Reference Number: UHB 214 **Version Number:** 2	**Date of Next Review:** 25 Apr 2020 **R&D Ref GR-RG-008**

Applying for Cardiff and Vale NHS University Health Board Sponsorship Guideline

Introduction and Aim

In accordance with the Research Governance Framework for Health and Social Care and the Clinical Trials Regulations, all studies must have a Sponsor identified. The Sponsor is responsible for confirming that there are proper arrangements to initiate, manage, monitor, and finance a study. In order to decide whether Cardiff and Vale University Health Board (UHB) is able to agree to the role of Sponsor and fulfil its responsibilities, a robust assessment process is required. For studies which are deemed 'low risk' (e.g. non-interventional studies) the routine governance checks will be carried out by the Cardiff and Vale Research Review Service (CaRRS). However for 'high risk' studies, a more rigorous process is required. This is known as the Sponsor Assessment Process (SAP) and the purpose of this document is to describe this process.

For the purpose of this document, 'high risk' studies include all Clinical Trials of Investigational Medicinal Products (CTIMPs) as well as complex interventional, complex surgical and complex device trials. A 'high risk' study does not refer to the clinical risk for the patients but to the risk of the UHB agreeing to take on the role of Sponsor.

The SAP will not replace scientific review – prior to a physical Sponsor Assessment Meeting (SAM) studies should have a science review either through C&V science review process or evidence of adequate science/peer review.

No CTIMP or high risk study will be presented to SAP without having a Clinical Trial Unit (CTU) involved.

Objectives

To describe the process for reviewing high risk studies in order to mitigate risk and form a view on whether the UHB is able to act as Sponsor.

Scope

This guideline applies to UHB Chief Investigators and research teams planning to undertake a UHB Sponsored Clinical Trial of Investigational Medicinal Products (CTIMP) as well as UHB Sponsored complex interventional, complex surgical and complex device trials.

Equality Impact Assessment	An Equality Impact Assessment has been completed on the Research Governance Policy (UHB099) under which this Guideline sits.

Health Impact Assessment	A Health Impact Assessment is not required for this Guideline.
Documents to read alongside this Guideline	Essentials to think about before applying for R&D approval (ISR-RP-001) Cardiff and Vale University Health Board Position Statement on Sponsorship of Research Studies (ISR-RG-012). Sponsor Request Form (FR-RG-016) FO-RG-001 Cardiff Risk Assessment Form (RAF) for CTIMP
Groups Consulted	Research Governance Group
Outcome of Consultation	Approved
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance Coordinator

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	21/01/2014	25/03/2014	New document
2	25/04/2017	06/09/2017	This document was due for 3 year review and Cardiff University have opted to devise a similar process internally therefore a joint process is no longer required. The amended document has been placed in the UHB format for controlled documents. The Sponsor Assessment Meeting membership has undergone revisions and the process and wording has been revised throughout, removing reference to Cardiff University.

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1.0 GENERAL INFORMATION

All research conducted in the NHS must have a Sponsor. For CTIMPs this is a requirement of the Medicines for Human Use (Clinical Trials) Regulations. A Sponsor is an organisation that takes responsibility for the quality and conduct of a research study. The responsibilities of a Sponsor are described in the Regulations. They incorporate the following areas of legal responsibility, which can be delegated as appropriate:

- Authorisation for clinical trials and research ethics committee opinion
- Good Clinical Practice and the conduct of the study
- Pharmacovigilance
- Manufacture and labelling of Investigational Medicinal Products (IMPs)

The Research Governance Team (RGT) will advise researchers regarding the process for obtaining sponsorship, plan feasibility meetings and forward necessary documentation to researchers to facilitate an application for Sponsorship of a high risk study.

2.0 SPONSOR ASSESSMENT PROCESS

The SAP will involve communications between a member of the RGT and the researchers in the first instance. (Please see Appendix 2 SAP Flow chart). Early meetings and discussions are essential to gaining further information regarding the planned intervention, the nature of the study, any IMP involved and funding plans for the study.

Stage 1:

Researchers must inform the R&D Office as early as possible to enable feasibility discussions, dissemination of essential documentation and to gain support and advice.

Where a C&V employee is making a grant application for external funding to conduct a non-commercial CTIMP or a high risk surgical, interventional or device study, the UHB employee must contact the R&D office. This allows the R&D Office to ensure that the grant application includes adequate resources for fulfilling Sponsor responsibilities, inclusive of reviewing proposed CTU involvement where relevant.

Essentials to think about before applying for R&D approval (ISR-RP-001) and **Cardiff and Vale University Health Board Position Statement on Sponsorship of Research Studies** (ISR-RG-012) should be read by researchers requesting C&V to take on the role of Sponsor for a high risk study.
If researchers are requesting C&V to sponsor the study then a **Sponsor Request Form (FR-RG-016)** should be completed and forwarded to the generic Research Governance inbox research.governance@wales.nhs.uk.

The Sponsor Request Form for a new enquiry will be reviewed by the RGT and R&D Director. The initial discussions will explore whether the proposed study meets the criteria laid out in the C&V Position Statement on Sponsorship and whether sufficient funding has been obtained/will be applied for to manage the study.

Stage 1 Outcome:

- The study is not suitable for sponsorship - decision and reasons communicated to CI
- The study is suitable - the outcome will be communicated to the CI. RGT will highlight any considerations that must be addressed to mitigate potential risk. It is recommended that these considerations are addressed prior to proceeding to the physical Sponsor Assessment Meeting (SAM).

3.0 SPONSOR ASSESSMENT MEETING

Stage 2:

When study feasibility has progressed, adequate resources identified and funding secured, the researcher will be informed that the study may now progress towards a physical review meeting or SAM. The RGT will organise the SAM including dissemination of all paperwork and confirmation of the venue.

Throughout the process the RGT will review study documentation and provide advice to CI and team as to the readiness of the study for a physical SAM. All study documentation, including the proposed roles and responsibilities of the various parties, including the CTU, must have undergone all external reviews and changes and be in **'final**' draft - before being forwarded to the R&D Office for SAM panel review, prior to the study being accepted for SAM. The physical SAM will not take place if the CI has not submitted final draft documents for review.

For high risk studies the CI will need to have secured adequate funding and adequate involvement of a CTU before review at the physical SAM.

Once a SAM date has been set the final draft documents need to be submitted to the generic Research Governance inbox research.governance@wales.nhs.uk.
The study documents need to be submitted by the CI to RGT **four weeks** prior to the physical SAM. This will allow time for the SAM panel to undertake a review prior to the meeting.

The purpose of the physical SAM is to enable a decision on whether:

- C&V can accept the role of Sponsor
- The study can be submitted for Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA) approval as appropriate

- The study can be submitted to the Health and Care Research Wales Permissions Service
- The joint arrangements for managing the study with the respective CTU are satisfactory
- The risks associated with the trial have been identified and appropriately mitigated in the RAF
- The study specific RAF can be signed off
- The resources required to undertake the study have been identified

3.1 Sponsor Assessment Meeting Membership:

R&D Director
R&D Contracts Representative
Data Protection Officer (will be a virtual member)
Research Governance Coordinator
Relevant statistician*
Clinical Trials Pharmacist
CRF Medical Lead/Assistant R&D Director and or CRF
Nurse (if CRF to be used for study)

**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 will be invited to the second part of the meeting to address comments and queries raised by the SAM members.

Chief Investigator (CI)
CTU Representative

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

- R&D Director
- Clinical Trials Pharmacist (for CTIMP trials)
- Research Governance Team (RGT) responsible for the study under review

The date, time and venue for the physical monthly SAM will be set annually by the UHB R&D Office and disseminated to SAM members accordingly. No more than one study will be reviewed at a physical SAM.

Documents required for SAM are:

- Completed Sponsor Request Form which must have been signed by the relevant Directorate R&D Lead.
- RAF (latest version) which has been preliminarily completed by the CI and CTU

- Protocol (final draft)
- Final draft Patient Information Sheet / Informed Consent Form/s and other documents as relevant to the study
- Draft contract templates and/or roles and responsibilities template

At the physical meeting panel members should undertake the following:

- Discuss the comments received and ask the CI to clarify during the second half of the meeting
- Confirm that the protocol has been reviewed
- Confirm that the specific risks/hazards of the study have been identified
- Confirm that the management strategies detailed in the RAF for reducing the risks/hazard are adequate
- Confirm that the benefits outweigh the risks, bearing in mind that there may be no direct benefit for participants
- R&D Director agree and signs the RAF, if satisfactory
- Make recommendations in regard to the proposed monitoring plan
- Make a recommendation on the acceptance of Sponsorship

4.0 SPONSORSHIP DECISION OUTCOMES:

- Accept Sponsorship in principle
- Accept Sponsorship in principle - subject to the actions following the SAM being completed in full. By agreeing to sponsorship in principle the UHB is **not** giving permission for the study to commence. Sponsorship in principle is conditional on all relevant approvals being in place.
- Reject Sponsorship

The SAM Review Template will be completed by the RGT based on the comments and responses discussed at the meeting and forwarded to the CI and research team for action. The RGT on behalf of the R&D Director will e-mail the CI stating the outcome of the meeting and provide the completed SAM Review Template.

A Sponsorship in Principle e-mail detailing the UHB Terms & Conditions of Sponsorship will be sent to the CI. Appendix 1 the Chief Investigator Declaration Form will be enclosed. The form must be signed and returned by the CI to the generic Research Governance inbox research.governance@wales.nhs.uk.

In the event that a study is deemed ineligible to proceed for REC/MHRA approval, 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 team to address any issues raised at the meeting to enable re-submission (where appropriate).

If the SAM 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.

After completion of all arising actions from the meeting, the R&D Director on behalf of the UHB acting as Sponsor should be in a position to sign off the RAF.

5.0 POST SPONSORSHIP IN PRINCIPLE DECISION

On receipt of a signed Chief Investigator Declaration Form returned by the CI to the generic Research Governance inbox (research.governance@wales.nhs.uk), the RGT will notify the Research & Permissions (R&P) managers of the Sponsorship in Principle decision and whether independent favourable science review has already been carried out.

The R&P managers will then liaise with the research team to obtain the necessary documentation and undertake the appropriate science/pre-submission governance reviews. If CaRRS science review is required, this will be done first. Once favourable science review is in place, pre-submission governance review of IRAS forms and associated documentation will be done.

Once the content of the application and documents is agreed, the IRAS sponsor's representative authorisation will be provided. This will enable the CI to submit to the relevant regulatory authorities and Health and Care Research Wales Permissions Service.

Following submission for regulatory approvals if further changes are requested by the MHRA or REC, the RGT will review the changes with the CI and CTU. This review will determine whether the requested changes necessitate a further physical SAM or whether the changes can be approved by the R&D Director providing chairs action. The RGT will document the outcome and ensure that any changes to documentation are considered by all relevant parties.

Once the study is submitted to Health and Care Research Wales Permissions Service and received by the R&D Office from Health and Care Research Wales, the study will undergo governance review by CaRRS.

Throughout the life cycle of a C&V Sponsored CTIMP study which necessitated a review via SAP, consideration will be taken as to whether any amendments to the study would necessitate the need to review the RAF. The CI and research team will ensure that the study specific RAF is reviewed updated and submitted to R&D taking into consideration proposed changes to the study.

6.0 ASSOCIATED DOCUMENTATION

FR-RG-016 Sponsor Request Form

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

FR-RG-017 SAM Review Template

TR-RG-015 Template Monitoring Plan produced by Wales Cancer Trials Unit and adopted by the UHB for use in UHB Sponsored trials

Up to date versions of the following documents are available on request from the R&D office or on the R&D web pages.

Appendix 1

Chief Investigator Declaration Form

Sponsorship is subject to the following provisions:

- The Chief Investigator has overall responsibility for ensuring that the study is conducted in accordance with all applicable regulations and in accordance with UHB policies and SOPs.

- The Chief Investigator must agree to the UHB Terms & Conditions of Sponsorship as detailed in the Sponsorship Decision E-mail.

- The Chief Investigator is accountable to the Sponsor.

- Sponsorship may be withdrawn where the Chief Investigator fails to comply with the UHB Terms & Conditions of Sponsorship.

If you agree to the above, please sign and return this Declaration form. Alternatively, please return the form via email, confirming that you accept the following terms (this must be sent from your professional email account).

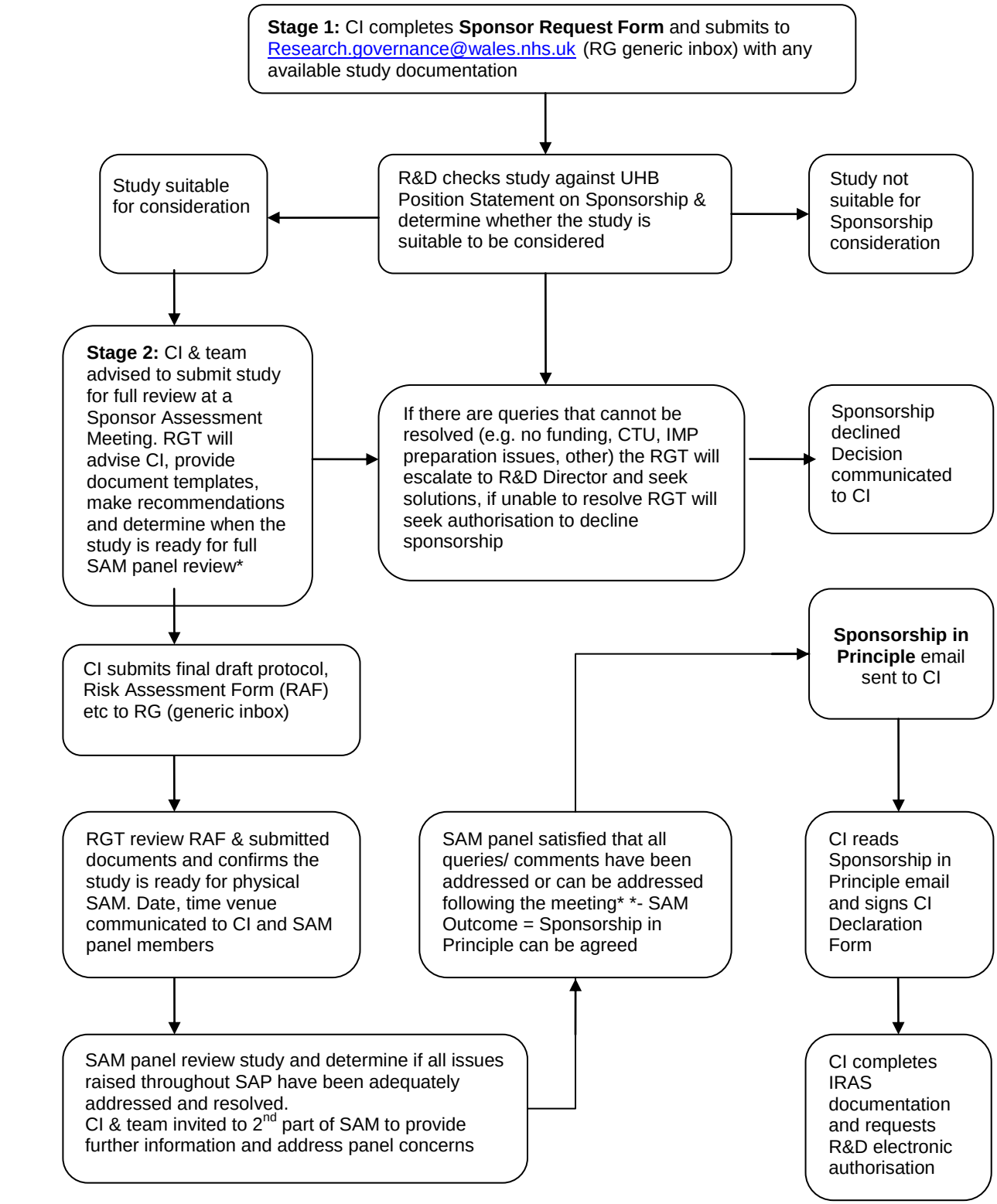
Declaration: I have read and agree to Cardiff and Vale UHBs Terms & Conditions of Sponsorship. I agree to ensure that the study is conducted in accordance with all applicable regulations and in accordance with the UHB SOPs available on the R&D webpages.

Investigator Name: _____

Chief Investigator Signature: _____

Date: _____

Appendix 2 SAP Flow chart



**** The RGT will review earlier drafts of the study paperwork to identify/ suggest necessary alterations and to determine readiness for physical meeting> Contacting the R&D office early is essential to allow time for these reviews. Final draft documents will be circulated to panel members before the SAM date.***
*****If satisfactory resolution cannot be reached following a full SAM review ,RGT will escalate to R&D Director who will determine whether sponsorship is to be declined.***