The University of Manchester

Standard Operating Procedure

Number:	UoM/SuitabilityCoSponsor/SOP05/6.0		
Title:	Assessing the suitability of a co-sponsor for CTIMP studies		
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Version	Date	Reason for change
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**

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

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 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.

All proposed research which falls under the above stated regulations, requires a Sponsor (Confirmation of Sponsorship SOP). A research Sponsor takes responsibility for the initiation, management and financing (or arranging the financing) of a trial. For some CTIMPs, 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.

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 sometimes act as a co-sponsor with that NHS organisation.

Where the University of Manchester agrees to entering in to a co-sponsorship arrangement, this arrangement will usually be in-line with the Regulations Section 3 of Part 1, whereby the University will be responsible for carrying out the functions of a Sponsor under Part 3 (Authorisation for Clinical Trials and Ethics Committee Opinion) 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 also be responsible for carrying out the functions of the Sponsor under Part 5 (Pharmacovigilance), in accordance with regulation 17. The co-sponsor arrangement, as outlined, does not confer joint responsibility. The specific responsibilities of each Sponsor will be clearly defined within a co-sponsorship agreement. This will be assessed on a trial by trial basis and is dependent on the resources available to undertake such duties.

Before formalising the division of responsibilities with a co-sponsor within a co-sponsorship agreement, the University of Manchester will determine the suitability of the proposed co-sponsor by assessing their systems in accordance with this SOP. The University of Mancehster acknowledges that the co-Sponsor will likely delegate some of the responsibilities that have been delegated to them

The University of Manchester recognises that the co-Sponsor will be undertaking a similar process in assessing the University of Manchester and will comply with all requests to provide evidence of our suitability to co-sponsor.

2.0 Purpose

This SOP relates to CTIMPs – (i.e. all Trials which come under the Regulations) where The University of Manchester is the Sponsor or co-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.

The purpose of this SOP is to define the process and procedures for how The University of Manchester will determine the suitability of a co-sponsor for CTIMP studies before the University of Manchester enters in to a co-sponsorship arrangement.

3.0 Roles and 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 of Manchester will assess whether the co-Sponsor has the ability to carry out/adhere to the following:

Under Part 3: Authorisation and Ethics Committee Opinion

1. Request clinical trial authorisation (CTA),
2. Undertake/allow inspection of co-Sponsor's premises
3. Give notice of amendments to CTA, make representations and amendments
4. Give notice of amendments to the protocol to the Regulatory Ethics Committee, HRA and MHRA as required.
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 need to be provided to the University of Manchester and will be assessed for suitability and approved by the University Clinical Trials Management Group (CTMG). .

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 CTIMP in a timely manner. The University would expect the 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.

The University, will undertake an annual review of the co-Sponsorship agreement to ensure that the terms and conditions of the contract are being adhered to by all parties.

4.0 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 http://www.legislation.gov.uk/2004-*?title=Clinical%20Trials%20Regulations
- 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

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Appendix 1: Example of a co-Sponsor Checklist

The University of Manchester will determine if a proposed co-Sponsor has adequate systems in place to undertake the main duties of a Sponsor under Parts 3, 4 and 5 of the Regulations or as defined:

Main Duties to be Assessed	Suitable Process in place	Supporting Documents (SOPs/Policies)	Check if Legally Compliant/GCP/Standard Practice
Under Part 3: Authorisation and Ethics Committee Opinion			
1. Request clinical trial authorisation (CTA)			
2. Undertake/allow inspection of co-Sponsor's premises			
3. Give notice of amendments to CTA, make representations and amendments			
4. Give notice of amendments to the protocol to the Regulatory Ethics Committee, HRA and MHRA as required.			
5. Give notice a trial has ended to the competent authority and ethics committee			

Under Part 4: Good Clinical Practice and Conduct			
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			