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VENDOR ASSESSMENT in CLINICAL RESEARCH STANDARD OPERATING PROCEDURE

Introduction and Aim

The Sponsor must ensure oversight of all study activities. A research study may require services that the sponsor is unable to perform in-house, thus requiring the sponsor to contract the service out. The vendor must be suitable to carry out the delegated tasks and must show due diligence when performing the required service, though the sponsor retains responsibility. The sponsor must ensure that conditions and principles of Good Clinical Practice (GCP) are satisfied and adhered to, and research studies are conducted in accordance with the protocol and subsequent amendments. To ensure the study runs efficiently and is compliant with the current protocol and all associated regulatory approvals, appropriate contracting should be in place with all applicable vendors. This ensures each vendor is clear on their responsibilities and commits to achieve the required work, to an appropriate standard and within timescales.

Objectives

To outline the procedure and processes required when assessing the suitability of third-party vendors to conduct specific delegated tasks in clinical research, on behalf of the Sponsor organisation.

Scope

The SOP is applicable to Chief Investigators (CI) and delegated trial staff conducting research studies sponsored by the Joint Research Office; Cardiff and Vale UHB (CAVUHB) and Cardiff University (CU) where a vendor will be required. Where duties are delegated to a Clinical Trials Unit (CTU), the SOP is also applicable to members of the CTU responsible for vendor management/oversight. Members of the Research Governance Team (RGT) with responsibility for performing sponsor activities on behalf of the JRO must also abide by this SOP.

Equality and Health Impact Assessment	An Equality Impact Assessment has been completed on the Research Governance Policy (UHB 099) under which this SOP sits. The Equality Impact Assessment completed for the policy found there to be no impact.
Documents to read alongside this Procedure	Research Governance Policy (UHB 099). SOP001/04 – Applying for C&V UHB Sponsorship SOP SOP/001/07- Cardiff Joint Research Office (JRO) Applying for Sponsorship- Non-CTIMPs SOP
Approved by	Joint Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Manager

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1.0	18/04/2024	01/08/2024	This is a new document to be used during the JRO Sponsorship process

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Abbreviations

CAVUHB	Cardiff and Vale University Health Board
CU	Cardiff University
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CRO	Clinical Research Organisation
CTR	Centre for Trials Research
CTU	Clinical Trial Unit
GCP	Good Clinical Practice
HTA	Human Tissue Authority
IT	Information Technology
JRO	Joint Research Office
QMG	Quality Management Group
QMS	Quality Management System
RGT	Research Governance Team
SL	Study Lead
SOP	Standard Operating Procedure
TM	Trial Manager

1. PURPOSE

This SOP outlines the process, selection and oversight of sub-contractors or external vendors providing services to support research sponsored by Cardiff and Vale University Health Board (CAVUHB) and Cardiff University (CU) managed through the Joint Research Office (JRO). Predominantly this SOP will be used for higher risk studies and may be utilised in other studies when deemed necessary. This will be detailed in the research specific risk assessments.

2. BACKGROUND

As per the MHRA GCP guide (1.3.1 Oversight of Internal Functions & External Vendors) although the Sponsor retains ultimate responsibility for all functions, all external vendors third-party vendors or service providers must demonstrate due diligence when undertaking any trial functions delegated to them. All persons involved in the conduct of a Clinical Trial of an Investigational Medicinal Product (CTIMP) have a legal responsibility to comply with Good Clinical Practice (GCP), the protocol and the relevant ethics and regulatory approvals. During the identification and selection of an external vendor, the Sponsor (or their delegate) must be assured that the external vendor can conduct the relevant trial activity(ies) in compliance with the protocol and applicable regulatory requirements.

Dependant on the outcome of the assessment, the Sponsor (or their delegate) may determine that an audit is required to provide confidence in the external vendor and demonstrate their compliance. Where possible the assessment will be utilised as a form of remote audit and referred to as required in situations such as ‘after a serious breach or disaster’.

The Sponsor (or delegate) must be confident that any potential risk can be minimised and mitigated against and will need to ensure that the external vendor:

- Can meet any contractual obligations
- are financially viable

- are able to maintain data integrity
- has processes in place so that all data received/transferred will be creditable and accurate with a full audit trail.

3. ROLES AND RESPONSIBILITIES

It is the responsibility of the Sponsor to ensure external vendors delegated trial tasks/responsibilities are working to the appropriate regulatory and industry standards to ensure compliance. Any external vendor delegated responsibilities in JRO Sponsored trials will need to be assessed to ensure they can adhere to any legal obligations via an audit or oversight arrangements.
Alongside this SOP the normal contracting and procurement processes will be adhered to and close collaboration and communication with the relevant personnel will occur as the necessary vendor assessments progress.

If a Clinical Trial Unit (CTU) has been costed into the grant application for a trial, the responsibility will be delegated to the CTU. The sponsor will complete a vendor assessment of the CTU involved and ascertain the suitability of the CTU to then conduct further vendor assessments, as required, of the trial. If deemed suitable, their equivalent Vendor Assessment SOP and procedures will be reviewed by JRO Research Governance team and followed. Further information may be requested during the process to ensure Sponsor and CTU processes align.

This will be detailed in the specific trial risk assessment during trial set up, and where feasible, at the grant application stage.

3.1 RESPONSIBLE PERSONNEL

The Sponsor, or CTU where delegated, is responsible for ensuring any external vendors are regulatory compliant and able to carry out the duties as delegated to them in line with any contractual arrangements and the trial protocol.

The JRO Research Governance Team are responsible for assuring the vendor assessment process is identified during trial set-up.

The JRO Research Governance Team, on behalf of the Sponsor, is responsible for ensuring any external vendors have been assessed to a satisfactory standard before any contracts are signed.

4. DEFINITIONS

Definition of a vendor- A vendor is a person, organisation, or agency external to the JRO that provides functions, services or products related to the conduct of trials sponsored by the JRO. External vendors can include (but are not limited to):

- Trials Units
- Device manufacturers/providers
- Transcription services
- Couriers
- Contract Research Organisations (CROs)
- Databanks[1]
- Drug manufacturers/suppliers
- Freelancers
- Central Laboratories (including those performing primary secondary and tertiary/exploratory analysis, eligibility and randomisation in CTIMPs)
- Commercial laboratories
- Archive facilities (where not covered by the central Cardiff University or CAVUHB procurement process)

Note:

Facilities such as bio banks are not included within the scope of this SOP if they are working in line with Human Tissue Authority (HTA) requirements.

Where unsure if a bio bank is working to HTA requirements a copy of the HTA Licence certificate should be requested which will include the specific HTA licence number.

Throughout this SOP '**trial'** will be used to refer to both clinical trials and well-designed studies". Predominantly this SOP will be used for higher risk trials and may

be utilised in other studies when deemed necessary. This will be detailed in the research specific risk assessments.

[1] *A databank is an organisation who provides a secure platform to store research data, external to the JRO, for access exclusively to approved individuals. This organisation will act as a data processor*.

5. PROCEDURE

The procedure will assess external vendors against their delegated duties as per the proposed contract and the scope of the work to be undertaken. Such assessment will need to be completed as soon as possible once potential vendors have been identified, prior to entering into any legally binding contractual arrangements. The contracting process, can however, be ongoing whilst the assessment is carried out.

Step 1: Identification of Clinical Trial Units that Require Assessment

During completion of the Sponsorship Request Form, (FRM-001-13), if the response to the question; "*Will any third parties be involved (e.g. Clinical Trial Units, or other service provider) at any stage of the research (e.g. management, supplies, sample processing?*" indicates that a CTU will be involved, then the JRO Research Governance Team should use this SOP to assess the CTU.

Step 2: JRO Research Governance Team prepares form for assessment of trial specific CTUs

a) The JRO Research Governance Team identifies if the CTU has been used by other JRO sponsored trials and whether a vendor assessment has been completed previously. *If so, it may not be necessary for the vendor assessment form to be completed again. An assessment of the delegated duties against the previously completed form should be made and documented.

Note:

In the case of CU sponsored studies where the Centre for Trials Research (CTR) are involved, there is an overarching Memorandum of Understanding that supersedes the need to conduct further vendor assessments.

b) If a previous assessment has not been completed, the JRO Research Governance Team role is to complete the CTU vendor assessment form

Step 3: Identification of Other Third-Party Organisations that Require Assessment

Where a CTU is involved and has completed a satisfactory vendor assessment, the JRO sponsor organisation will delegate responsibility for any further vendor assessments to the CTU.
Where any other organisations are actively involved in the management of, or provision of services for the trial, the equivalent CTU vendor assessment processes must be followed.

Step 4- Trials where no CTU is involved or the CTU is unsuitable to conduct the necessary vendor assessments, the JRO Research Governance Team will conduct any further trial specific vendor assessments

The JRO Research Governance Team will complete the vendor assessments required using the correct template, and document this in the trial specific risk assessments. One of the following templates will be completed as required:

- Assessment of Laboratory-Based Organisations – TPL/001/07 (see Appendix 1 for laboratory considerations)
- Assessment of CTU/CRO– TPL/001/06
- Assessment of External Vendor (non-laboratory)–TPL/001/08

The assessment will determine risk by obtaining –

- Relevant accreditation certificates
- Audit information
- Review of CVs and experience (obtaining references as required)
- Assessment of Quality Management Systems (QMS) focusing on procedures that will be adhered to for the scope of the work
- Data protection and confidentiality
- Use and access of IT

The JRO Research Governance Team will amend the templates according to the specific trial**.**

The JRO Research Governance Team will send the final version of the template to the individual whose details have been provided by the vendor undergoing assessment.

Step 5: Receipt of Completed Vendor Assessment Form

This section applies where;

I. The JRO Research Governance Team are assessing a CTU
II. The JRO Research Governance Team are assessing all Vendors
III. The CTUs, following completion of vendor assessments, require escalation to Sponsor

a) On receipt of a completed vendor assessment form, the JRO Research Governance Team will review the form and any accompanying documentation to assess compliance against the trial protocol and any proposed contractual arrangements. If a completed vendor assessment form is not received in a timely manner, the JRO Research Governance Team should request that the Chief Investigator (CI) Trial Manager (TM) or Study Lead (SD) where appropriate, to chase this with the external vendor. If after this chase there is still no response, or the vendor refuses to complete the form, this should be escalated to the QMG and a decision made on if the external vendor can be used.

b) If additional information is required, this will be directed to the relevant individual who has completed the assessment form at the external vendor by the JRO Research Governance Team (or delegated CTU). This process will continue until a satisfactory response is received.

c) If a satisfactory response cannot be agreed, the JRO Research Governance Team will seek advice from the QMG. A teleconference will be arranged with the relevant individuals (to include JRO Research Governance Team and relevant personnel from the external vendor at a minimum) to agree on a way forward. If an agreement cannot be met, the need for an on-site or remote audit may be considered.

d) If on the completion of an audit, the JRO Research Governance Team determine it is not possible to proceed, they will discuss with QMG whether there is another external vendor who could provide the service as required by the protocol.

e) If there is not another external vendor advice will be sought from QMG and JRO Director.

f) If there is another external vendor - the external vendor will be approached, the Sponsor Request Form and Trial Risk Assessment will be updated to reflect any changes and the relevant contracts team will be informed.

g) Once a satisfactory response is agreed the vendor assessment form will be signed by the JRO Research Governance Team Lead (or delegated CTU as appropriate).

h) A fully signed PDF copy of the vendor assessment form will be saved by the JRO Research Governance Team Lead in the sponsor folder and a copy sent to the CI/TM/SL for placing in the TMF.

i) Relevant contract staff will be notified of completed vendor assessment so they can move forward with the contractual arrangements.

j) The JRO Research Governance Team will notify the contact at the external vendor that the assessment is complete and to request that the Sponsor is notified if there are any substantial changes to the information provided during the time over which the external vendor is contracted.

k) The JRO Research Governance Team will add the external vendor information to the relevant Sponsor log.

Step 6: Ongoing Oversight and Compliance

a) If at any time point during the lifecycle of the trial, any concerns about the external vendor are raised or any non-compliances are identified (see JRO Protocol/GCP Non-Compliance & Serious Breaches), the completed vendor assessment form should be reviewed to by the JRO Research Governance Team and delegated CTU as appropriate. Any issues identified should be referred by the JRO Research Governance Team to QMG and other appropriate committees.

b) The JRO Research Governance Team (or delegated CTU) are responsible for overseeing the ongoing compliance and performance of external vendors and reporting any issues to the Sponsor. If any concerns are raised, a re-assessment of the external vendor may be required.

c) If the JRO Research Governance Team (or delegated CTU), in collaboration with the Sponsor, agrees that a re-assessment is required a new vendor assessment form will be sent to the external vendor for completion (as per step 5 above).

d) For JRO Sponsored trials, ongoing oversight of the CTU and other vendors will be maintained by a variety of methods e.g. Annual REC reports, TMG membership/minutes, regular communication, receiving monitoring reports, any audit reports and/or safety reports (as required and stipulated in trial specific documents).

6. REFERENCES

6.1 Referenced Standard Operating Procedures & Policies

SOP001/04 – Applying for C&V UHB Sponsorship SOP

SOP/001/07- Cardiff Joint Research Office (JRO) Applying for Sponsorship- Non-CTIMPs SOP

SOP009/01 – Research Audit

SOP/009/02 - Notification of Serious Breaches of GCP or the Study Protocol

SOP001/05 – Guidance on Databases and Required Approvals for Research Use

6.2 Referenced Forms & Templates

FRM/002/1 - JRO Sponsorship Request Form

FRM/001/05- Cardiff Risk Assessment Form for CTIMPs & Complex Studies

TPL/001/06- Assessment of CTU/CRO– JRO Template

TPL/001/07 -Assessment of Laboratory-Based Organisations

TPL/001/08- Assessment of External Vendor (non-laboratory)– JRO Template

TPL/001/04 JRO Sponsor Risk Review Template (internal)

Appendix 1 – Considerations for Vendor Assessment of Laboratories

All Central Laboratories involved in the processing of samples for JRO Sponsored CTIMPs must be GCP compliant (there is no distinction between Primary, Secondary, Tertiary and Exploratory outcome analysis). Even though the results of Tertiary analysis may not lead to practice changing outcomes, the results still contribute to the research.
NHS site laboratories are not expected to demonstrate GCP compliance unless they are performing a complex assay (e.g. prepping samples for long-term freezing then demonstrable GCP compliance is not expected).

Central Laboratories must be able to demonstrate the following:

- The laboratory is accredited (e.g. CPA, UKAS) with no outstanding non-compliances that could affect the integrity and analysis of the research sample
- There are approved, written procedures in place for processes that are specific both to research samples and routine samples. The procedures should be managed through document version control with regular review and update. Procedures should be in place for the following;
    - Traceability - Sample labelling, receipt, preservation, storage, transport and chain of custody
    - Cleaning and decontamination and disposal
    - Data Integrity
    - Method validation, recording and reporting
    - Equipment maintenance
    - Validated computerised systems
    - Evidence of consent/withdrawal
    - Quality Assurance

- There is a senior laboratory contact with knowledge of the trials requirements for research sample processing and appropriate GCP training
- Storage stability data if samples are to be stored prior to analysis
- Method validation with defined acceptance criteria. If methods have been validated in a different laboratory, then replication of the validation needs to be demonstrated using the different technology
- Systems with audit tracking to prevent tampering of results

For further information, please see the EMA Reflection paper on laboratories that perform the analysis or evaluation of clinical trial samples (EMA/INS/GCP/532137/2010)

The above information must be demonstrable from completion of the vendor assessment form by the laboratory for the laboratory to be contracted to analyse samples in any JRO Trial. If there are gaps in processes the trial team may work with the laboratory to improve the standard to a regulatory compliant level (it may be a case of defining what the laboratory are doing more formally via SOPs).