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CARDIFF JOINT RESEARCH OFFICE (JRO) STANDARD OPERATING PROCEDURE (SOP) FOR VENDOR ASSESSMENT in CLINICAL RESEARCH (INCLUDING CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS)

Introduction and Aim

In accordance with the UK Policy Framework for Health and Social Care Research (UKPF), the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended (referred to throughout this document as The Regulations) and the UK Medical Device Regulations 2002 (UK MDR 2002), as amended, 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.

Vendor selection, qualification, and oversight shall be conducted in accordance with a risk-based quality management approach, ensuring oversight activities are proportionate and focused on Critical-to-Quality factors, in line with ICH E6(R3) and UK Clinical Trial Regulations.

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) or Cardiff University (CU) and which are managed through the Joint Research Office (JRO). Predominantly this SOP will be used for higher risk studies (including Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of a Medical Device (Medical Device Trials) and may be utilised in other studies when deemed necessary and at the discretion of the Sponsor organisation. This will be detailed in the research specific risk assessments.

The sponsor and any organisation or individual they delegate activities to, 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 modifications. 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 Cardiff and Vale UHB (CAVUHB) or Cardiff University (CU) where an external vendor will be required to undertake a service for the study. Where duties are delegated to a Clinical Trials Unit (CTU), the CTU should rely on their own SOP for vendor assessments unless the Sponsor as specified otherwise. Members of the Research Governance Team (RGT) with responsibility for performing sponsor activities on behalf of the JRO must also abide by this SOP.

The JRO vendor assessment process does not include the academic/collaborative role of Co-Applicants, unless specifically requested by the Sponsor, as these positions should be subject to a separate contracting process. However, it may include such individuals if they are associated with an external vendor providing services for the project.

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.

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. Where vendor assessment activities are delegated to a CTU, the Sponsor shall maintain oversight and retain visibility of vendor performance.

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.

The JRO Research Governance Team is responsible for authoring, reviewing and updating this SOP. The JRO Quality Management Group is responsible for reviewing the SOP. The Joint Research Governance Group (JRGG) are responsible for approving the 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). SOP-001-05 Applying for JRO Sponsorship_Higher Risk Studies_SOP SOP-001-07 Applying for JRO Sponsorship_Low-Med Risk Studies_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
V1.0	18 April 2024	01 August 2024	This is a new document to be used during the JRO Sponsorship process
V2.0	16 July 2026	23/07/2026	Reviewed and updated to align with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Contents

1.0 DEFINITIONS/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
CtQ	Critical to Quality
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
TMF	Trial Master File

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)

Trial

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*.

2.0 GENERAL INFORMATION

In accordance with section 3.6 of ICH GCP E6(R3), the Sponsor retains ultimate responsibility for the trial-related activities, including protection of participants' rights, safety and well-being and the reliability of the trial data. The Sponsor may delegate several or all trial-related activities but it is responsible for:

3.6.7 …assessing the suitability of and selecting the service provider to ensure that they can adequately undertake the activities transferred to them. The sponsor should provide the service providers with the protocol where necessary as well as any other documents required for them to perform their activities.

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 additional assurance activities (e.g. audit, targeted review, or enhanced oversight) are required based on the vendor risk assessment to 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(s):

- 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.

In accordance with ICH GCP E6(R3):

> 3.6.9 The sponsor should ensure appropriate oversight of important trial-related activities that are transferred to service providers, including activities further subcontracted by the service provider.

It is the responsibility of the Sponsor to ensure that all external vendors appointed to carry out delegated trial tasks/responsibilities are working to the appropriate regulatory and industry standards to ensure compliance. Any external vendor

delegated responsibilities in a trial Sponsored by a JRO organisation 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 organisational 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. Formal agreements with vendors shall clearly define:

- Roles and responsibilities
- Delegated activities
- Oversight arrangements
- Data ownership and access
- Requirements for compliance with applicable regulations.

If a Clinical Trial Unit (CTU) has been costed into the grant application for a trial, the responsibility for conducting vendor assessments will be delegated to the CTU. Where the CTU belongs to an organisation which is separate to the Sponsor organisation, the sponsor will complete a vendor assessment of the CTU involved and ascertain the suitability of the CTU to manage the trial and t conduct further vendor assessments, as required. If deemed suitable, the CTU's 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.

3.0 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

The involvement of a Clinical Trials Unit (CTU) will be identified at the JRO Project Initiation Review stage, prior to the submission of a grant application. Where the proposed CTU belongs to a different legal entity to the proposed Sponsor organisation, the JRO Research Governance Teams should follow this SOP to assess the suitability of the external CTU. For example, if Cardiff University is the proposed Sponsor and the Cardiff University Centre for Trials Research (CTR) is the CTU costed to support the trial, a vendor assessment of the CTR will not usually be required.

Occasionally, a CTU may only be identified during completion of the JRO 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 an external 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.

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

c) The scope of the vendor assessment form shall be tailored by the JRO Research Governance Team prior to sending to the CTU, based on the identified Critical-to-Quality (CtQ) factors, with particular focus on activities that may directly impact participant safety or data integrity.

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.

Where responsibility for further vendor assessments has been delegated to the CTU, the sponsor organisation remains accountable for trial quality and participant safety.

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 forms will be completed as required:

TPL-001-07 JRO Assessment of Laboratory Based Organisations (v1)
TPL-001-06 JRO Assessment of CTU CRO (v1)
TPL-001-08 JRO Assessment of External Vendor (v1)

The scope of the vendor assessment shall be tailored based on the vendor's role in relation to identified CtQ factors, with particular focus on activities that may directly impact participant safety or data integrity.

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 (SL) where appropriate, to chase this with the external vendor. If 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 meeting 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. The justification for vendor selection and level of assessment performed shall be documented and retained within the log and be traceable to the trial risk assessment.

Step 6: Ongoing Oversight and Compliance

Ongoing vendor oversight shall be conducted using a risk-based approach, with the type, frequency, and intensity of oversight activities proportionate to the vendor's impact on Critical-to-Quality factors and as documented within the trial risk assessment. The Sponsor shall maintain continuous oversight of all delegated activities to ensure participant safety, data integrity, and compliance with ICH E6(R3) and UK Clinical Trial Regulations.

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., TMG attendance/minutes, regular communication, receiving monitoring reports, any audit reports and/or safety reports (as required and stipulated in trial specific documents).

4.0 REFERENCES

Referenced Standard Operating Procedures & Policies

SOP001/07 – Cardiff JRO Applying for Sponsorship Low-Med Risk Studies

SOP001/05 - Applying for JRO Sponsorship Higher Risk Studies

SOP009/01 – Research Audit

SOP009/02 – Managing Breaches of GCP or the Study protocol

SOP001/08 – Research Database SOP for Cardiff JRO projects

Referenced Forms & Templates

FRM/002/1 - JRO Sponsorship Request Form

TPL-001-07 JRO Assessment of Laboratory Based Organisations (v1)

TPL-001-06 JRO Assessment of CTU CRO (v1)

TPL-001-08 JRO Assessment of External Vendor (v1)

TPL/001/04 JRO Sponsor Risk Review Template

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 laboratories undertaking Primary, Secondary, Tertiary or 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 also expected to operate in accordance with the principles of GCP. The extent to which formal GCP compliance mechanisms are required should be applied proportionately, based on the laboratory's impact on CtQ factors and as documented within the trial risk assessment. Routine clinical testing with minimal impact on trial endpoints or participant safety may be subject to reduced oversight, whereas laboratories performing activities critical to safety, endpoints, or specialised sample handling shall demonstrate appropriate GCP-compliant processes.
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 trial's 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).