The University of Manchester

Standard Operating Procedure

Number:	UM/UoM Delegation of Responsibilities/SOP06/7.0		
Title:	**Delegation of Sponsor responsibilities**		
Version:	7.0 (November 2018)	**Effective Date**	November 2018
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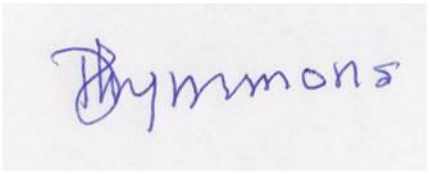
Signature: 		**Signature:** 	

Version	Date	Reason for change
2.0	**January 2013**	**Update of weblinks and office details**
3.0	**May 2014**	**Addition of version control statement for SOP**
3.0	**May 2014**	**Addition of 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**

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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 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 Purpose

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 Procedure

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.

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.

4.0 Appendix

- Appendix I: Example of a Delegation of Responsibility Schedule with a UKCRC-CTU
- Please also see SOP15: Selection and Overview of a Clinical Trial Unit

Appendix I: Example of a Delegation of Responsibilities Schedule with a UKCRC-CTU

Note that where a particular activity is the responsibility of the UKCRC-CTU, costs associated with this activity will be borne by the UKCRC-CTU and should be provided in the cost estimate. The table below should be reviewed and ALL relevant activity not listed should be added.

Please note that the following activities are not always covered by UKCRC-CTU costs and must be considered and provided to the Research Support Manager:

- MHRA fees
- Sponsor/ local R&D fees
- Drug/ IMP management (including pharmacy advice, QP release, drug distribution and pharmacy manual)
- Laboratory analyses, kits and manuals
- MedDRA dictionary coding (not all UKCRC-CTU's provide a coding service)
- Vendor assessment and selection
- Amendments resulting in increased study duration, sample size and/or scope of work (not all UKCRC-CTU's support "no-cost extensions")
- Archiving
- Data sharing arrangements
- Study-specific equipment
- Courier costs (e.g. sample transportation)Publication preparation costs and submission fee

TRIAL NAME:
CI NAME:
Division/Delegation of Duties with a CTU

"✓" = Completes the task

"(✓)" = Supports completion of the task

Note: "Regulatory" refers to Competent Authorities and Research Ethics Committees (including GTAC)

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
1.0 Trial Sponsorship	1.1	Undertake role of Sponsor	✓		
	1.2	Appoint the MAHSC-CTU as Sponsor's delegate as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004, ICH Guideline for Good Clinical Practice and DH Research Governance Framework 2005, as applicable.	✓	(✓)	
	1.3	Accept role of Sponsor's delegate (MAHSC-CTU)	(✓)	✓	
	1.4	Perform Sponsor risk assessments	✓		
	1.5	Accept CI responsibilities			✓
	1.6	Provide conditional letter regarding sponsorship arrangements	✓		
	1.7	Ensure principal study insurance/ indemnity arrangements are in place	✓		
	1.8	Assign a pharmacy representative; including input into the protocol, prepare pharmacy manual and ensure IMP supply	✓		

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
2.0 Grant funding applications	2.1	Accept MAHSC-CTU Terms and Conditions	✓		✓
	2.2	Confirm potential investigator sites	(✓)		✓
	2.3	Perform initial site feasibility assessment			✓
	2.4	Assist with trial design and methodologies		(✓)	✓
	2.5	Secure funding for the trial	✓		
	2.6	Perform initial MAHSC-CTU study risk assessment	(✓)	✓	(✓)
	2.7	Co-ordinate grant application and submission	(✓)		✓
3.0 Trial approvals	3.1	Prepare protocol, PIS, ICF		✓	(✓)
	3.2	Review protocol, PIS, ICF	✓		(✓)
	3.3	Approve protocol, PIS, ICF	(✓)		✓
	3.4	Prepare Regulatory applications (via IRAS)		✓	(✓)
	3.5	Review Regulatory applications and study documentation	✓	(✓)	✓
	3.6	Authorise Regulatory application (via IRAS)	✓		(✓)
	3.7	Attend REC meeting to present study		(✓)	✓
	3.8	Coordinate Regulatory 'green-light' process	(✓)	✓	
	3.9	Provide Regulatory 'green-light' approval (sponsor approval to begin the study)	✓		

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
	3.10	Coordinate, apply and obtain local NHS approval * (including site PIs)			✓*
	3.11	Coordinate, apply and obtain other local approvals (e.g. ARSAC) * (including site PIs)			✓*
4.0 Contracts and agreements	4.1	Agree grant holder/ contractor/ contractee	✓		(✓)
	4.2	Ensure appropriate contracts/ agreements are prepared and executed	✓		(✓)
	4.3	Authorise contracts	✓		
	4.4	Vendor assessment and selection	✓		
5.0 Trial management	5.1	Study project management; including prepare project and monitoring plans, report in accordance with the protocol, and maintain essential documentation (TMF)		✓	
	5.2	Study data management; including database design, build and testing, data management manual, data entry instructions, data check definition and programming, validation guidelines, data handling during conduct, prep for study milestones and data analyses		✓	
	5.3	Prepare CRF		✓	
	5.4	Review & approve CRF		(✓)	✓
	5.5	Prepare non-standard CRF (e.g. QoL health economy data forms)			✓
	5.6	Review & approve non-standard CRF (e.g. QoL health economy data forms)		(✓)	✓

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
	5.7	Perform detailed MAHSC-CTU study risk assessment	(✓)	✓	(✓)
	5.8	Perform detailed participating site feasibility assessment		✓	
	5.9	Set-up registration and randomisation procedure		✓	(✓)
	5.10	Ensure specific site insurance/ indemnity arrangements are in place	✓		
	5.11	Ensure safety reporting process is in place	(✓)	✓	
	5.12	Ensure a safety review committee is in place	✓		
	5.13	Perform SUSAR reporting to Regulatory Authorities	(✓)	✓	(✓)
	5.14	Secure appropriate supplies of resources of IMP/ devices	✓	(✓)	
	5.15	Secure appropriate supplies of resources of laboratory services	(✓)	✓	
	5.16	Manage grant funds	<XXX>	<XXX>	
	5.17	Facilitate completion of financial reports	<XXX>	<XXX>	
	5.18	Ensure maintenance of the Investigator Brochure/ SmPC annually and provide to participating sites (where applicable)	(✓)	✓	
	5.19	Annual validation of Investigator Brochure/ SmPC	(✓)		✓
	5.20	Annual review of study reference safety information	(✓)		✓
	5.21	Prepare and submit reports (e.g. DSUR, APR) and data as required by Regulatory bodies, Trial Oversight Committees etc.		✓	(✓)

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
	5.22	Authorise reports (e.g. DSUR, APR)	(✓)		✓
	5.23	Ensure appropriate trial oversight committees are in place (Trial Management Group, Trial Steering Group, Independent Data Monitoring Committees) and schedule committee meetings	(✓)	✓	(✓)
	5.24	Prepare oversight committee charters		✓	(✓)
	5.25	Review & approve oversight committee charters	✓		(✓)
	5.26	Provide statistical support during study conduct		✓	
6.0 Investigational Product(s)	6.1	Manage IMP/ Drug/ Device	<XXX>	<XXX>	<XXX>
7.0 Trial conduct	7.1	Ensure that the Trial Site team members are appropriately qualified and experienced to undertake the conduct of the Trial * (including site PIs)			✓*
	7.2	Perform site initiation /study specific training		✓	(✓)
	7.3	Ensure CI is aware of responsibilities with regard to PI, sub-investigators and research team	✓		
	7.4	Register/ randomise participants * (including site PIs)			✓*

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
	7.5	Supply investigator sites with study documents to ensure that Investigator Site Files can be maintained		✓	
	7.6	Complete CRFs and data queries in line with the agreed timeframes * (including site PIs)			✓*
	7.7	Prepare Sponsor's quarterly CTMG report		✓	
	7.8	Management of data flow		✓	
	7.9	Remediate data flow issues (where longstanding significant issues)	✓	(✓)	(✓)
	7.10	Categorisation of amendments (substantial or non-substantial)	✓	(✓)	
	7.11	Prepare protocol amendments		✓	(✓)
	7.12	Review & approve protocol amendments (as per trial approvals)	✓		✓
	7.13	Management of CTA conditions	(✓)	✓	(✓)
8.0 Governance	8.1	Monitor investigator sites		✓	
	8.2	Provide routine monitoring reports to sponsor (on request)		✓	
	8.3	Investigate site non-compliance/ deviations/ research misconduct (including potential serious breaches)	✓	(✓)	(✓)
	8.4	Report major deviations to the sponsor		✓	
	8.5	Remediate site non-compliance/ deviations/ research misconduct	✓	✓	(✓)

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
	8.6	Suspend or terminate non-compliant sites	(✓)	✓	
	8.7	Report suspected research misconduct to Regulatory Authorities	✓	(✓)	(✓)
	8.8	Notify serious breaches of GCP or the trial protocol to the Sponsor		✓	
	8.9	Notify serious breaches of GCP or the trial protocol to the Regulatory Authorities	(✓)	✓	
	8.10	Notify Competent Authorities of any events impacting the conditions of approval	(✓)	✓	
9.0 Trial closure	9.1	Notify the Regulatory Authority(ies) of trial closure/ early termination		✓	
	9.2	Prepare data for final study report (including statistical analysis)	(✓)	✓	(✓)
	9.3	Coordinate site closure(s)		✓	
	9.4	Prepare final study report	(✓)	✓	✓
	9.5	Review & approve final study report	✓		✓
	9.6	Issue final study report		✓	
10.0 Publication	10.1	Prepare data for publication, including statistical analysis		✓	(✓)
	10.2	Write publication			✓
	10.3	Approve publication	✓	(✓)	
	10.4	Initiate and coordinate review and submission of abstracts, posters and publications	(✓)		✓

AREA	ITEM	RESPONSIBILITY	SPONSOR	CTU	CI
11.0 Archiving	11.1	Ensure that all Trial records are archived appropriately on conclusion of the Trial and retained in accordance with Sponsor and statutory requirements.	(✓)	✓	
	11.2	Agree an appropriate archiving process with all parties, including vendors where applicable	✓	✓	✓