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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 (C&VUHB) 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

- 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:

- C&VUHB Chief Investigators, Principal Investigators and research team members planning to undertake C&VUHB Sponsored clinical research
- R&D Office staff

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/policies-standards-legislation/uk-policy-framework-health-social-care-research/
Approved by	Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Coordinator

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	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.

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1.0 DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
C&V 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:

- 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 UHB Sponsorship must be discussed with the R&D Office at the study development, grant application stage. The 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 C&VUHB.

The CI should liaise with the R&D team as early as possible to discuss the Sponsor Assessment Procedure (SAP). It is recommended that the R&D team be contacted for initial advice during the study development phase.

Any UHB employee planning to apply for a research grant to fund a study in which he/she would be requesting C&VUHB Sponsorship must contact the 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

4.1 Step 1: Assessment of Eligibility for Sponsorship

In order to assess eligibility for Sponsorship the R&D Office requires a completed **Sponsor Request Form (FR-RG-016).** 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 R&D team and the R&D Director. If the CI is unsure whether the study meets the criteria for consideration of C&VUHB Sponsorship, it is recommended that the CI contacts R&D 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 C&VUHB deviate from the criteria in Column A of Table 1, when considering Sponsorship.

If the research study meets the criteria for consideration of C&VUHB 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 R&D office will categorise the study according to the perceived risk. It is 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 UHB Sponsorship.
  This decision and reasons will be communicated to CI and relevant parties.
- The study is acceptable for consideration of UHB 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 R&D team 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 R&D team 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 (FO-RG-001) 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 FR-RG-001 is not required. However, a study risk assessment will be undertaken as part of SAM and documented in the SAM Review Template FR-RG-017.

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:

- The UHB 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:
R&D Director
R&D Contracts Representative (as required)
Data Protection Officer (virtual member)
Research Governance Team member
Relevant statistician*
Clinical Trials Pharmacist (if CTIMP or IMP involved)
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.

- Chief Investigator
- CTU Representative

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

- R&D Director
- 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 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 RGT after the study has been deemed eligible for consideration for UHB Sponsorship. However, documentation for High Risk studies must be submitted to the R&D team at least four 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 Sponsor Request Form
- Protocol
- Participant information sheet
- Informed consent form
- Privacy Impact Assessment (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

5.3 Sponsorship Decision Outcomes

There are three possible decision outcomes from the meeting:

- Acceptance in principle of UHB 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. C&VUHB 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 RGT based on the risk review of all the study documents reviewed and on the comments and responses discussed at the meeting. The RGT on behalf of the SAM panel and R&D 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 R&D Director on behalf of the UHB 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 TR-RG-018 will be attached to the email, and must be signed and returned by the CI to research.governance@wales.nhs.uk. When issued with a Sponsorship in principle decision, 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 RGT will communicate this decision to both the CI and the R&D Office to ensure that the study documentation and status is recorded. The RGT 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.

If the outcome is to reject Sponsorship and the study is to be ‘withdrawn’, the RGT will inform the CI and ensure 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 the Delegation of Responsibilities Template TR-RG-019. Where a different delegation of Sponsor responsibilities has been reviewed and agreed at SAM that delegation will take precedent over the delegation outlined in TR-RG-019. 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 C&VUHB Sponsored Research (FR-RG-020). This provides assurance that the study is ready for regulatory submission. The CI should return the signed form to the R&D Office, via research.governance@wales.nhs.uk

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

Please note: If amendments to the study or study documentation are required, following review by any of the relevant authorities, the R&D team 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 R&D Director in his capacity as Chair. The RGT 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).

6.2 Sponsor Green Light

For UHB Sponsored CTIMPS, R&D must also issue Sponsor green light for each participating site (including C&V) prior to that site opening to recruitment. R&D 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 C&V UHB 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 R&D 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, C&V UHB 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

FO-RG-001 Cardiff Risk Assessment Form (RAF) for CTIMPs

FR-RG-016 Sponsor Request Form

FR-RG-017 SAM Review Template

FR-RG-019 Setting up new studies where C&V are the Sponsor

FR-RG-020 HRA HCRW Checklist

TR-RG-016 Non CTIMP Protocol template for C&V UHB Sponsored Studies

TR-RG-019 Delegation of Responsibilities Template

TR-RG-018 Terms and Conditions of Sponsorship

SR-RP-011 Capacity and Capability SOP (UHB 448)

Appendix 1: Sponsorship Flow Chart