Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Delegation of Responsibilities**		
SOP Reference Number:	QUB-RGEI-005	Version Number:	FINAL v 1.0
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	Name and Position	**Signature**	**Date**
Author:	Research Governance, Ethics and Integrity Team	----------	----------
Reviewed and Approved by:	Chair, Research Governance, Ethics and Integrity Committee	----------	----------

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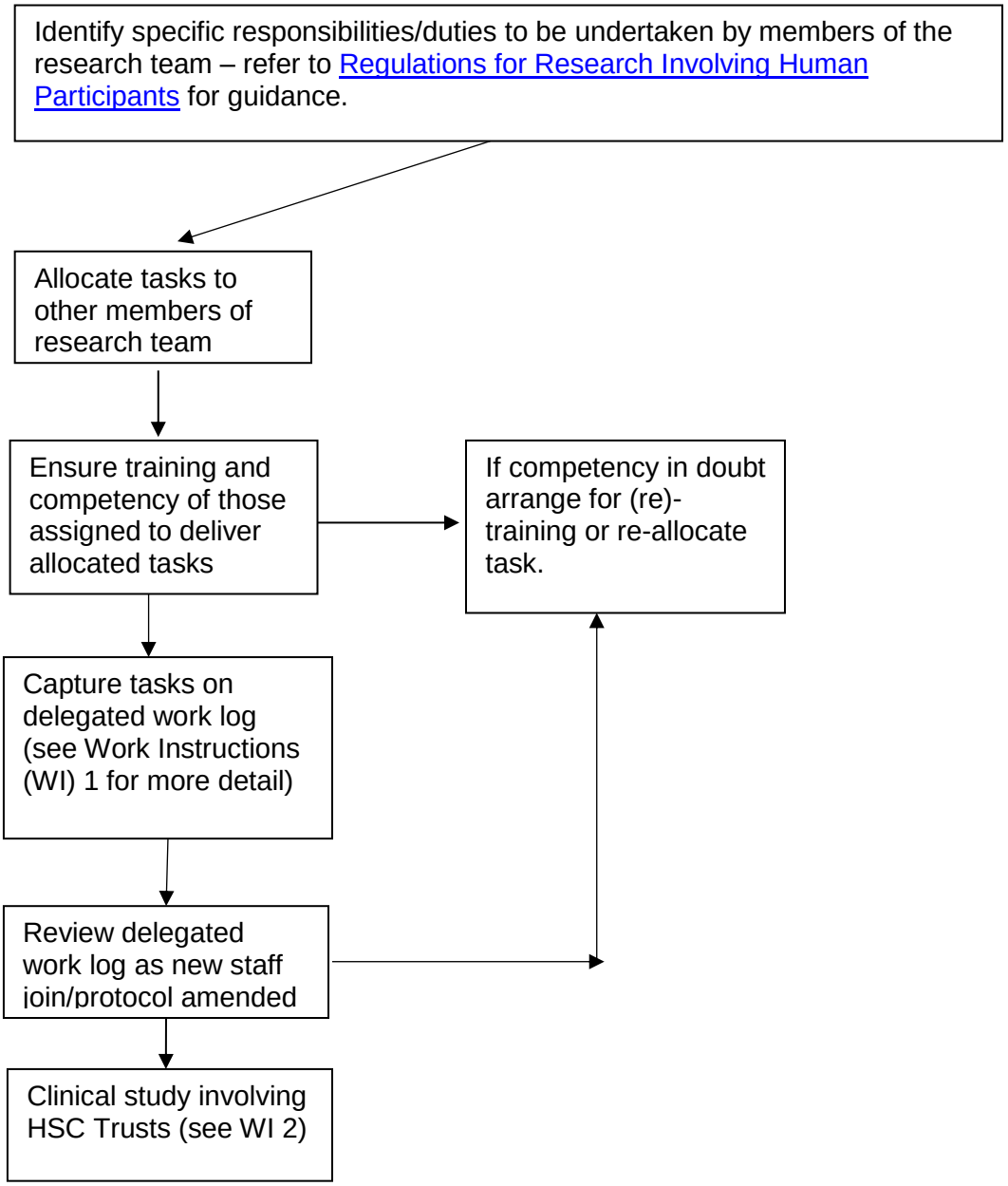
Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) describes how responsibility and accountability can be delegated among members of the research team.

2. Procedure



3. References

UK policy framework for health and social care research
(weblink checked 16 March 2021)

4. Appendices

Work Instructions 1
Work Instructions 2

Appendix 1 - Study Delegation Log.
Appendix 2 - Clinical Trial Study Sponsorship: Roles and Responsibilities.
Appendix 3 - Services.
Appendix 4 - Division of Responsibilities and Delegation of Activities.

Work Instructions 1

- The CI, will discuss and agree the allocation of tasks with other members of the research project, as outlined in Appendix 1.
- Task should be allocated to appropriately qualified staff. Training and Competency must be checked as part of the allocation process, where a need is identified training must be undertaken or the task re-allocated.
- The Study Delegation Log must be completed, as exampled in Appendix 1. The SDL will:
  - i List the names of staff and the procedures that have been delegated to them.
  - ii Be signed and dated by the CI/PI and filed appropriately within the Trial Master File.
  - iii Be updated when new staff are recruited, but superseded versions must not be destroyed in order to provide for an audit trial.
- The SDL should be reviewed at appropriate intervals to ensure that it is kept up to date.

Work Instructions 2

- For multi-centre studies the CI should specify the responsibilities delegated to a site Principal Investigator.
- Where the University is operating as a co-sponsor with another organisation (e.g. Health and Social Care Trust), signatures will be required on the co-sponsorship agreement, attached as Appendix 2, and retained in the University's Research Governance Project File.
- For projects sponsored by the University, Sponsors responsibilities will be delegated to the CI or Clinical Trials Unit (CTU)/Clinical Research Organisation (CRO) who have been appointed to deliver the study, Appendices 3 and 4 should be used to capture the services to be provided (Appendix 3) and the activities delegated (Appendix 4).

Delegation and Staff Signature Log

Study Title:	**Protocol No:**
Chief Investigator:	**EUDRACT No:**
REC Reference Number:	**Sponsor:**

Staff signature and site delegation of tasks

Name	Initials	Study Role	Key Delegated study Task(s)*	Duration From:	To:	Signature	CI/PI Signature

***Key for list of delegated study task(s)**

1. Obtain informed consent	6. Drug Dispensing	11. Data Query Signature	16. Archiving	21. Other: ……...
2. Physical Exam/ Clinical Evaluations	7. Drug Accountability	12. Resolving data queries	17. Other: ……...	22. Other: ……...
3. Source document entry (i.e. Medical notes)	8. Case Report Form Completion	13. Reviewing and Reporting Adverse Events	18. Other: ……...	23. Other: ……...
4. Inclusion/ Exclusion Assessment	9. Case Report Form Signature	14 Medical Prescriptions	19. Other: ……...	24. Other: ……...
5. Investigational Product Accountability	10. Data Query Completion	15.Maintaining Trial Master File (TMF)	20. Other: ……...	

*NB: This is not an exhaustive list and will require annotating at a local level.

Sponsorship Framework

Insert logo of lead sponsor **Insert logo of Co-sponsor**

Clinical Trial Study Sponsorship: Roles and Responsibilities

Project Details			
Full Research Title:			
Chief Investigator:			
Lead Sponsor:		**Co-sponsor:**	
Funder:		**Financial Management:**	
Investigator(s)		**Role**	**Employer**

Completion notes	
1.	All persons or organisations sponsoring the research are jointly responsible for the first five responsibilities.
2.	The Sponsoring organisation (s) must indicate which of the responsibilities they are going to assume in the "Sponsor" column and identify which of those responsibilities are being delegated to the Chief Investigator in the "Delegated to" column. Where responsibilities are shared equally, the lead sponsor is named first.
3.	A Project is not fully sponsored until the sponsor for **all** responsibilities has been assigned.

Description		**Sponsor**	**Delegated to**
1. Responsibility			
1.1	The research respects the dignity, rights, safety and well-being of all participants.	All	All
1.2	The work is consistent with the Research Governance Framework.	All	All
1.3	Everybody involved in the research agrees the division of responsibilities.	All	All
1.4	All scientific judgements are based on independent and expert advice.	All	All
1.5	Assistance is provided to any enquiry, audit or investigation.	All	All
2. Study preparation:			
2.1	Design of the protocol and associated documents (GCP)		
2.2	Ensure statistical review (GCP)		
2.3	Ensure Independent scientific review		
2.4	Design Investigators Brochure (Reg. 3)		
2.5	Annually review Investigators Brochure (Reg. 3)		
2.6	Secure study funding and secure agreement between Sponsor and Investigator/Institution were required. (GCP)		

2.7	Researchers have the experience and expertise and access to the resources needed for the research. (GCP)		
2.8	Identify, develop and secure third party contracts (GCP)		*
2.9	Ensure necessary indemnity arrangements in place (GCP)		
2.10	Ensure all approvals in place and start certificate issued.		
2.11	Obtain Management (NHS R&D/University Governance) approval(s)		
2.12	Ensure appropriate employment/honorary contracts in place for investigators		#
2.13	Risk assess the Trial		#
3. Authorisation and ongoing Management of Clinical Trials			
3.1	Apply for EudraCT No		
3.2	Register study on Clinical Trial database		
3.3	Request authorisation to conduct Clinical Trial (Reg. 12)		*
3.4	Request permission from licensing authority for substantial amendment (Reg. 22)		*
3.5	Address amendments requested by the licensing authority (Reg. 23)		
3.6	Give notice of conclusion to licensing authority (Reg. 27)		#
3.7	Notify licensing authority of serious breaches (Reg. 29a)		
4. Ethics Committee Opinion			
4.1	Apply to Ethics Committee for approval (Reg. 14)		
4.2	Request permission from ethics committee for substantial amendment (Reg. 24)		*
4.3	Submit annual progress report (Reg. 29)		#
4.4	Submit end of study report (Reg. 27)		#
4.5	Submit Final report within one year of trial end		#
5. Good Clinical Practice			
5.1	Ensure trial conducted in accordance with protocol (Reg. 29)		
5.2	Development of Trial specific SOPs to maintain clinical trial quality control (GCP)		
5.3	Supply IMP / Medical Device free of charge (Reg. 28)		
5.4	Suspend or terminate clinical trial (Reg. 31)		*
5.6	Maintain Trial Master File in accordance with Regulation 31a		
5.7	Archive the Trial Master File (Reg. 31a)		#
5.8	Ensure medical files of trial subjects retained for 5 years after conclusion of trial (Reg. 31a)		
5.9	Approving and recording transfer of ownership of data or documents used in a clinical trial (Reg. 31a)		*
5.10	Take the lead when investigating any complaint arising from clinical trial (GCP)		
5.11	Lead any Misconduct in Research Allegation		
6. Pharmacovigilance:			
6.1	Keep records of all adverse events reported by the investigators. (Reg. 32)		
6.2	Assess Serious Adverse Events not identified in trial protocol for expedited reporting to licensing authority/ethics committee (Reg. 32)		*
6.3	Ensure SAEs are reviewed by an appropriate committee for monitoring trial safety (GCP)		
6.4	Ensure recording and prompt reporting of suspected unexpected serious adverse reactions, (SUSARs) (Reg. 33)		
6.5	Onward reporting of SUSAR to licensing authority/ethics committee (Reg. 32)		
6.6	Ensure investigators are informed of SUSARs. (GCP)		
6.7	Ensure all SUSARs are entered into the European database. (GCP)		

6.8	Provide annual list of SSARs and a safety report to ethics committee and relevant licensing authority (Reg. 35)		#
7. Data Management			
7.1	Design of case report forms (GCP)		
7.2	Design of database (GCP)		
7.3	Collect high quality and accurate data from research subject (GCP)		
7.4	Ensure high quality data analysis (GCP)		
7.5	Comply with Data Protection Act (GCP)		
8. IMP Management:			
8.1	Liaise with site pharmacists regarding the provision and accountability of the drugs.		
8.2	Ensure that the IMP is not used for any purposes other than the conduct of the study and is used in strict accordance with the protocol. (Reg. 13)		
8.3	Ensure necessary agreements are in place with IMP provider		
8.4	Ensure IMP is provided and labelled in accordance with the Regulations (Reg. 46)		
8.5	Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.		
9. Monitoring and Audit:			
9.1	Frequency of monitoring to be: *{insert frequency}*		
9.2	Securing monitors (GCP)		
9.3	Sharing monitors reports		#
9.4	Development and execution of audit plan (GCP)		
9.5	Sharing audit reports		
10. Intellectual Property and Dissemination of Results:			
10.1	Engage with HSC Innovations and Knowledge Transfer/Exploitation Units to ensure Intellectual property rights and their management are appropriately addressed.** (RGF)		
10.2	At the conclusion of the study, plans are in place for disseminating the findings. (GCP)		#

Declaration:
I agree to the responsibilities set in this document

Signatures
Add additional rows below if necessary.

Signatory *please print relevant person's name*	***Signature***	***Date***
For Lead Sponsor:		
For Co-Sponsor:		
Chief Investigator:		
Site Principal Investigator:		

* Where sponsor responsibilities are delegated to the CI or PI – the CI or PI must seek approval of the responsible sponsor BEFORE acting with delegated responsibility.
# Where sponsor responsibilities are delegated to the CI or PI – the CI or PI must send a copy to the responsible sponsor.
~ Allocation of Intellectual Property will be addressed through a separate agreement.

SERVICES

Overview

Insert description/overview of Services to be provided.

Detail

Scope of Work

	Activity	**Delegated To (eg CI/CTU)**	**Months**
Study Documentation	Prepare the protocol and associated trial documentation		
Study Start-up	Prepare and submit ethics application* Obtain ethical approval		
	Prepare and submit NHS/HSC Trust applications Obtain research governance/management approvals		
	Complete site initiation and training		
	Set-up Trial Master File		
	Register the trial on a suitable publically available database		
Study Management	Prepare and submit trial amendments to the Sponsor, relevant ethics committee and NHS/HSC Trust as appropriate		
	Co-ordinate and attend TMG, TSC and DMEC committee meetings		
Study Conduct	Prepare Investigator Site File		
	Maintain Trial Master File		
	Maintain records of all adverse events as specified in the protocol		
Data Management	Prepare the data management plan		
	Design case report form		
	Develop database and ensure accuracy of trial data		
Monitoring	Prepare monitoring plan*		

	Monitor the trial in accordance with the trial monitoring plan and provide copies of the monitoring reports to the Sponsor		
Analysis	Prepare statistical analysis plan		
	Complete statistical and health economics analysis		
	Prepare data for publication		
Reporting	Provide 6 monthly reports to the Sponsor on trial progress		
	Provide reports to the TMG, TSC and DMEC committee		
	Prepare and submit annual progress reports to the relevant ethics committee and to Sponsor		
	Report all adverse events as specified in the protocol in accordance with legal and regulatory requirements		
	Upload the results on a publically accessible database		
Study Close-out	Complete and submit the end of trial declaration to the relevant ethics committee		
	Archive Trial Master File for period of *5 years* following close of the study Obtain Sponsor approval prior to destruction of Trial Master* File		
	Prepare final study report and submit within 1 year of study end to ethics and Sponsor		

*Where Sponsor responsibilities are delegated the CI/CTU must seek approval of the Sponsor before acting with delegated responsibility.

Division of Responsibilities and Delegation of Activities

Queen's University Belfast as Sponsor, formally delegate specific roles to other organisations/individuals in accordance with the table below.

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
1. Study preparation (All studies)	a) Ensure that the Study and its Protocol have received robust and favourable scientific and, where applicable, statistical peer review	Yes		
	b) Ensure appropriate insurance is in place for the design and management of the Study	Yes		
	c) Ensure that indemnity arrangements are in place to cover Participating Site liabilities		Yes	
	d) Ensure that insurance or indemnity arrangements are in place to cover Sponsor liabilities	Yes		
	e) Secure and administer funding for the research costs of the Study	Yes		
	f) Secure and contract for the supply of resources, where applicable, including medicinal products / devices / Contract Research Organisation services	Yes		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	g) Ensure that the appropriate contracts and agreements are in place for the Study	Yes		
	h) Ensure adequate facilities, resources and support (capacity and capability) are available to conduct the Study at the Participating Site		Yes	
2. Applications, authorisations and registration (all studies)	a) Ensure that the Protocol is compliant with the relevant regulations/ guidelines	Yes		
	b) Prepare Participant information sheet and consent form (and assent form where applicable), including, where appropriate, consent for: provision of Material(s) and Personal Data, Clinical Data or other data, as required, to the Sponsor	Yes		
	c) Register the Study on an appropriate clinical trial register	Yes		
	d) Obtain approvals from relevant Ethics Committee(s)	Yes		
	e) Obtain HRA Approval (for NHS sites in England) and/or NHS management permissions as applicable	Yes		
	f) Ensure that all relevant departments at the Participating Site are aware of and, where necessary, have agreed to their role in the Study		Yes	

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	g) Obtain a Clinical Trials Authorisation for a CTIMP from the regulatory authority (MHRA in the UK)	Yes		
	h) Obtain a Letter of no objection for the clinical investigation of a non-CE marked medical device from the regulatory authority (MHRA in the UK)	Yes		
	i) [Insert ANY ADDITIONAL PERMISSIONS APPROVALS TO BE SOUGHT]	Yes		
3. Protocol Amendments (all studies)	a) Prepare and submit proposed substantial (and, for any Study of investigational medical devices, non-substantial) amendments to all relevant ethics committee(s) and, if appropriate, regulatory authority(ies)	Yes		
	b) Ensure the Principal Investigator is informed of all amendments requiring implementation at the Participating Site, including the date on which the amendment should be implemented	Yes		
	c) Ensure all amendments of which the Participating Site is notified and that require local implementation are implemented at Participating Site, or that the sponsor is promptly notified that the amendment cannot be implemented and given the reason for this		Yes	
4. Study Conduct (all studies)	a) Ensure that the Study is managed according to GCP (as defined in the Protocol), all relevant legislation, and the Protocol	Yes		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	b) Ensure that the Study is conducted locally according to GCP, all relevant legislation, and the Protocol		Yes	
	c) Submit all Study Data and Materials required for the Study, in accordance with the Protocol and any Study specific manuals provided by the Sponsor		Yes	
	d) Ensure that the Participating Site team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive and/or honorary employment contracts in place, where required		Yes	
	e) Ensure that no Participant is recruited at Site until the Participating Site has been activated by the Sponsor		Yes	
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol and/or agreed monitoring plan.	Yes		
	g) Maintain Investigator Site File (and Pharmacy Site File, where relevant) at Participating Site, ensuring compliance with Sponsor requirements and applicable guidance/ legislation		Yes	
	h) Maintain Trial Master File/Sponsor File, ensuring compliance with applicable guidance/ legislation	Yes		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	i) Assess capability of Participants to give informed consent		Yes	
	j) Ensure no Study procedure is carried out on a Participant until consent (where required) is obtained in accordance with the Protocol		Yes	
	k) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.		Yes	
	l) Ensure that all Clinical Data and documentation are available for the purposes of monitoring, inspection or audit		Yes	
	m) Inform appropriate health or social care professionals if their patient is a Participant in the Study, if required		Yes	
	n) Ensure relevant Protocol deviations, and all serious breaches of Study conduct and/or GCP are reported to the Sponsor		Yes	
	o) Report serious breaches of Study conduct and/or GCP to relevant ethics committees and regulatory authority(ies) (as applicable)	Yes		
	p) Report suspected research misconduct, identified by the Sponsor, to the Participating Site	Yes		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	q) Report suspected research misconduct, identified by the Participating Site, to the Sponsor		Yes	
	r) Notify the Participating Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) of the end of the Study	Yes		
	s) Notify the Participating Site, relevant ethics committee(s) and, if applicable, regulatory authority(ies) if the Study is terminated early	Yes		
5. Adverse events (all studies)	a) Maintain detailed records of all adverse events as specified in the Protocol		Yes	
	b) Report adverse events as defined in the Protocol and to legal requirements and in accordance with Participating Site policy		Yes	
	c) Ensure that procedures are in place for emergency unblinding of the randomisation code. (If applicable)	Yes		
	d) Promptly notify the Sponsor of any urgent safety measure taken to protect Participants at Site		Yes	

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	e) Promptly inform relevant ethics committee(s), regulatory authority(ies) (if applicable), and all Principal Investigators of any urgent safety measures taken to protect Participants in the Study	Yes		
	f) Ensure that all Serious Adverse Events (SAE) are reported to the Sponsor, as specified in the Protocol		Yes	
	g) Ensure all SAEs are promptly assessed, and expedited reporting to the relevant ethics committee(s) and regulatory authority (if applicable) is undertaken where necessary	Yes		
	h) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of Study safety	Yes		
	i) Ensure that annual safety/ progress reports and final Study report are generated and submitted to relevant ethics committee(s) and regulatory authority(ies) (e.g. Development Safety Update Reports, if applicable) within the required timeframes	Yes		
	j) Ensure that the Principal Investigator is, at all times, in possession of the current relevant safety information for the Study	Yes		
	a) Design of case report forms (eCRFs/CRFs) and database	Yes		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
6. Data Management (all studies)	b) Complete eCRFs/CRFs fully, accurately in a contemporaneous manner, and submit in a timely manner and in accordance with the Protocol		Yes	
	c) Respond to the Sponsor's requests for data clarification		Yes	
	d) Process and code Study Data	Yes		
	e) Ensure appropriate analysis of Study Data	Yes		
7. Publication (all studies)	a) Prepare and submit abstracts, posters and publications of the Study endpoints b)	Yes		
8. Archiving (all studies)	a) Ensure that the Trial Master File is archived appropriately on conclusion of the Study and retained as required by the Protocol	Yes		
	b) Ensure that all Study records held at Site are archived appropriately when notified by the Sponsor and retained as required by the Protocol		Yes	

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
9. Clinical Trials involving Investigational Medicinal Products	a) Ensure appropriate arrangements are defined for the supply, labelling, storage and destruction of Study Drug(s)	N/A		
	b) Ensure ability to comply with the arrangements for the Study Drug(s)		N/A	
	c) Ensure that Study Drug(s) supplied for specific use in the Study is/are used in strict accordance with the Protocol and is/are not used for any other purpose		N/A	
	d) Ensure that Study Drug(s) is/are stored in appropriate and secure conditions		N/A	
	e) Ensure approvals are in place and issue regulatory 'green light' for release of Study Drug(s)	N/A		

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
	f) Ensure that appropriate accountability and destruction records are maintained, as required by the Sponsor		N/A	
	g) Ensure that the Site is provided with a sufficient number of investigational medical devices/ disposables required for proper functioning of the device for the planned number of Participants	N/A		
10. Studies involving CE-marked medical devices for new purpose or non-CE marked Medical Device	a) Ensure that investigational medical devices are not used for any purposes other than the conduct of the Study, unless Sponsor permits continued intended use for CE marked device after conclusion of the Study		N/A	
	b) Ensure that investigational medical devices are stored in appropriate, secure conditions and returned as instructed by Sponsor. Further to ensure that detailed records are maintained regarding its movement from delivery to return/destruction.		N/A	
	c) [Insert additional Study-specific responsibilities, not covered elsewhere, if necessary.]			
11. Material Transfer	a) Ensure appropriate and timely collection of Material and transfer to the Sponsor's nominated laboratory(ies), all in accordance with the Protocol and in compliance with Schedule 4.		Yes	

	RESPONSIBILITY to:	Sponsor (where Co-Sponsored, name the responsible Party)	Participating Site	If ACTIVITY is delegated, name the body / individual delegated to (eg CTU, CRO, CI):
12. [Insert other responsibilities, if necessary eg] *Statistics*	*a) Develop statistical analysis plan*			
	b) Conduct statistical analysis according to the protocol, relevant SOPs and statistical analysis plan.			
	c) Provision of final tables figures and listings			
	d) Develop and approve Statistical 'final' Analysis Report			
13. [Insert other responsibilities, if necessary eg] *Health Economics*	*a) Develop Health Economics Analysis Plan*			
	b) Conduct economic analysis in accordance with protocol, SOPs and Health Economics Analysis Plan.			
	c) Provision of final tables, figures and listings, develop and approve Health Economics 'final' analysis report			
	d) Review Health Economics 'final' analysis report			