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Cardiff Joint Research Office (JRO) Applying for Sponsorship- Low and Medium Risk Studies Standard Operating Procedure (SOP)

Introduction and Aim

In accordance with the UK Policy Framework for Health and Social Care Research (UKPF) and The Medicines for Human Use (Clinical Trials) Regulations 2004 (The Regulations), as amended, all health and social care research studies must have an identified Sponsor. In accordance with the UKPF, the Sponsor "…is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project." 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) or Cardiff University (CU) must undertake a risk assessment to ensure that Sponsorship conditions are met. This SOP describes the process for applying for Sponsorship from CAVUHB or CU, via the Cardiff Joint Research Office (JRO). The Sponsorship application and review process is overseen by the JRO Research Governance Team.

Objectives

To explain the JRO research governance Sponsorship application process for clinical research projects:

- led by CAVUHB or CU which **are not** categorised as Clinical Trials of Investigational Medicinal Products (CTIMPs), Clinical Trials of Medical Devices or which are otherwise deemed as high risk by the JRO;
- and for which CAVUHB or CU have been approached to take on the role of Sponsor.

Scope

This SOP applies to:

- Non-commercial health and social care research (also known as clinical research) falling under the scope of the UKPF, i.e. that which includes the following:
  - NHS patients and/or social care service users;
  - Relatives and/or carers of NHS patients;
  - Healthy volunteers identified through the NHS;
  - NHS staff recruited in their NHS place of work;
  - Human tissue and DNA classed as relevant material under the Human Tissue Act;
  - NHS data;
  - NHS premises and/or equipment

- studies involving ionising radiation
- studies involving adults who lack capacity to consent for themselves.

For which a Sponsor is required and which:

- is to be led by employees of CAVUHB or CU;
- is to be conducted by CU postgraduate students for the purposes of an educational qualification to be awarded by CU and for which a CU staff member has been appointed as the Chief Investigator;
- meets the definition of research in accordance with the UKPF, that is a study which:

  "…attempt(s) to derive generalisable or transferable…new knowledge to answer or refine relevant questions with scientifically sound methods." (Section 3.1, UKPF, as amended).

This SOP does **not** apply to the following categories of activity:

- work which is wholly categorised as Public and Patient Involvement (PPI);
- projects meeting the criteria for service evaluation, audit or quality improvement which should be referred to the appropriate CAVUHB department;
- commercially Sponsored research.

Projects meeting the criteria for service evaluation, audit or quality improvement and which are led by CAVUHB employees, should refer to the CAVUHB Service Evaluation Guidelines (ref: UHB 116) and liaise with the CAVUHB Quality Improvement department.

Where the categorisation of a project is not clear, staff may consult the HRA's 'Defining Research' table, use the HRA's 'Is my study research?' decision tool, or request an Early Project Review meeting via the JRO (refer to section 3.2 of this SOP).

- **This SOP does not apply to the process for the Sponsorship of Clinical Trials of Investigational Medicinal Produces (CTIMPs), Clinical Trials of Medical Devices or studies deemed to present a higher level of risk (as confirmed by the JRO). Researchers seeking Sponsorship of these categories of studies should consult the JRO SOP for *Applying for Sponsorship of Higher Risk Studies (including Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Trials of Medical Devices (Medical Device Trials))* [SOP-001-05]**

Responsible Personnel:
All Chief Investigators (CIs), Principal Investigators and Research Team members (including postgraduate student researchers) from both CAVUHB and CU, who are working on a CAVUHB or CU Sponsored study, or who are planning to conduct a Sponsored study are required to read and familiarise themselves with this SOP.

A CI must be appointed for all studies to be Sponsored by CAVUHB or CU.

Throughout this SOP, the term 'CI' is used to refer to the individual leading the specific study (normally the individual who is responsible for designing the study protocol and/or the named lead grant recipient, in the case of funded studies). The CI may delegate their duties as appropriate to other suitably qualified members of the study team (e.g. Clinical Research Fellows, NHS Principal Investigators, Research Associates, Trial Managers, Statisticians, Technicians and postgraduate research students). However, the CI is considered by the JRO to hold overall responsibility for the design, conduct and management for the study and must hold a contract of employment with either CU or CAVUHB.

In the case of studies conducted for the purpose of an academic qualification, students cannot take on the role of CI. For student projects, the lead Academic Supervisor is normally appointed as the CI.

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 Cardiff Joint Research Governance Group (JRGG) is responsible for approving the SOP.

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-researchliciesstandards-legislation/uk-policy-framework-health-social-careresearch/
Approved by	Joint Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	JRO Research Governance Team

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	16/07/2024	This new procedure will sit alongside UHB 214: Applying for Cardiff and Vale NHS University Health Board Sponsorship, which will remain in place for CAVUHB Sponsored CTIMP Sponsorship set up. This procedure reflects the formation of the JRO and the alignment of the Sponsorship risk assessment process for both CAVUHB and Cardiff University for setting up non-CTIMP studies.
2.0	30.01.2025	08.05.2025	The title of the SOP has changed from *Applying for Sponsorship- non-CTIMPs* to *Applying for Sponsorship-* ***Low and Medium Risk Studies*** Clarification added to the 'Scope' section of the SOP (p.2) with a reference to the Higher Risk-CTIMPs SOP Section 3.1.1 (*Procedure for studies applying for funding)-* removal of the JRO Costing Model table (Table 1- p.8) and references to this. Green light section 5.3 has been updated to reflect the new green light process.

Contents

1.0 DEFINITIONS/ABBREVIATIONS

ARSAC	Administration of Radioactive Substances Advisory Committee
C&C	Capacity and Capability
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
CAVUHB	Cardiff and Vale University Health Board
CU	Cardiff University
DMP	Data Management Plan
EPR	Early Project Review
HCRW	Health and Care Research Wales
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
JRO	Joint Research Office
MHRA	Medicines and Healthcare Products Regulatory Agency
OID	Organisation Information Document
PI	Principal Investigator

QMG	Quality Management Group
RAF	Risk Assessment Framework
REC	Research Ethics Committee
R&D	Research and Development
SAM	Sponsor Assessment Meeting
SAP	Sponsor Assessment Process
SOP	Standard Operational Procedure
SoE	Schedule of Events
SoECAT	Schedule of Events Cost Attribution Template
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 (as amended)

2.0 GENERAL INFORMATION

All health and social care research requires a Sponsor. In the context of research governance, the Sponsor is an organisation, individual or partnership that takes responsibility for the quality and conduct of a research study. In accordance with the Regulations and the UKPF (as amended), the Sponsor is responsible for the initiation, management and financing (or arranging the financing) of a health and/or social care research study and has specific responsibility for the following areas:

i. identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols;
ii. satisfying itself that the investigators, research team and research sites are suitable;
iii. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;
iv. ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project;
v. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (where appropriate);
vi. agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished;
vii. ensuring arrangements for information about the findings of the research are made available;

viii. ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;
ix. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;
x. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;
xi. ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, Pharmacovigilance and safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments;
xii. the manufacture and labelling of Investigational Medicinal Products (IMPs), where applicable

Sponsor responsibilities may be delegated as appropriate.

All health and social care research requiring CAVUHB or CU Sponsorship must be discussed with the Cardiff JRO at the study development or grant application stage. The CI (or their delegate) should arrange an Early Project Review (EPR) Meeting with the JRO during the study design or grant application phase.

The JRO Research Governance Team will provide guidance regarding the requirements of the Sponsor Assessment Process (SAP) in order to facilitate the application. The SAP must be completed and Sponsorship in Principle confirmed prior to the CI submitting the study to the relevant approval bodies and regulatory authorities (where relevant) (e.g. HRA/HCRW, NHS RECs and other bodies as appropriate, such as the Confidentiality Advisory Group (CAG)).

3.0 PROCEDURES

3.1 WHEN TO REQUEST SPONSORSHIP

Sponsorship of a research study is normally determined by the employment status of the proposed Chief Investigator (CI) and/or the organisation leading on the grant application. Usually, Sponsorship will be considered for CIs whose primary contract of employment is with CAVUHB or CU.

It is recommended that the CI or study lead contacts the JRO Research Governance Team for initial advice during the study development or grant application phase. The contact details for the relevant CAVUHB/CU team are:

Proposed Sponsor organisation	Contact email address
Cardiff and Vale UHB	research.governance@wales.nhs.uk
Cardiff University	resgov@cardiff.ac.uk

3.1.1 Procedure for studies applying for funding

In the case of funded studies, the CI should liaise with the JRO Research Governance Team as early as possible to discuss the Sponsor Assessment Procedure (SAP) and to arrange a JRO EPR meeting.

Any CAVUHB or CU employee planning to apply for a research grant to fund a study for which Sponsorship may be required, should arrange an EPR meeting prior to submitting the grant application (see point 3.2 of this SOP).

Where a study meets the JRO criteria for moderate or higher-level additional contracts and research governance support, the CI may be asked to cost in additional staff costs to cover contracts and research governance resource. This will be discussed during the EPR meeting. Requirements for additional JRO support is determined based on the JRO Costing Model (available upon request). A further follow-up meeting should then be arranged if the funding application is successful, or reaches the second round.

A further follow-up meeting should then be arranged if the funding application is successful, or reaches the second round.

The following Pre-Awards teams should be contacted for assistance with costing a grant application involving NHS sites:

Employing organisation of the CI	Pre-Awards Team Contact	Email address
CAVUHB	CAVUHB Grants Team	Research.GrantSupport@wales.nhs.uk
CU	School of Medicine Research Office (for staff in MEDIC, HCARE and DENTL) Researchers from other CU academic schools should	Somres@cardiff.ac.uk

	contact their Research Office Central CU Pre-Awards	

3.1.2 Procedure for unfunded studies

Researchers applying for Sponsorship of studies without funding (or which do not require funding), should arrange an EPR meeting (refer to section 3.2 of this SOP) as early on in the study design process as is practical.

Not all studies will require an EPR meeting and this will be confirmed by the JRO Research Governance Team.

3.2 Arranging an EPR meeting

The EPR meeting is the first stage in the Sponsorship application process. Studies led by either CAVUHB or CU are required to arrange an EPR meeting with the JRO. CIs (or their delegates) should request an EPR meeting through the JRO website (New Study - Cardiff Joint Research Office (cardiffjro.com)).

The purpose of the EPR meeting is to confirm the following:

i. the categorisation of a project in accordance with the NHS definition of research (i.e. that it intends to generate generalisable new knowledge). Studies meeting the criteria for service evaluation, quality improvement or clinical audit do not fall within the remit of the JRO and will be directed towards the relevant CAVUHB/CU department. Further information on the categorisation of a study may be found by using the HRA 'Is my study research?' Decision Tool, or by consulting the HRA 'Defining Research' document. If a project is not classified as research, then there is no requirement to arrange an EPR meeting or request Sponsorship;
ii. for funded studies- whether any additional contracts or research governance support is required to manage the study and whether this can be incorporated into the grant application stage (determined in accordance with the JRO Costing Model- refer to Table 1 of this SOP);
iii. which organisation will be the most appropriate Sponsor for the study;
iv. the ethical and governance approvals that will likely be required for the project following an initial discussion, as well as discussing any potential barriers to gaining these approvals;

v. the relevant JRO Research Governance Team contact to take the application forward.

3.3 Eligibility for Sponsorship

3.3.1 Staff-led research

To be eligible for Sponsorship from either CU or CAVUHB, the following requirements must be fulfilled:

i. the CI must hold a substantive contract of employment with either CU or CAVUHB; AND
ii. in the case of funded research- CU or CAVUHB will be the primary grant holder.

Other Sponsorship eligibility factors may also apply and will need to be discussed with the JRO, these include (but are not limited to):

- if the study is appropriately designed and is deliverable (especially if the study is unfunded);
- if the study involves international sites.

3.3.2 Research conducted for the primary purpose of an educational qualification

In the case of research conducted for the purposes of an educational qualification:

i. the main Academic Supervisor must act as the CI and must be a CU or CAVUHB employee;
ii. only PhD and certain Masters level projects will be considered for Sponsorship. Undergraduate level research projects are not permitted to take place in the NHS.

Those conducting research for an educational qualification should first check that it meets the criteria outlined in the HRA's Student Research Toolkit.

Eligibility for Sponsorship is confirmed during the EPR meeting. **Please note that this does not constitute confirmation of Sponsorship in Principle (see section 4.0). Confirmation of Sponsorship in Principle is subject to the conditions outlined in Section 4.0 of this SOP being met.**

If the project is **not** deemed to be research, the JRO Research Governance Team will direct the CI to the relevant department to register the project accordingly and the meeting outcomes can be used as evidence for publication.

3.4 JRO Project Set-Up Meeting

For studies deemed to be more complex and/or higher risk studies, the JRO Director may determine that an additional Project Set-Up Meeting is required following the initial EPR meeting and before Sponsorship approval is granted. This may be arranged following confirmation of funding, or where further information and detail about the study is required. Project Set-Up Meetings are agreed following the initial EPR meeting and are arranged via the JRO Administrative team. A Project Set-Up meeting is not normally required for studies deemed to be low-risk.

4.0 SPONSOR ASSESSMENT PROCEDURE (SAP)

Following the EPR meeting, the CI (or their delegate) should liaise with the relevant Lead Sponsor Contact (as agreed at the EPR Meeting) to commence the Sponsor Assessment Procedure (SAP). The SAP consists of the following stages:

i. Submission of the application for Sponsorship
ii. Sponsor Assessment Process (SAP)- conducted by the JRO Research Governance Team
iii. Confirmation of Sponsorship in Principle

4.1 Applying for Sponsorship and submission of the Sponsorship Application

In order to confirm Sponsorship in Principle, the CI (or their delegate) must complete and provide the following documents to the relevant member of the JRO Research Governance Team:

- a completed JRO Sponsorship Request Form (FRM/001/13)
- evidence of appropriate independent peer/scientific review
- the study Protocol (completed in accordance with the JRO Protocol Template for non-CTIMPs TPL/001/01)
- the study Participant Information Sheet(s) (designed in accordance with the HRA Quality Standards and Design Standards)
- the study Informed Consent Form(s) (designed in accordance with the HRA Quality Standards and Design Standards)
- any other participant-facing documents, or documents concerning participation in the study (e.g. GP letters, Consent to Contact forms, study posters, patient diaries etc.)
- draft interview schedules and surveys (where appropriate)
- model contracts and costings (where appropriate). N.B. contracts will usually be arranged by the JRO Research Governance Team during the SAP;
- copies of any other documents required for the IRAS submission.

The collection of documents listed above constitute the Sponsorship Application. The JRO Research Governance Team cannot commence the Sponsorship Assessment Process (SAP) until all documents in the Sponsorship Application are received.

The Sponsorship Application should be emailed to the JRO Research Governance Team Lead Sponsor Reviewer. The Lead Sponsor Reviewer will be identified and made known to the CI during the EPR. The general team email addresses of the JRO Research Governance teams can be found in section 3.0 of this SOP.

4.2 Sponsor Assessment Process (SAP)

Upon receipt of the Sponsorship Application, the study will be registered in the JRO and assigned to the relevant member of the JRO Research Governance Team (the Lead Sponsor Reviewer) in order to commence the Sponsor Assessment Process (SAP).

The following aspects are reviewed during the SAP:

- the planned study methodology;
- that the study has been designed and will be conducted in line with the relevant legislation and Good Clinical Practice (GCP);
- the proposed study intervention(s) (where relevant);
- study management and monitoring arrangements;
- the scientific integrity and quality of the study;
- the financial and contractual arrangements for the study.

The JRO Sponsor Risk Assessment is the method used to assess and record the risk level of the project and determines the Sponsor oversight arrangements for the project.

During the SAP, the Lead Sponsor Reviewer may request further information from the CI (or their delegate) and may request updates to the documents in the Sponsorship Application in order to ensure compliance with the relevant procedure, policy or area of legislation. The Lead Sponsor Reviewer may also seek further advice and input from departments external to the JRO, such as:

- CAVUHB Information Governance/ CU Data Protection Team;
- Human Tissue Act personnel;
- CAVUHB/CU Contracts Teams;
- CAVUHB/CU Pre-Awards Teams and/or Finance Department;
- NHS Radiology and/or Medical Physics Departments;
- NHS Pharmacy teams;
- NHS Support departments;
- NHS directorate managers/R&D leads;

- CU academic schools.

4.3 Confirmation of Sponsorship in Principle

In order to finalise the Sponsor Risk Assessment and confirm Sponsorship, the Lead Sponsor Reviewer must be satisfied that:

- all potential risks have been considered and raised with the CI (or their delegate) and that adequate mitigation strategies have been adopted where possible;
- the documents contained in the Sponsor Application meet the requirements for REC and/or HRA/HCRW review;
- that the necessary approvals have been received as applicable, (e.g. from Information Governance, Clinical Board R&D Leads and Finance);
- that the CI understands their roles and responsibilities in respect of the safe and ethical conduct of the study and the terms and conditions of Sponsorship;
- any potential contractual requirements for the study have been considered and flagged with the relevant Contracts Team;
- an outline Organisation Information Document and Schedule of Events or SoECAT form has been drafted (where appropriate).

4.3.1 Sponsorship in Principle Letter

Upon satisfactory completion of the SAP, a Sponsorship in Principle letter is issued to the CI (with all key study contacts copied in), confirming that CU or CAVUHB accepts the role of Sponsor in Principle and outlining any key requirements for the study (e.g. certain contracts).

Sponsorship in Principle is granted on the assumption that the study:

- achieves a favourable REC and/or HRA/HCRW approval (and any other approvals as specified in the Sponsorship in Principle letter, e.g. CAG approval)

AND that it is conducted in compliance with:

- the principles of GCP;
- the UK Policy Framework (as amended);
- the applicable CU and CAVUHB policies and procedures;
- applicable laws and regulations, including but not limited to the Human Tissue Act, the Data Protection Act and the Mental Capacity Act (as amended).

A PDF copy of the letter will be issued to the CI and any other key study team members by email and a copy saved on the electronic Sponsor file. The

Sponsorship in Principle letter is the record of Sponsorship and a copy of this letter should be retained by the CI in the Investigator Site File or the Study Master File.

The Sponsorship in Principle letter is then uploaded by the CI (or their delegate) to the study IRAS Form as part of the IRAS submission.

5.0 POST SPONSORSHIP IN PRINCIPLE DECISION

5.1 Sponsor Authorisation via IRAS

Following the issue of the Sponsorship in Principle letter, the CI (or their delegate) may send a request for Sponsorship Authorisation via IRAS.

The Lead Sponsor Reviewer will provide Sponsor authorisation of the IRAS Form when they are satisfied that the content of the IRAS Form is:

- accurate in accordance with the study documentation (e.g. the Protocol, Participant Information Leaflets and Consent Forms) and the terms of the funding award (where applicable), and;
- written in compliance with the relevant national and University legislation, policies and governance frameworks.

The CI (or their delegate) is then responsible for submitting the authorised IRAS Form to the HRA via the HRA Online Booking Service.

All delegated responsibilities must be recorded in a Study Delegation Log and stored in the Trial Master File/Investigator Site File, before the study opens to recruitment.

5.2 Final confirmation of Sponsorship

Studies are considered to have Sponsor approval when the terms of the Sponsorship in Principle letter have been fulfilled. Recruitment may not commence in an NHS organisation or social care setting until Capacity and Capability (C&C) approval has been granted by the relevant NHS organisation (or the equivalent permission to commence has been granted by a social care setting) and the Sponsor has issued the Green Light to commence recruitment.

The Sponsorship in Principle letter will outline the requirements of Sponsorship. This will normally include confirmation that the following approvals have been secured by the CI (or their delegate):

- a favourable ethics opinion from an approved Research Ethics Committee (the appropriate category of REC will be listed on the Sponsorship in Principle letter);

- any other approvals as listed on the Sponsorship in Principle letter (e.g. CAG, ARSAC);
- HRA/HCRW Approval (or the Scottish/Northern Irish equivalent);
- Confirmation of Capacity and Capability (C&C) for a specific NHS site, or the equivalent permission to commence in a social care setting (where relevant. The form of this will vary in accordance with the setting/Local Authority).

A final confirmation of Sponsorship letter will not normally be issued unless deemed necessary by the JRO.

Please note: If amendments to the study or study documentation are required, following review by any of the relevant authorities, the JRO Research Governance team will liaise with the CI (or their delegate) in order to discuss and review the required changes. The process for the review and approval of amendments is covered in the relevant Amendments SOP.

5.3 Sponsor 'Green Light' to commence recruitment

Recruitment cannot commence in an NHS organisation or social care setting until Capacity and Capability (C&C) approval has been granted by the relevant NHS organisation (or the equivalent permission to commence has been granted by a social care setting) and the Sponsor has issued the Green Light to commence recruitment at the individual site.

For low and medium risk studies, unless otherwise agreed, issuing of the Sponsor Green Light is usually delegated to the CI (or their delegate), in response to an NHS site issuing confirmation of Capacity and Capability. A Green Light checklist is not normally required for low and medium risk studies, unless pre-determined by the Sponsor.

The CI (or delegate) should copy the JRO Governance team into the Green Light confirmation email/letter to site(s).

For multi-centre studies under CTU management, where agreement is in place to do so, the CTU's Green Light processes may be followed.

On occasion, a member of the JRO Research Governance Team may respond to NHS R&D offices to confirm Sponsor 'Green Light' and oversee the Green Light process This will be determined on an individual study basis.

5.4 DURATION OF SPONSORSHIP

Sponsorship is considered to apply for the duration of the study until the study is archived, providing the following approvals are maintained by the CI (or their delegates):

- A valid favourable REC opinion (maintained through the provision of Annual Progress Reports to the appropriate REC, for which the CI is responsible for submitting);
- A valid HRA/HCRW Approval;
- Continued support for the study from the NHS/social care site organisation(s)- provided through the confirmation of C&C;
- All other study approvals are maintained as appropriate (e.g. CAG, ARSAC approvals);
- All changes and updates to the study are formally recorded via the HRA Amendment process and approved by the relevant Sponsor organisation;
- There is adequate funding and resource in place to support the study, or the CI is able to confirm that additional support can be sourced (e.g. via additional funding, staffing support or extensions to funding arrangements).

6.0 RIGHT TO WITHDRAW SPONSORSHIP

In line with its responsibilities as Sponsor, CAVUHB and CU may withdraw Sponsorship of a study where it is deemed that there has been a breach of the Terms and Conditions of Sponsorship. A copy of the Terms and Conditions of Sponsorship is provided to the CI with the JRO Sponsorship Application Form.

7.0 ASSOCIATED DOCUMENTATION

FRM/001/13 JRO Sponsorship Request Form

TPL/001/01 Non CTIMP Protocol template for JRO Studies

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

Appendix 1: Applying for Sponsorship Process Flowchart