsor of the study. This is particularly important if any of the funding for the trial is coming via the University.

2.0 Purpose

This SOP describes the process for registration of involvement or proposed involvement in a Clinical Trial/Investigation, for which the University of Manchester (UoM) is not and will not be asked to take on the role of Sponsor. This registration should be completed if all of the following apply:

- The Chief Investigator or other lead investigators (e.g. Laboratory Lead Investigators) of the Clinical Trial/Investigation is an employee of the UoM.
- Full sponsorship of the trial is being undertaken by an organisation(s) other than the University
- The study falls under the UK Policy Framework for Health and Social Care Research and The Medicines for Human Use (Clinical Trials) Regulations 2004.

UoM employees whose only involvement in a Clinical Trial/Investigation is to recruit, treat or follow patients according to a standard protocol (for example a commercial trial or an investigator led trial) need not register that study.

Each Clinical trial/Investigation need only be registered once by the most senior University of Manchester investigator.
This process of registration will allow the University of Manchester to:

- Retain a record of clinical trials undertaken by its staff

- Where appropriate, discuss UoM processes with the UoM lead investigator
- Where appropriate, discuss research governance issues with the UoM lead investigator
- Allow the UoM, as the employer of the investigator, to have oversight of the research activities
- Ensure that the investigator(s) have suitable insurance in place before the project starts
- Have oversight of samples being stored and/or analysed on University premises, where such samples form primary or secondary endpoints of a Clinical Trial/Investigation.

3.0 Procedure

This procedure only concerns studies that fall into (or potentially fall into) the category of clinical trial of an investigational medicinal product or a Clinical Trial/Investigation, as defined by the Clinical Trials Regulations.

3.1 The University of Manchester Investigator should register their research with the Research Governance, Ethics and Integrity team by completing the Study Registration Form (Appendix 1) and send through the study protocol. If in doubt as to whether or not to register a study please contact the Research Governance, Ethics and Integrity Team (clinicaltrials@manchester.ac.uk).

3.2 Registration should take place at the time of application for funding if the submission for funding is being processed via the UoM. Registration should take place after funding has been awarded if another institution is taking the lead with regards to securing funding.

3.3 The Research Governance, Ethics and Integrity Manager may require evidence of external sponsorship and details of the funding of the study (e.g. a confirmation of engagement with the UoM Research Support Services or Pure record).

4.0 Appendix

Appendix I: Registration form for a Clinical Trial/Investigation in which the University of Manchester is not acting as Sponsor

5.0 References:

- UK Policy Framework for Health and Social Care Research
- Clinical Trials Regulations

Appendix I. Registration form for a Clinical Trial/Investigation in which the University of Manchester is not acting as Sponsor

Please answer as many questions as possible and forward this form to Research Governance, Ethics and Integrity Manager (clinicaltrials @manchester.ac.uk) together with the study protocol and evidence of external sponsorship and Faculty/School approval.

Study Details	
Full Project Title:	
EudraCT Number (if applicable) or other registration number	
REC Ref (or IRAS number if available):	
Chief Investigator:	
Institution of the chief investigator (if not the University of Manchester)	
Senior University of Manchester investigator (if not the CI)	
Role of the senior University of Manchester investigator in the trial (if not the CI)	
Funding body/bodies	
Sponsor(s):	

		Yes	No
1	**Is the attached protocol the final version?**	☐	☐
2	**Is the research a clinical trial of an investigational medical product (CTIMP)?**	☐	☐
3	**Is the research a clinical trial of a Medical device?**	☐	☐
4	**Does the research involve non University of Manchester researchers?**	☐	☐
5	**Has funding been awarded for this trial?**	☐	☐

6	**Is any/all of the confirmed/potential funding commercial?**	☐	☐
7	**Is any/all of the confirmed/potential funding non-commercial?**	☐	☐
8	**Does any of the confirmed/potential funding for the trial come via the University of Manchester?**	☐	☐
9	**Is the University of Manchester the lead institution with respect to the confirmed/potential funding?**	☐	☐
10	**If funding is via the University is there evidence of School level approval (e.g. a Pure record)?**	☐	☐
11	**Are any samples stored and/or analysed on University premises that form primary or secondary endpoints associated with a CTIMP?**	☐	☐