University Hospitals Plymouth NHS Trust

STANDARD OPERATING PROCEDURE

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Trust Sponsorship of Studies

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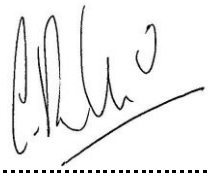
AUTHORISED BY

Name: Chris Rollinson

Job Title: Research Governance Manager

Signature: 

Date: 21st Jan 2019

1 Purpose and Scope

The purpose of this procedure is to describe the sponsorship review and authorisation process. The nature and complexity of the study varies depending on the type of project proposed. Typically clinical trials of investigational medicinal products (CTIMPs) or clinical investigations of medical devices (CMDs) (or combinations thereof) require a more detailed sponsorship review to be undertaken, whereas studies not defined as CTIMPs or CMDs in general require a less detailed sponsorship review.

The sponsor is the individual or organisation (or group of individuals or organisations) that takes on responsibility for confirming that there are proper arrangements to initiate, manage and monitor, and finance a study.

Under the terms of the Medicines for Human Use (Clinical Trials) Amended Regulations (2006) and the UK Policy Framework for Health and Social Care Research (2017), every research study that takes place in the context of the NHS or social care services in England, be it a randomised controlled trial of a medicine, a qualitative questionnaire based study or a comparison of two surgical techniques, must have a nominated sponsor. The Research Sponsor is normally the organisation which substantively employs the Chief Investigator.

Where the study is funded by a research council, medical charity or other non-commercial body, the funder may be willing to act as a Sponsor, especially if it employs members of the research team or retains an interest in any intellectual property that is generated.

Where a project is being undertaken as part of academic study, then the University where the course is being undertaken will usually be the research sponsor. If a University is the sponsor then the University and the project supervisor are responsible for the design, management and running of the study. The student and supervisor will be responsible for ensuring that they have checked that all regulatory approvals are obtained prior to the project commencing.

1.1 Role of the Sponsor

An organisation with the status and authority to sponsor research in health and social care must be in a position to ensure that:

- The dignity, rights, safety and well-being of participants are given priority at all times by the research team
- The research proposal is worthwhile, of high scientific quality and represents good value for money
- An appropriate research ethics committee has approved the research proposal
- Appropriate arrangements are in place for the registration of trials
- The principal investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully

- The arrangements and resources proposed will allow the collection of high quality accurate data and the systems and resources being proposed are those required to allow appropriate data analysis and data protection
- Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards
- Arrangements proposed for the work are consistent with the applicable laws, guidance and regulations, including ICH GCP, Medicines for Human Use (Clinical Trials) Regulations and/or the UK Policy Framework for Health and Social Care Research
- Organisations and individuals involved in the research all agree the division of responsibilities between them
- There is a clear written agreement identifying the organisation responsible for the ongoing management and monitoring of the study, whether this is the organisation employing the researchers, the sponsor, or another organisation
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction
- An agreement has been reached about the provision of compensation in the event of non-negligent harm and any organisation, including the sponsor itself, offering such compensation has made the necessary financial arrangements
- Arrangements are proposed for dissemination of the findings
- All scientific judgements made by the sponsor in relation to responsibilities set out here are based on independent and expert advice
- Assistance is provided to any enquiry, audit or investigation related to the work.

In scope: this standard operating procedure (SOP) applies to any research study where UHPNT is requested to act as sponsor or joint-/co-sponsor. UHPNT may act as sponsor or joint-/co-sponsor if at least one of the following criteria are met:

i. UHPNT is the main funder of the research;

ii. the Chief Investigator (CI) holds a substantive or honorary contract with UHPNT;

iii. UHPNT is the leading care organisation where the research is to take place.

If research is being undertaken at UHPNT for an educational qualification the awarding institution (e.g. university) should normally act as sponsor. If any of the above criteria are met and the research is being undertaken at UHPNT for an educational qualification the awarding institution should act as sponsor in the first instance, however in certain circumstances UHPNT may agree to act as sponsor; this will be assessed on an individual basis.

Sponsorship is not guaranteed if any or all of the above criteria are met. UHPNT will sponsor studies which are of high scientific worth and will be of benefit to patients and/or the Trust.

UHPNT may decline sponsorship if there is evidence that there are insufficient facilities and/or inexperienced/unqualified personnel conducting the research, or if there is insufficient financial resources available for the safe and effective conduct of the research.

This SOP does not apply to research that is not sponsored by UHPNT.

Definitions

CI	Chief Investigator
CMD	Clinical investigations of Medical Devices
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH GCP	International Council for Harmonisation of Good Clinical Practice
IP	Intellectual Property
MHRA	Medicines and Healthcare products Regulatory Agency
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigator
RD&I	Research, Development & Innovation
REC	Research Ethics Committee
RGF	Research Governance Framework
RO	Research Office
SOP	Standard Operating Procedure
UoP	University of Plymouth

2 Who should read this document?

All staff involved in setting up research projects e.g. The Trust Research Advisor, the Research Governance Manager, Chief Investigators (CI), Principal Investigators (PI), the RD&I Manager and Deputy and RD&I Office Clinical Trial Administrative staff.

3 Procedure to Follow

A flow diagram of this procedure is available for reference in Appendix 1 of this document.

3.1 Responsibility

Chief Investigator

Ensure that the Trust is aware of the research proposal and accepts sponsor responsibilities prior to submitting any other application (e.g. for grant funding, HRA, Research Ethics Committee (REC), clinical trial authorisation (CTA) or NHS Capacity & Capability).

Not agree any funding amount prior to requesting sponsorship authorisation. If funding is secured prior to requesting sponsorship authorisation there may be insufficient funds available to cover the sponsor management costs and the request for sponsorship may be rejected.

Sponsor (fulfilled by the Research, Development & Innovation (RD&I) Department on behalf of UHPNT).

The Research Advisor & Trust Innovation Lead will acknowledge sponsorship requests and prepare an electronic file of submitted documentation.

The Research Advisor & Trust Innovation Lead will assess all sponsorship requests and facilitate sponsorship authorisation.

RD&I personnel representative of regulatory compliance, quality assurance, finance, intellectual property (IP) and grants will provide input into sponsorship decision-making where appropriate.

The RD&I Manager (or their delegate) will authorise UHPNT sponsorship.

3.1. When

This SOP should be used when developing a new research project, prior to submitting the research protocol to the relevant regulatory authorities (e.g. HRA and MHRA). All sponsorship decisions are made once all the reviewers' comments have been addressed by the researchers and updated protocols and appendices are submitted to the RD&I Research Advisor.

In all cases the CI must notify RD&I of a request for Trust sponsorship as early in the research study design stage as possible so that appropriate support and guidance can be provided. The CI may contact RD&I on Int. tel: 39991 or by emailing plh-tr.researchandinnovation@nhs.net

3.2.How

The CI must submit as a minimum a study protocol, participant information sheet and the consent form to the Research Advisor & Trust Innovation Lead in RD&I plh-tr.researchandinnovation@nhs.net . Upfront provision of accurate documentation and information will reduce the time taken for RD&I to complete the sponsorship review and obtain sponsorship authorisation.

The RD&I Research & Innovation Facilitator will email confirmation to the CI within 1 working day of receiving the sponsorship request documentation.

The RD&I Research & Innovation Facilitator will register the sponsorship request, email confirmation of receipt to the CI and prepare a file of the documentation for review within 3 working days of receiving the sponsorship request.

The Research & Innovation Facilitator will notify a Research Advisor & Trust Innovation Lead or their delegate, of the submission to RD&I so that an initial assessment on the funding & feasibility of the study may be made.

It is the responsibility of the RD&I Office to confirm that there are proper arrangements to initiate, manage, monitor and finance a study. Before agreeing to sponsor a project the RD&I Office must ensure that clear agreements are in place. Therefore, before the Trust takes on the role of Sponsor for a project the RD&I Office will ensure that:

Science

- The study conforms to the Trust RD&I strategy.
- An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile and of high scientific quality.
- The proposed arrangements allow the collection of high quality, accurate data and the proposed systems allow for appropriate data analysis and data protection
- The study is feasible, within the setting of University Hospitals Plymouth NHS Trust.

Governance

- The arrangements for the project are consistent with the UK Policy Framework for Health and Social Care Research
- The Chief Investigator and other key researchers, including those at other sites, have the necessary expertise and experience and have the necessary resources to run the project successfully.
- The research proposal respects the dignity, rights, safety and well-being of the participants and their relationship with care professionals.
- An appropriate ethical review will be sought to approve the project.
- In the case of a clinical trial involving a medicine, that someone acting on behalf of the sponsor will obtain a Clinical Trials Authorisation and the arrangements for the trial comply with the requirements of the Medicines for Human Use (Clinical Trials) Amended Regulations 2006.
- Appropriate arrangements are in place for the registration of a clinical trial.
- Organisations and individuals involved in the research have agreed the division of responsibilities between them.

	• There are written agreements about the arrangements for management and monitoring of the study. • Arrangements are in place for the sponsor and other stakeholders to be alerted to significant developments during the study, whether in relation to the safety of individuals or to scientific direction. • There are arrangements for the conclusion of the study, including archiving, and appropriate plans for the dissemination of the findings.
Finance	• An appropriate process of review has identified that the costs for the research are accurate, that there is sufficient financial support for the study, and that the study demonstrates good value for money. • Agreements have been reached about compensation in the event of harm to research participants, and if any organisation offers compensation without proof of negligence, then it has made the necessary financial arrangements • The potential for any intellectual property arising from the study has been considered and appropriate steps are underway to protect this

In order to undertake these reviews:

The protocol for all studies where UHPNT sponsorship is sought will undergo scientific and peer review. The reviews will be conducted by reviewers identified in UHPNT and the University of Plymouth (UoP). The extent of review will be dependent on the nature and complexity of the study.

The Research Advisor & Innovation Lead, Research Governance Manager, RD&I Manager and the Deputy Research Manager will scrutinise all study protocols to ensure compliance with regulatory requirements and that CTIMPs are compliant with ICH GCP.

The study will be assessed by the RD&I Office feasibility and finance team to ensure costing and available capacity to conduct the project is in place.

When deciding on sponsorship, the Research Advisor & Innovation Lead will consider all aspects of proposed studies with the comments from the scientific and peer reviews and make a recommendation to the Research Manager or their delegate on the proposed projects suitability for Trust sponsorship.

3.3 Sponsorship Authorisation

Once the sponsorship review has been completed the Research Advisor & Innovation Lead will request sponsorship authorisation from the RD&I Manager or their delegate.

There are two types of sponsorship authorisation:

i. Sponsorship in principle (provisional) is granted to allow the CI to name UHPNT as the sponsor on a grant/funding application and to enable contract negotiation. The CI is not permitted to submit applications for the HRA, REC and/or the MHRA with only provisional sponsorship authorisation. The CI should submit all outstanding and/or follow up information to RD&I as soon as it becomes available to request sponsorship authorisation.

ii. Sponsorship Authorisation is granted when UHPNT is satisfied all study and sponsor arrangements are in place and study documentation has been finalised. This authorisation allows the CI to submit an application to the HRA, REC and is applicable the MHRA.

If the sponsorship review has been completed and all sponsorship criteria have been fulfilled the Research Advisor and Innovation Lead will request Sponsorship Authorisation. This is granted *via* RD&I Manager or their delegate in the form of the Trust sponsorship letter agreement.

If the study was previously given provisional sponsorship authorisation, the Research Advisor & Innovation Lead will recommend the sponsorship authorisation to the RD&I Manager or their delegate, once sponsorship criteria have been fulfilled.

If the RD&I Manager does not approve the study; researchers may be invited to further consult with nominated RD&I personnel to improve the proposed study before the study is submitted again for consideration.

If there are queries that cannot be resolved to the satisfaction of the RD&I Manager, the study may be referred to the Director of Research. The decision of the Director of Research will be final.

UHPNT agreement to act as sponsor is not approval for the study and is conditional on full regulatory permissions being gained through the normal study approval processes.

3.4 Sponsorship Rejection and Withdrawal

UHPNT may decline to sponsor a study, or may withdraw sponsorship if any of the following become known at any time. This list is not exhaustive:

i. the research design is not worthwhile, of high scientific quality or good value for money;

ii. the research is unethical or individuals or organisations are at risk;

iii. there are inadequate resources, facilities, expertise and support to deliver the research safely and successfully;

iv. there is lack of research management, monitoring and auditing allocated;

v. relevant contracts are not in place;

vi. the appropriate research approvals are not obtained;

vii. the research is not compliant with applicable regulations (e.g. RGF, International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH-GCP), Clinical Trials Regulations, Medical Devices Regulations);

viii. there is insufficient finance available.

The Research Advisor & Innovation Lead or Research Governance Manager will notify the CI in writing, giving reasons, if sponsorship is rejected or withdrawn.

If the research has already received a REC favourable opinion or Clinical Trial Authorisation (CTA) and sponsorship is withdrawn the RD&I Office will notify the relevant bodies.

3.5 Joint-/Co-Sponsorship and Delegated Sponsor Responsibilities

The Trust may act as joint-/co-sponsor with another organisation, such as another NHS Trust. Specific sponsor responsibilities may be delegated to any other individual (e.g. CI) or organisation (e.g. Clinical Trials Unit) that is willing and able to accept them. Responsibilities must be formally agreed and documented either as part of an agreement / contract or by the use of a task allocation matrix.

The CI must consider if joint-/co-sponsorship or study management by an external service provider is required as soon as possible to ensure appropriate financial and logistical arrangements can be made.

3.6 Sponsor Management Costs

Sponsor management activities (such as monitoring, pharmacovigilance, IP management) must be appropriately financed for the duration of the study. There is no fixed cost for sponsor management; this will be priced on an individual basis.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

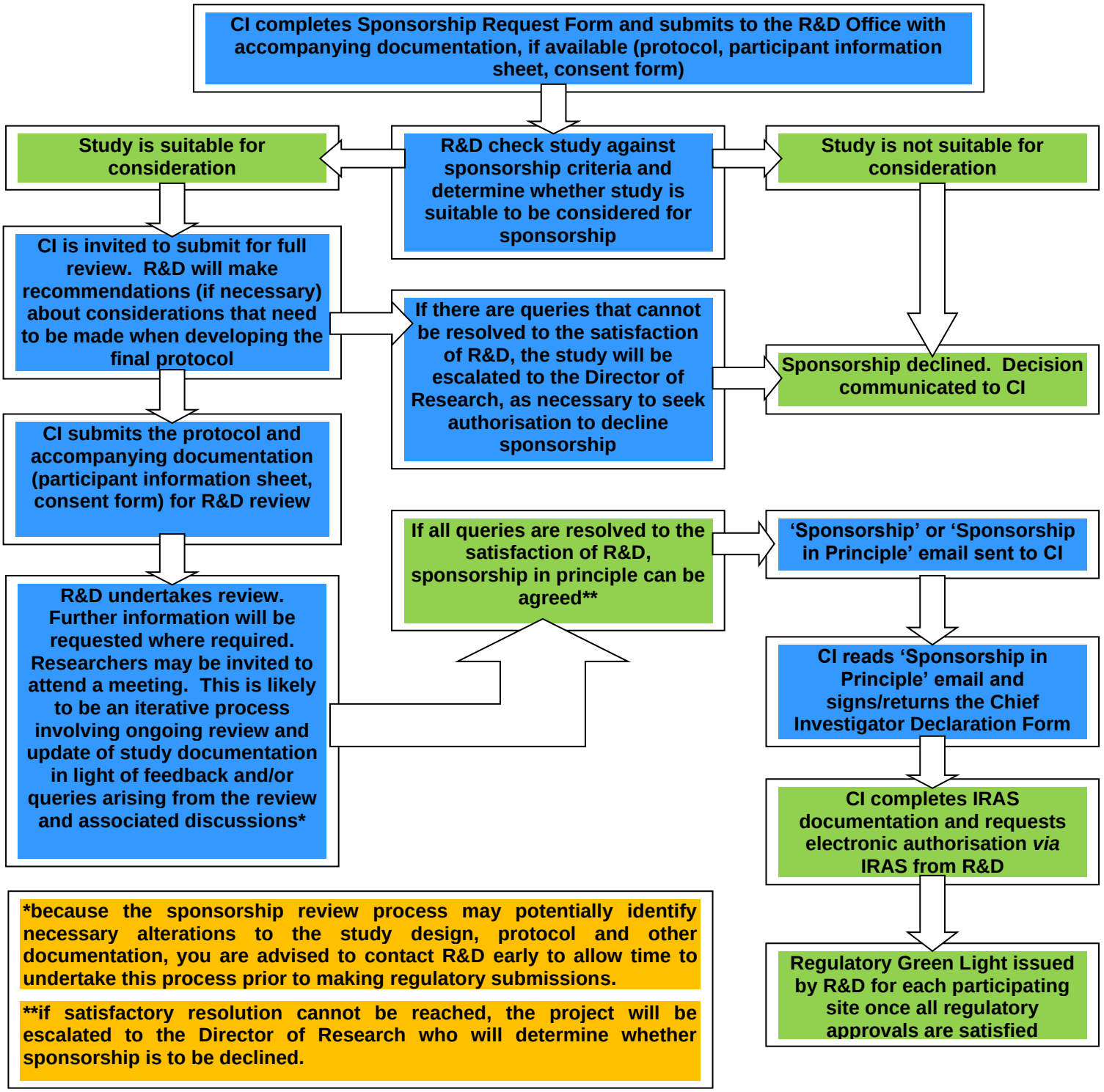
Department of Health
UK Policy Framework for Health and Social Care Research
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

ICH Secretariat
Guidelines for Good Clinical Practice (GCP) (E6 R1 Step 4, 1996) (and subsequent addendums)
www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

UK Government
Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments)
www.legislation.gov.uk/uksi/2004/1031/contents/made

Medical Device regulations
http://www.hra.nhs.uk/documents/2013/09/approval-of-medical-devices-research-version-2-april-2008.pdf

Appendix: Sponsorship Flow diagram — Appendix 1



6 Amendment History

Version Number:	3.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Update logo and Trust name, updated to reference the UK Policy Framework for Health and Social Care Research (2017).
Version Number:	3.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Update of SOP template and numbering system. SOP reviewed and completely re-written.
Version Number:	2.1 (minor amendment)
Date Of Amendment:	Mar 2012
Details Of Amendment:	Updated review and sponsorship decision processes
Version Number:	2.0
Date Of Amendment:	Oct 2011
Details Of Amendment:	Cover page - Change of SOP location address.