MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

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Title:	Delegation of Responsibilities		
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Version	Date	Summary of Changes
2.0	January 2013	Update of web links and office details.
3.0	May 2014	Addition version control statement for SOP and contractual obligations (Appendix I)
4.0	October 2015	Update of weblinks and office details
5.0	August 2016	Update of weblinks and office details
6.0	March 2018	Updated process documented
7.0	November 2018	Changes to Appendices
8.0	February 2025	Change of template, correction of inclusion, minor addition to responsibilities, added references and separation of appendix

1.0 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 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 research which falls under the regulation to have a Sponsor. As stated in the Regulations, the role of 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 will require a formal confirmation from the Sponsor.

Regulation 3 allows for two or more parties to take on the responsibilities of the Sponsor (co-sponsorship). One of the co-sponsors must take on responsibility for carrying out the functions of a Sponsor under Part 3 (authorisation for clinical trials and ethics committee opinion) of the Regulations and shall make the request for authorization to conduct the trial. The request for authorization shall specify who is responsible for carrying out the functions of the Sponsor under Part 3 of the Regulations, Part 4 (good clinical practice and the conduct of clinical trials) of the Regulations and Part 5 (pharmacovigilance) of the Regulations.

Paragraph 12 of Regulation 3 allows that "a person who is a Sponsor of a clinical trial in accordance with this regulation may delegate any or all of his functions under these Regulations to any person but any such arrangement shall not affect the responsibility of the Sponsor."

2.0 Scope

This Standard Operating Procedure (SOP) describes the process to be followed for dividing responsibilities between the University of Manchester (the University) and another organization when there is a co-sponsorship arrangement whereby the University is one of the Sponsors. It also describes the process for delegating these divided responsibilities to other individuals, notably the Chief Investigator (CI), Clinical Trial Unit (CTU) or Principal Investigator (PI) at a site.

3.0 Procedures and Responsibilities

3.1 Agreeing the division of responsibilities between the co-sponsors

3.1.1 Where the University is being asked to enter into a co-sponsorship arrangement with another organisation, the University will require that a co-sponsorship agreement is negotiated via the University Contracts Team. This agreement will contain a Division of Responsibilities which will be negotiated on behalf of the University by the Research, Governance, Ethics and Integrity Team. An example template for the Division of Responsibilities is contained in Appendix I.

3.1.2 On the basis of the research protocol and risk assessment of the study, the Research, Governance, Ethics and Integrity team will discuss the division of responsibilities with the Chief Investigator and a representative from the co-sponsor to determine which organisation is best suited to take responsibility for each item on the Division of Responsibilities.

3.1.3 Where the University is the substantive employer of the Chief Investigator, the University would usually take on the responsibilities of the Sponsor under Part 3 of the Regulations.

3.1.4 The University would not usually take on responsibilities under Part 5 of the Regulations, but would require the Chief Investigator to copy the University into safety reports and for higher risk studies a receipt of SAE and SUSAR reports.

3.2 Delegation of Sponsor responsibilities

3.2.1 Where the University intends to delegate some of its responsibilities as Sponsor, as defined in the Division of Responsibilities, for example to the Chief Investigator, Local PI or CTU, this will be indicated on the Division of Responsibilities. The University will also list the responsibilities that it has delegated to the CI and local Principal Investigator in a written agreement with each site.

3.2.2 Where the University delegates responsibilities to the Chief Investigator it will assure itself that the Chief Investigator has the necessary experience and training to fulfil these responsibilities.

3.1.3 Where the University delegates responsibilities to a third party it will put a formal agreement in place to be negotiated by the University Contracts Team again detailing the responsibilities of the Sponsor, third party and CI.

3.1.4 Where the Chief Investigator or Principal Investigator intends to delegate some of his/her responsibilities to another member of his/her research team. S/he should do so using a delegation log which should be signed by all parties. The CI or Principal Investigator should assure him/herself that the researcher to whom s/he delegates responsibilities has adequate experience and training to undertake the delegated responsibilities.

4 Related Documents

Reference Number	Document Title
06/A	Delegation of Responsibilities Schedule with a UKCRC-CTU Appendix

5 References

- The Medicines for Human Use (Clinical Trials) Regulations 2004 (https://www.legislation.gov.uk/uksi/2004/1031/regulation/3#regulation-3-12)
- Please also see SOP15: Selection and Overview of a Clinical Trial Unit