TAYSIDE MEDICAL SCIENCE CENTRE POLICY

SELECTION AND OVERSIGHT OF VENDORS FOR CLINICAL RESEARCH

POLICY NUMBER :	TASC POLICY 012 v1
AUTHOR:	Valerie Godfrey
EFFECTIVE DATE:	02 Aug 2021
REVIEW DATE:	02 Aug 2023

Third Party/Vendor definition

A third party or vendor is considered to be any organisation or individual (commercial or non-commercial), other than the University of Dundee (UoD) or NHS Tayside (NHST), undertaking agreed duties at the request of the Sponsor where such duties are relating to the Sponsor's responsibilities in relation to a study.

Such duties may include drug and/or medical device suppliers/distributors, archiving providers, laboratory service providers, courier services, transcription services, translation services, statistical analysis and data management providers.

There should also be appropriate vendor oversight processes in place for collaborators who are conducting trial duties on behalf of Sponsor.

Co-sponsors and co-investigators (who are named on grant applications) and collaborators, who are only providing an opinion in relation to a study but not a service, are excluded from the definition of third party/vendor in this policy.

Background

The process of vendor oversight begins with the selection of a suitable vendor which may be initiated by the Chief Investigator (CI). As such, the Sponsor should implement processes for assessing the suitability of a vendor prior to the signing of contracts. These processes will vary depending on the risks associated with the tasks being delegated and what is previously known about the vendor.

Contracts should clearly detail the delegated tasks, duties and functions between the parties, the required standards of service (including Good Clinical Practice [GCP]) and the process for subcontracting work (to ensure that subcontracting does not occur without Sponsor approval). Contracts must be kept current.

Work must not commence until the contract is signed by all parties.

Applicability

This policy applies to TASC staff, Sponsor, CI and researchers conducting Clinical Trials of an Investigational Medicinal Product (CTIMP) sponsored or co-sponsored by UoD and/or NHS Tayside NHST. The policy should also be considered best practice for any other clinical research project.

Selection of vendors

The CI must inform the Sponsor at the earliest opportunity of any external company or service provider that they wish to engage to deliver the research. The rationale for using and the decision to select a particular vendor will be taken by the CI and Sponsor and shall be subject to the vendor meeting the standards expected for compliance with GCP and UK regulations following the checks made on behalf of Sponsor.

When the CI engages vendor services via UoD, the CI must follow the UoD Procurement Policy. When the CI engages vendor services via NHST, the appropriate NHST tender process must be followed.

Vendors may be 'Known' or 'Unknown' to TASC. 'Known' is defined as any company or service provider used previously by TASC and deemed acceptable. 'Unknown' is defined as any company or service provider that is new to TASC and requires a vendor assessment. If circumstances have changed considerably, a 'Known' vendor may require to be re-assessed. TASC Legal will keep a list of vendors who have been used and/or assessed during the last 10 years.

Vendor assessment

Unless the vendor is 'Known' and acceptable, then TASC Quality Assurance (QA) and TASC Legal will begin a process for assessing vendor suitability. The level of checks will be proportionate to the study and service that will be provided and risks involved. If technical expert advice is required, support from appropriately qualified members of staff in UoD and NHST will be requested.

Results of the checks will be presented to TASC Research Governance. Upon documented agreement that the vendor is acceptable to the Sponsor, the CI will be informed and TASC Legal will progress the contract with the vendor (refer to Appendix 1 for the TASC Vendor Assessment Checklist). The vendor is required to be informed that they are working under the Medicines for Human Use (Clinical Trials) Regulations 2004 and must report serious breaches and provide relevant safety information to the Sponsor as detailed.

The CI or delegate is responsible for ensuring that vendors are provided with all the appropriate documentation (including updates) to enable them to perform their contracted activities.

The Sponsor retains the right to decline the use of a proposed vendor. Where an unfavourable review leads to a decision resulting in non-acceptance by the Sponsor, the CI will be informed and the vendor will be advised of the rejection by the CI.

Oversight of vendors

The CI shall maintain regular contact with the third party/parties.

After Sponsorship Approval, any additional vendor or change of vendor will be reported to TASC Research Governance by the CI so that vendor assessment can be carried out if required (in accordance with the criteria above). The Research Governance Manager shall also advise whether a protocol amendment is required.

Any significant issues arising in connection with potential or current vendors must be escalated to TASC Research Governance and/or TASC R&D Director.

TASC QA will carry out audits as scheduled and/or vendor assessments upon request by the Sponsor.

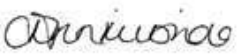
Annual review of the vendor list held by TASC Legal will be carried out by TASC QA, TASC Legal and TASC Research Governance. Updates and adjustments to the list will be made as required.

ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
NHST	NHS Tayside
QA	Quality Assurance
RG	Research Governance
TASC	Tayside Medical Science Centre
UoD	University of Dundee

DOCUMENT HISTORY

Version Number	Edited by (Job Title)	Effective Date	Details of editions made
1	Valerie Godfrey (TASC QA Manager)	02/08/2021	New.

Sign		Date
RATIFIED BY:	Professor Lynn Kilbride, Dean, School of Health Sciences, University of Dundee – on behalf of TASC Research Governance and Oversight Committee	
Signature		27th July 2021
RATIFIED BY:	Professor Jacob George, R&D Director, NHS Tayside	
Signature		28.7.21

Appendix 1 - TASC Vendor Assessment Checklist (for TASC use only)

Vendor Name:

Address:

Contact details:

TASC QA	Reviewed Y/N/NA	Comments (if applicable)	Satisfactory Y/N/NA
Staff CVs, GCP training and relevant experience			
Registrations and accreditations			
Evidence of a Quality Management System and documented processes (e.g. SOPs)			
References			
Other			
TASC Legal	**Reviewed Y/N/NA**	**Comments (if applicable)**	**Satisfactory Y/N/NA**
Vendor's Companies House entry if UK registered			
Vendor's website			
Co-ordination of Financial due diligence (via UoD or NHST Finance)			
Insurance certificate			
Adjustment of the Co-Sponsor Agreement and Delegation			
Service Contract preparation			
Other			

TASC QA Manager:

TASC Legal Manager:

TASC Senior Research Governance Manager:

Vendor Accepted/Not Accepted **Date:**

CI informed **Date:**