MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

Number:	UoMCTSOP05/2024/V7.0		
Title:	Assessing the suitability of a co-sponsor for CTIMP/Medical Device studies		
Version:	7.0	**Effective Date:**	30 Oct 2024
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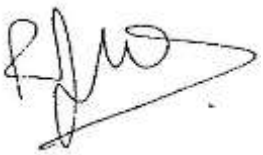
Signature:		**Signature:**	

Version	Date	Summary of Changes
2.0	January 2013	Update of weblinks and office details.
3.0	May 2014	Additional conditions including review of ongoing sponsorship; receiving monitoring reports; DMEC reports
3.0	May 2014	Addition of version control statement for SOP
4.0	October 2015	Update of weblinks and office details
5.0	August 2016	Update of weblinks and office details
6.0	October 2018	Review and update in line with current processes
7.0	October 2024	Minor changes, update of weblinks, transfer to new template and separation of the SOP template.

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1 Introduction

The European Clinical Trials Directive 2001/20/EC ("the Directive") 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 Trial) Regulations 2004, SI 2004/1031, which came into force on 1 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 the document.

All proposed research which falls under the above stated regulations, requires a Sponsor (Confirmation of Sponsorship, SOP03). A research Sponsor takes responsibility for the initiation, management and financing (or arranging the financing) of a trial. NB: for non-commercial clinical trials where the lead investigator (Chief Investigator) is a University of Manchester employee holding an honorary contract with a NHS organisation, the University of Manchester will usually act as a co-sponsor with that NHS organisation.

For some CTIMPs/Medical Devices, where the University of Manchester is prepared to act in principle as a Sponsor, this will be as part of a co-sponsor arrangement.

The Regulations in Section 3 of Part 1 provide the role of the Sponsor under the Directive to be undertaken by two or more parties such that each party assumes responsibility for fulfilling specified aspects of that role. The CTMG will determine whether circumstances require a departure from this SOP, otherwise it should be followed. Where the University of Manchester agrees to co-sponsorship, as per Regulations Section 3, Part 1, the University will be responsible for carrying out the functions of a Sponsor and shall make the request for authorisation to conduct the trial. The co-sponsor will be responsible for carrying out the functions of the Sponsor under Part 4 (Good Clinical Practice and the Conduct of Clinical Trials); and be responsible for carrying out the functions of the Sponsor under Part 5 (Pharmacovigilance), in accordance with regulation 17. Co-sponsorship does not confer joint responsibility: specific responsibilities of each Sponsor will be clearly defined within a co-sponsorship agreement on a trial by trial basis. The co-Sponsor will likely delegate some of the responsibilities that have been delegated to them and likely will undertake a similar process in assessing the University of Manchester. We will comply therefore with requests to provide evidence of our suitability to co-sponsor.

2 Scope

This SOP relates to Clinical Trials which come under the Regulations where The University of Manchester is the Sponsor or co-sponsor. The requirements of this SOP are a minimum for such trials and apply in conjunction with all applicable University

policies and procedures and, as far as appropriate, the policies and procedures of the relevant NHS Trust.

The purpose of this SOP is to define the process and procedures for The University of Manchester determining the suitability of a co-sponsor for trials were the Regulations apply, before the University of Manchester enters in to a co-sponsorship arrangement.

3 Responsibilities

3.1 Procedures

3.1.1 Assessment of co-Sponsor

The University of Manchester will determine if a proposed co-Sponsor has adequate systems in place to undertake the main duties of a Sponsor as proposed in the division of responsibilities. Where these responsibilities are Parts 3, 4 and 5 of the Regulations. The University will assess (see Appendix for methods) whether the co-Sponsor has the ability to adhere to the following:

Under Part 3: Authorisation and Ethics Committee Opinion

1. Request appropriate clinical trial authorisation (CTA, e.g. in UK, Europe, US),
2. Participate in inspection of their (the co-Sponsor's) premises
3. Give notice of amendments to CTA, make representations and amendments
4. Give notice of amendments, as required, to the protocol to the Regulatory Ethics Committee, and competent regulatory authorities (e.g. HRA and MHRA and/or EMA or FDA etc. as applicable) .
5. Give notice a trial has ended to the competent authority and ethics committee.

Under Part 4: Good Clinical Practice and Conduct (GCP)

1. Put and keep in place arrangements to adhere to GCP at all participating sites
2. Ensure IMPs are made available to subjects free of charge
3. Take responsibility for the handling, storage and distribution of the IMP
4. Take appropriate urgent safety measures (if no other person is specified to do so)

Under Part 5: Pharmacovigilance

1. Keep records of all adverse events reported by investigators
2. Ensure recording and prompt reporting of Suspected Unexpected Serious Adverse Reactions (SUSAR's)
3. Ensure investigators are informed of SUSAR's
4. Ensure all SUSAR's, including those in third countries, are entered into a European database
5. Provide annual list of suspected adverse reactions and a safety report

The proposed co-Sponsor will have to satisfy the University of Manchester prior to any agreement being formalised, ensure that there are appropriate SOPs and policies in place to cover the main duties as listed under Parts 3, 4 & 5 (or as agreed), before the University of Manchester enters in to a co-Sponsorship arrangement and before formalising the division of responsibilities. These SOPs and policies will be provided to the University of Manchester and will be assessed and approved by the University Clinical Trials Management Group (CTMG).

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3.1.2 **On-going Assessment of co-Sponsor**

The co-Sponsor will be expected to keep the University apprised of any changes to SOPs and policies which will affect the management of a trial according to a schedule determined by the RGEIT staff per trial. The University expects a co-Sponsor to ensure the timely sharing of monitoring reports, audit reports and data monitoring and research ethics committee reports. These responsibilities, where appropriate, will be included in any contract agreed between the co-sponsors. RGEIT will undertake an annual review of the co-Sponsorship agreement to ensure that all parties adhere to the terms and conditions of the contract.

4 Related Documents

Reference Number	Document Title
05/A	Appendix Example of Co-Sponsor Checklist

5 References

- Directive 2001/20/EC The Clinical Trials Directive
- Directive 2005/28/EC The Good Clinical Practice Directive
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031)
- The Medicines for Human Use (Clinical Trials) Regulations 2004 https://www.legislation.gov.uk/uksi/2004/1031/regulation/3/made
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (SI 1928) The above can be accessed via/ downloaded from https://www.legislation.gov.uk/uksi/2006/1928/contents/made
- Clinical Trials Toolkit information on 'Substantial Protocol Amendments', which can be accessed via/downloaded from http://www.ct-toolkit.ac.uk/routemap/substantial-amendments
- UK Policy Framework for Health and Social Care Research

6 Appendices

Appendix: Example of a co-Sponsor Checklist