

Document Title: Applying for Cardiff and Vale NHS University Health Board Sponsorship SOP	1 of 13	Approval Date: 02/11/2023
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Reference Number: UHB 453 Version Number: 2	Date of Next Review: 02/11/2026
Applying for Cardiff and Vale University Health Board Sponsorship Standard Operating Procedure	
Introduction and Aim In accordance with the UK Policy Framework for Health and Social Care Research 2017 (UKPF) and The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments 2006, 2008 (The Regulations), all studies must have an identified Sponsor. A Sponsor is an organisation that takes responsibility for the quality and conduct of a research study. The Sponsor must confirm that there are adequate arrangements to initiate, manage, monitor, and finance a study. Prior to accepting the role of Sponsor, Cardiff and Vale University Health Board (CAVUHB) must undertake a risk assessment to ensure that Sponsorship is desirable and acceptable. This SOP will describe the risk assessment process, and the delegation of roles and responsibilities to be assigned where UHB Sponsorship is confirmed.	
Objectives <ul style="list-style-type: none"> To describe a consistent procedure for the review and authorisation of sponsorship for all research using human subjects or their data, for which UHB has been asked to take on the role of 'Sponsor' in order to assist the researcher navigate the process 	
Scope This procedure applies to: <ul style="list-style-type: none"> CAVUHB Chief Investigators, Principal Investigators and research team members planning to undertake C&VUHB Sponsored clinical research CAVUHB R&D Office staff, which are part of the Joint Research Office (JRO). 	
Equality Health Impact Assessment	An Equality Health Impact Assessment has been completed on the Research Governance Policy and Procedure (UHB099) under which this procedure sits.
Documents to read alongside this Procedure	UK Policy Framework for Health and Social Care Research 2017 - https://www.hra.nhs.uk/planning-and-improving-research/policiesstandards-legislation/uk-policy-framework-health-social-careresearch/
Approved by	Joint Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Team
<u>Disclaimer</u>	

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Summary of reviews/amendments			
Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	30/01/2019	07/06/2019	This new procedure replaces the Guideline UHB 214: Applying for Cardiff and Vale NHS University Health Board Sponsorship. Updated to reflect changes to the UK policy and Sponsorship responsibilities.
2	02/11/2023	02/01/2024	This SOP remains valid while a new C&V/CU SOP is being drafted and new processes have been piloted successfully. Minor updates and edits only in this update. Naming convention of CAVUHB R&D office standardised throughout

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1.0 DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
CAV UHB	Cardiff and Vale University Health Board
DMP	Data Management Plan
HCRW	Health and Care Research Wales
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
PI	Principal Investigator
REC	Research Ethics Committee
R&D	Research and Development
MHRA	Medicines and Healthcare Products Regulatory Agency
SAM	Sponsor Assessment Meeting
SAP	Sponsor Assessment Procedure
SOP	Standard Operational Procedure
Sponsor	The individual, company, institution or organisation, which takes on the ultimate responsibility for the initiation, (management or arranging the initiation) of and/or financing (or arranging the financing) for that research
UKPF	UK Policy Framework for Health and Social Care Research 2017

2.0 GENERAL INFORMATION

A Sponsor is an organisation that takes responsibility for the quality and conduct of a research study. Sponsor responsibilities are described in the Regulations and the UKPF. They incorporate the following areas of legal responsibility, which can be delegated as appropriate:

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- Obtaining all appropriate regulatory authorisations and research ethics committee opinion
- Ensuring the study is conducted to appropriate standards, in accordance with legislation, in the best interest of the participants and ensuring data integrity
- Pharmacovigilance and monitoring
- Manufacture and labelling of Investigational Medicinal Products (IMPs)

All studies requiring CAVUHB Sponsorship must be discussed with the CAVUHB R&D Office at the study development, grant application stage. The CAVUHB R&D team will provide guidance regarding the requirements of the Sponsor Assessment Procedure (SAP) in order to facilitate the application. The SAP must be completed and Sponsorship confirmed prior to submitting the research protocol to the relevant authorities (e.g. HRA/HCRW and MHRA).

3.0 WHEN TO REQUEST SPONSORSHIP

Sponsorship of a research study is generally determined by the employment status of the proposed Chief Investigator (CI). Usually sponsorship will be considered for CIs whose primary contract of employment is with CAVUHB.

The CI should liaise with the CAVUHB R&D office as early as possible to discuss the SAP. It is recommended that the CAVUHB R&D office be contacted for initial advice during the study development phase.

Any CAVUHB employee planning to apply for a research grant to fund a study in which he/she would be requesting CAVUHB Sponsorship must contact the CAVUHB R&D office for advice before the grant is costed and submitted.

4.0 SPONSOR ASSESSMENT PROCEDURE

This SOP outlines the two-step process that will be followed when a request for UHB Sponsorship is received.

Step 1: Assessment of Eligibility for Sponsorship

Step 2: Sponsor Risk Assessment at Sponsor Assessment Meeting

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4.1 Step 1: Assessment of Eligibility for Sponsorship

In order to assess eligibility for Sponsorship the CAVUHB R&D Office requires a completed JRO Sponsorship Request Form (FRM/001/13). This should be emailed to research.governance@wales.nhs.uk by the CI or delegate.

The Sponsor Request Form will be reviewed against criteria detailed in **Table 1** below by a member of the CAVUHB R&D office and the JRO R&D Director. If the CI is unsure whether the study meets the criteria for consideration of CAVUHB Sponsorship, it is recommended that the CI contacts the CAVUHB R&D office to discuss, before submitting the Sponsor Request Form.

TABLE 1: Types of studies UHB will/will not consider for Sponsorship

	A. Will consider	B. Will not consider
1	Research where the Chief Investigator holds substantive employment contract with the UHB	Research where the Chief Investigator holds substantive employment contract with an organisation other than UHB
2	Research studies involving C&VUHB patients, staff or data	Phase 1 Clinical Research involving healthy volunteers
3	Research studies conducted within the UK	Research studies conducted outside of the UK
4	Non-commercial research	Commercial contract research
5	Student training studies where the student holds a substantive employment contract with the UHB	Research undertaken as part of an academic qualification, the CI should usually be the academic supervisor and the university at which the student is registered should act as Sponsor
6	Where there is evidence of sufficient funding being secured/applied for to cover all the study costs	Where there is no evidence of sufficient funding being secured/applied for

Only in exceptional circumstances will CAVUHB deviate from the criteria in Column A of Table 1, when considering Sponsorship.

If the research study meets the criteria for consideration of CAVUHB Sponsorship, the application will progress to the next stage, where the planned methodology, intervention, study management and monitoring, the nature of the IMP or device and the scientific integrity of the study will be assessed. Following this, the CAVUHB R&D office will categorise the study according to the perceived risk. It is

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important to note that this categorisation is not based solely on the clinical risks of the study. CTIMPs and Clinical Device trials will always be considered high risk, due to the enhanced Sponsor responsibilities in the applicable legislation, and the increased risk to the Organisation.

Outcomes following STEP 1:

There are two possible outcomes:

- The study is not suitable to be considered for CAVUHB Sponsorship.
This decision and reasons will be communicated to CI and relevant parties.
- The study is acceptable for consideration of CAVUHB Sponsorship
The outcome will be communicated and the next steps, including timelines for submission of the required documentation will be provided. If adequate funding has not been secured, the CAVUHB R&D office may be able to signpost the CI to further resources in order that the CI may ensure the research costs have been attributed correctly.

The CAVUH R&D office will highlight any issues that must be considered and addressed to mitigate potential risk. These issues should be addressed prior to proceeding to the full risk assessment and Sponsor Assessment Meeting (SAM).

4.2 STEP 2: Sponsor Risk Assessment

Invitation to proceed to full risk assessment does not constitute agreement to Sponsor; agreement to Sponsor can only be confirmed once a full risk assessment has been undertaken as outlined in the next section of this SOP.

For high risk studies adequate funding should be secured and adequate involvement of a Clinical Trials Unit (CTU) should be agreed before a Sponsor Assessment Meeting (SAM) takes place. Studies classified as high risk will require the CI and research team to complete a Risk Assessment Form (FRM/001/05) in order to determine and identify risks and provide mitigation strategies to manage the risks.

For studies deemed low risk the completion of the Risk Assessment Form FRM/001/05 is not required. However, a study risk assessment will be undertaken as part of SAM and documented in the SAM Review Template FRM/001/10.

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5. SPONSOR ASSESSMENT MEETING

The purpose of the SAM is so that the SAM panel can assess the proposed study and associated documentation to determine whether the study is needed, ethical, statistically sound, well designed and any identified potential clinical, legal, financial or reputational risks to the participants, research staff and organisation have been sufficiently mitigated. They will also determine whether they are satisfied that the research study has had adequate science review.

Based on the documentation provided, the SAM panel will carry out the risk assessment review. This includes a review of the following non-exhaustive list:

- CAVUHB can accept the role of Sponsor
- CI suitability to lead the research
- Study research costs and evidence of funding
- Arrangements for meeting excess treatment costs
- Portfolio eligibility or other arrangements for covering support costs
- Peer review including suitability of study design
- Feasibility to undertake the study at UHB and/or other trial sites
- Compliance with required regulatory standards
- Contractual requirements
- Arrangements for managing study data and documentation, including a Data Management Plan
- The joint arrangements for managing the study with the respective CTU are satisfactory (where CTU is required)
- The risks associated with the trial have been identified and appropriately mitigated (in the RAF for CTIMP and high-risk studies, in the SAM Review Template for all other studies).

Where required, the panel may request further information to facilitate the full review and researchers may be invited to attend meetings with members of the SAM panel to discuss, prior to the SAM.

5.1 Sponsor Assessment Meeting Panel

Membership:

JRO Director

CAVUHB R&D Contracts Representative (as required)

Data Protection Officer (as required)

CAVUHB Research Governance Team member

Relevant statistician* (as required)

Clinical Trials Pharmacist (if CTIMP or IMP involved)

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CRF Medical Lead/Assistant R&D Director and or CRF Nurse (if CRF to be used for study)
Other support department (as required) *

Note: Where additional expertise is required, an internal or external reviewer may be co-opted.

**Not all studies will require independent statistical input therefore statistical expertise will be co-opted as required.*

Attendants listed below may be invited to the second part of the meeting to address comments and queries raised by the panel if required.

- Chief Investigator
- CTU Representative

Additionally, the meeting will not take place without the minimum representation of the following members:

- JRO Director
- CAVUHB Research Governance Team (RGT) member

5.2 Documentation required for SAM

All changes requested in the previous stages of assessment should be incorporated and documentation must be in **'final'** draft version, before being forwarded to the CAVUHB R&D Office for SAM panel review. The SAM panel review will not take place if the CI has not submitted final draft documents.

Timelines for submission of required documentation should be agreed with the CAVUHB R&D office after the study has been deemed eligible for consideration for CAVUHB Sponsorship. However, documentation for High Risk studies should be submitted to the CAVUHB R&D office at least two weeks before the SAM, in order for the SAM panel of reviewers to complete a full review, prior to the SAM.

As a minimum, the following documents are needed to undertake the review.

- Completed JRO Sponsor Request Form
- Protocol
- Participant information sheet
- Informed consent form
- Pre-Data Privacy Impact Assessment- (Pre DPIA) (as required by UHB Information Governance)
- Cardiff Risk Assessment Form (CTIMPS & other studies as required)
- Any other documentation which the R&D team deems necessary

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5.3 Sponsorship Decision Outcomes

There are three possible decision outcomes from the meeting:

- Acceptance in principle of CAVUHB Sponsorship
Acceptance in principle is not permission to commence the study, but permission to progress to the next stage of seeking necessary Approvals.
- Provisional acceptance in principle, pending the satisfactory resolution of identified issues
- Rejected with comments
If the changes required to approve sponsorship are deemed too numerous or require re-application. CAVUHB reserves the right to refuse sponsorship if the research study cannot be adequately supported or it does not meet relevant regulatory requirements. Feedback of the reasons for the rejection will be given.

5.4 Actions Following SAM

The SAM Review Template will be completed by the CAVUHB R&D office based on the risk review of all the study documents reviewed and, on the comments, and responses discussed at the meeting. The CAVUHB R&D office on behalf of the SAM panel and JRO Director will e-mail the CI stating the outcome of the meeting and provide advice on next steps.

Once any actions arising from the meeting have been completed by the CI and deemed satisfactory by the SAM panel members, the JRO Director on behalf of the CAVUHB R&D office may be able to agree Sponsorship in principle, on behalf of the SAM panel, or it may be decided that a further SAM meeting is required.

Where Sponsorship in principle is given, the decision will be communicated to the CI in an e-mail detailing the UHB Terms & Conditions of Sponsorship. The Terms & Conditions of Sponsorship TPL/002/01 will be attached to the email, and must be signed and returned by the CI to research.governance@wales.nhs.uk. The CI will be emailed a link to UHBs suite of SOPs which must be followed throughout study delivery.

In the event that a study is deemed ineligible to proceed to submission in IRAS, the CAVUHB R&D office will communicate this decision to both the CI and the CAVUHB R&D Office to ensure that the study documentation and status is recorded. The CAVUHB R&D office will then work with the CI and research team to enable them to address any issues raised at the meeting and discuss re-submission for SAM review.

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If the outcome is to reject Sponsorship and the study is to be 'withdrawn', the RGT will inform the CI and ensure CAVUHB R&D records are updated accordingly.

6.0 POST SPONSORSHIP IN PRINCIPLE DECISION

A number of responsibilities are delegated to the CI (and PIs) of study sites as documented in a Delegation of Responsibilities Template TPL/003/08. Where a different delegation of Sponsor responsibilities has been reviewed and agreed during contractual negotiations that delegation will take precedent over the delegation outlined in TPL/003/08. This will be detailed in a collaboration agreement or similar.

All delegated responsibilities must be recorded in a Study Delegation Log and stored in the Trial Master File/Investigator Site File.

6.1 Sponsor Authorisation via IRAS

Following a successful SAM and after completion of all arising actions from the meeting the CI must complete and sign a HRA/HCRW Checklist for CAVUHB Sponsored Research (FRM/001/12). This provides assurance that the study is ready for regulatory submission. The CI should return the signed form to the CAVUHB R&D Office, via research.governance@wales.nhs.uk

Once the signed HRA/HCRW Checklist has been received and reviewed by the CAVUHB R&D office, and the study is deemed ready for regulatory submission. The CAVUHB R&D office will e-mail the CI to inform them that they may proceed to submission. The R&D team will review the submission in IRAS and provide Sponsor authorisation. This will enable the CI to submit to the relevant regulatory authorities and REC/HCRW/HRA.

Please note: If amendments to the study or study documentation are required, following review by any of the relevant authorities, the CAVUHB R&D office will liaise with the CI and other relevant research team members, in order to discuss and review the required changes. This review will determine whether these changes would necessitate a further SAM or whether they can be approved by the JRO Director in his capacity as Chair. The CAVUHB R&D office will document the outcome.

Following regulatory submission, the SOP UHB 448: Obtaining Capacity & Capability Confirmation for Research to Start should be followed in order to formally Assess, Arrange and Confirm Capacity and Capability (C&C).

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6.2 Sponsor Green Light

For CAVUHB Sponsored CTIMPS/Complex studies, CAVUHB R&D office must also issue Sponsor green light for each participating site (including C&V) prior to that site opening to recruitment. The Sponsor may delegate this role to a CTU. CAVUHB R&D office (or delegate) will require that a set of core documentation be received from each site in order to issue Sponsorship green light.

Throughout the life cycle of CAVUHB Sponsored studies consideration will be given to whether any amendments to the study would necessitate the need to review the original risks and update the RAF (where used) or for a further SAM. Confirmation of ongoing Capacity and Capability will also be considered. The CI and research team should ensure that the study specific RAF (where used) is reviewed updated and submitted to CAVUHB R&D office taking into consideration proposed changes to the study.

7.0 RIGHT TO WITHDRAW SPONSORSHIP

In line with its responsibilities as a recognised Sponsor of research, CAVUHB may withdraw Sponsorship of a study where it is considered that there has been a breach of the UHB Terms & Conditions of Sponsorship or if during the study, it becomes apparent that there are issues which have significant safety, legal, regulatory, financial or reputational consequences.

8.0 ASSOCIATED DOCUMENTATION

FRM/001/05 Cardiff Risk Assessment Form (RAF) for CTIMPs

FRM/001/13 JRO Sponsorship Request Form

FRM/001/10 SAM Review Template

FRM/001/11 Setting up new studies where C&V are the Sponsor

FRM/001/12 HRA HCRW Checklist

TPL/001/01 Non CTIMP Protocol template for C&V UHB Sponsored Studies

TPL/003/08 Delegation of Responsibilities Template

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TPL/002/01 Terms and Conditions of Sponsorship

SOP/001/03 Capacity and Capability SOP (UHB 448)

Appendix 1: Sponsorship SOP Flow chart

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