

<b>Title: Selection and management of third parties</b>	
Effective Date: 30-11-21	Review Date: 30-11-24
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**Document History**


Version	Description of update	Date Effective
1	Removal of reference to third party oversight spreadsheet Change of number for Q-Pulse	2-10-15
2	Reformatted and reference to medical device trials at 1.1	1-4-17
3	Revised scope at 1 Reference to Third Party list at 3.1 and 5	19-9-18
4	Updated CTFG responsibilities at 2 Reference to procurement regulations at 3.1 Reference to Business Development Officer and two-yearly checks at 3.2	30-11-21

**1. Scope**

1.1 This SOP applies to Chief Investigators (CI), Sponsor staff and any researcher from University of Aberdeen (UoA) and/or NHS Grampian (NHSG) conducting a Clinical Trials of an Investigational Medicinal Product (CTIMP) or medical device clinical investigations. The SOP should also be considered best practice for any other clinical research activity.

1.2 Sponsor must be able to demonstrate oversight and approval of third parties and any sub-contracted duties. This SOP describes the procedure for issuing and completing agreements required for such projects.

1.3 A third party is considered to be any organisation, other than the UoA or NHSG, which performs a task or service as part of a research project. This includes drug and/or medical device supply providers/distributors and third party laboratory service providers. This may also include archive providers, courier services, transcription services, translation services, statistical services and data management providers sub-contracted to UoA and/or NHSG to deliver services to a specific Trial.

 For the avoidance of doubt the co-sponsors, co-investigators and collaborator institutions are excluded from the definition of third party as it applies to this SOP.

**2. Responsibilities**

Chief Investigator (CI)	Identify appropriate third parties.
Sponsor	Facilitate appropriate oversight of contracted third parties.
Quality Assurance Manager	Undertake proportionate due diligence of third parties.
Business Development Officer	Review and execution of contracts with third parties.
CTFG	May review use and performance of contracted third parties.

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**Key to symbols**  = Important point to note  = Warning

### 3. Procedure

#### Trial set-up

3.1 The CI shall confirm any third parties they wish to engage at sponsor registration and risk assessment stage and, if appropriate, complete a list of all third parties using TMP-QA-74 (Third Party List) which shall be submitted to Sponsor for approval. The CI shall also confirm at sponsor registration and risk assessment stage that the budget is in place, or has been applied for, to cover all third party activities. The CI is responsible for ensuring compliance with procurement regulations.

3.2 As required, the Quality Assurance Manager shall coordinate proportionate, pre contract due diligence review on any identified third party/parties. For example: requesting copies of relevant accreditation/certification/licences (eg to manufacture/distribute MP), requesting and taking up references or remote/on-site audit. The Quality Assurance Manager shall document due diligence which may be presented to the Clinical Trials Facilitation Group (CTFG) for information and/or comment. The Quality Assurance Manager shall also liaise with the Business Development Officer as required. Third party assessments shall be repeated every two years during the active phase. Any actions arising shall be taken forward by the Quality Assurance Manager.

3.3 If an alternative third party needs to be identified, the due diligence described in 3.2 shall be repeated. The Business Development Officer in Research & Innovation (R&I) shall advise whether the funder will need to be informed.

! The Research Governance Manager shall also be consulted and shall advise whether a protocol amendment is required.

3.4 Third party contracts, and any amendments, shall be managed according to SOP-QA-13 - Generation of contracts.

3.5 For third parties providing laboratory/data analysis services an Analytical Protocol (TMP-QA-18) may be completed by the CI and reviewed by the Quality Assurance Manager prior to inclusion in the contract with the third party. However, if a third party provides their own contract template the Quality Assurance Manager shall assess if this adequately addresses the management of trial samples or data, or whether a separate Analytical Protocol is also required.

! The CI shall ensure that all relevant documentation is provided to the third party in a timely manner ie research protocol, approved protocol amendments, associated documentation and copies of required approvals.

! The CI shall ensure that no activities are implemented by the third party until appropriate approval and contracts are in place.


#### Active phase management


! The CI shall maintain regular contact with the third party/parties. Key correspondence and meeting minutes shall be retained in the Trial Master File (TMF).

3.9 The CI shall discuss any protocol amendments which impact the services provided by the third party with the third party and Research Governance as appropriate. ! Research Governance and/or CI shall advise the Business Development Officer of any amendments which may require a change to contract(s).

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3.10  The CI shall notify the Business Development Officer and Quality Assurance Manager of any issues regarding the delivery of the third party services. Where necessary the Quality Assurance Manager may arrange for an audit of the service.

3.11  Where performance issues with a third party have been identified the Quality Assurance Manager shall co-ordinate the ongoing Sponsor oversight and management of the third party and shall action any identified issues as appropriate.

### Project closure

3.12 Feedback on overall performance of the third party shall be collected at the monitoring close-out visit, where applicable, for future reference and be reviewed by CTFG.

## 4. Abbreviations and definitions

Medicinal Product - The EU Directive 2001/20/EC (Clinical Trials Directive) defines a medicinal product as:

*'A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.'*

CTFG	Clinical Trials Facilitation Group
CTIMP	Clinical Trial of Investigational Medicinal Product
R&I	Research and Innovations (UoA)
TMF	Trial Master File

## 5. Related documentation and references

SOP-QA-6	Study start-up
SOP-QA-7	Trial Master File
SOP-QA-13	Generation of contracts
SOP-QA-15	Management of medicinal products used in research projects
SOP-QA-19	Amendments
SOP-QA-31	Research project closure
TMP-QA-18	Analytical Protocol template
TMP-QA-74	Third Party list

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