Standard Operating Procedure

RESEARCH SPONSORSHIP AT UH BRISTOL

SETTING Trustwide

AUDIENCE Research staff including Chief Investigators (CI) and Principal Investigators (PI) and those involved in study design and co-ordination for studies requesting sponsorship by UH Bristol.

ISSUE To describe the process for applying, authorising and retaining UH Bristol sponsorship for research studies.

QUERIES Contact Research & Innovation (R&I) department : Ext 20233 or research@uhbristol.nhs.uk

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Version Number	Reason for change
Original V1.0	N/A
V2.0	Major revision to sponsorship process to align with HRA processes and to ensure appropriate documentation of risk for CTIMPs.
V2.1	Incorporation of consultation feedback
	Updated in line with new SOP template

1. Introduction

All research conducted within the NHS must have a sponsor. This requirement is driven by the UK Policy Framework for Health and Social Care Research (UKPF) and the Medicines for Human Use (Clinical Trials) Regulations (Clinical Trials regulations). The former applies to all research, and the latter applies to clinical trials of Investigational Medicinal Products (CTIMPs).

A sponsor is an organisation which takes responsibility for the quality and conduct of a research study:

"The organisation or partnership that take on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project." [UK Policy Framework for Health and Social Care Research]

"…the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial". [United Kingdom Statutory Instrument 2004/1031 (The Medicines for Human Use (Clinical Trials) Regulations 2004]

For CTIMPs the responsibilities of a sponsor incorporate the following areas of legal responsibility:

- Authorisation for clinical trials and research ethics committee (REC) opinion
- Good Clinical Practice (GCP) and the conduct of clinical trials
- Pharmacovigilance
- Manufacture and labelling of investigational medicinal products

Further details relating to sponsor responsibilities can be found in the MHRA Good Clinical Practice Guide and within the Clinical Trials Regulations (SI 1031)

The responsibilities of a sponsor may be delegated. Any delegated responsibilities must be documented. Ultimately the sponsor remains accountable for all functions of sponsorship regardless of whether they have been delegated.

2. Purpose

This SOP describes the process for applying, agreeing and maintaining UH Bristol sponsorship in order to ensure that UH Bristol sponsorship requirements are and continue to be met throughout the duration of the research.

3. Scope

In Scope: UH Bristol sponsored research.
Out scope: Research sponsored by other organisations.

4. Responsibilities

The Chief Investigator is responsible for applying to UH Bristol for sponsorship and to ensure that all of the supporting documents are provided for the sponsorship review process.

The Senior Management Team are responsible for discussing all applications for sponsorship.

The Research Management Facilitator (RMF) or Research Projects Manager (RPM), is responsible for liaising with the CI and communicating all sponsorship requests and decisions.

The sponsor is responsible for the quality and conduct of a research study and ensuring compliance with all applicable regulations.

5. Abbreviations and Definitions

Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMS	Document Management System
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
MEMO	Medical Equipment Management Organisation
MHRA	Medicines and Healthcare products Regulatory Agency
NRES	National Research Ethics Service
PI	Principal Investigator
PoC	Point of Contact
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
RMF	Research Management Facilitator
RMO	Research Management Office
RPM	Research Projects Manager
RSS	Research Support Services
SOP	Standard Operating Procedure
UKPF	UK Policy Framework for Health & Social Care

Definitions	
Sponsor	The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial.
CI	The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

6. Procedure

6.1 Applying for UH Bristol sponsorship

- The substantive employer of the CI usually takes on the role of sponsor. For clinical research, it may be appropriate for UH Bristol to sponsor a study led by clinical academics practising in UH Bristol that hold an honorary contract with the trust.
- For research undertaken as part of a qualification, the university at which the student is registered should be the sponsor.
- When a sponsorship application is submitted to UH Bristol, it is reviewed to determine whether UH Bristol is the most appropriate sponsor.
- Prior to applying for UH Bristol sponsorship, please consider the study design, costings, funding, resources, the scientific quality and impact of the research. Please refer to *SOP_003 Developing and Designing your study*, *SOP_004 Writing a Research Protocol to Good Clinical Practice* and to the R&I website for more information.

- In order to apply for sponsorship, researchers should complete *TMPL_003 Request for UH Bristol to be Research Sponsor form* and submit it with a copy of the study protocol via e-mail to R&DSponsorship@uhbristol.nhs.uk.

- Completed forms will be discussed at the weekly R&I Senior Management Team (SMT) meeting in order to assess whether it is appropriate for UH Bristol to sponsor and therefore continue through the sponsorship process. Providing that the documentation is complete, a decision can usually be made and communicated to the applicant within seven working days after submission. If UH Bristol is not the most appropriate sponsor, the UH Bristol R&I staff will liaise with partner organisation research management offices before proposing that they may be a more suitable sponsor.
- There are a number of potential outcomes, which UH Bristol R&I will lead on:
  (i) Agreement that UH Bristol is a suitable sponsor and progression of an application
  (ii) Referral of the applicant to a partner organisation for sponsorship
  (iii) Referral of the applicant to their Higher Education Institution
  (iv) Referral of the applicant to a commercial funder

- This SOP refers only to research which falls under the first option (i) above. If it is appropriate for UH Bristol to sponsor the research, the researcher is sent an email containing the following information:
  - Confirmation that a study record has been created on the EDGE research management system.
  - The name of the RMF or RPM (sponsor representative) who will take the study through sponsorship. The RPM will be assigned to guide CTIMPs and complex interventional trials through sponsorship and all other study types will be delegated to an RMF.
  - The R&I reference number that has been allocated. Description of the next steps in the process, signposting to appropriate documents to support the applicant and any queries on the proposed research highlighted during senior management review.

6.2 Agreeing sponsorship

- The next step is to agree sponsorship. The following documents are required to provide assurance to the assigned sponsor representative that the research can be carried out to the required standards.

Chief investigator CV

- The CI should include a current copy of their CV which is signed and dated within the last 3 years, along with any relevant training records to demonstrate that the CI is suitably qualified to lead the research. This may be a shortened CV (see *TMPL_022*).

Study costing

- All research incurs a cost. A statement of the approximate costs that will be incurred and how they will be met should be provided (see evidence of funding section below).
- These costs can be attributed to a number of different categories (e.g. support costs, treatment costs, research costs) and the way in which the costs are met varies depending on the type and scale of research and how they are attributed. ACoRD guidance from the Department of Health provides further information on how these costs should be categorised: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research). Further information regarding costing can also be found in *SOP_003 Developing and Designing your study*.

Evidence of funding

- A copy of the funding award letter (if applicable) provides evidence that certain elements of the costs incurred will be met by the grant. The grant should usually meet all research costs, which may be incurred within the trust or by other organisations.
- Elements of researcher time may not be costed, either because they are already funded and agreement has been reached to use the time for the study, or because the researcher expects not to be paid for the time spent carrying out the research. This should be stated.
- Evidence that arrangements are in place to meet excess treatment costs should be provided. This may be in the form of email correspondence with service managers or other relevant personnel.
- Confirmation of likely NIHR portfolio eligibility or other arrangements for funding support costs must be provided. It is likely that support costs will be incurred, and these can be met via the Clinical Research Network for NIHR portfolio studies, or via the funder (eg for commercial grants). If the funder is not defined as an 'eligible funder' by the NIHR then support costs must be met by the grant or other means. For the definition of an 'eligible funder' see https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support/

Evidence of Peer Review

- Evidence should be provided that a review of scientific quality has been conducted as part of an external funding award, along with confirmation that reviewer comments have been addressed. In this case, no further peer review will be carried out.
- If the study has not been reviewed by an external funder, or further review is considered desirable, the applicable person in R&I will arrange for this to be undertaken prior to agreeing to act as sponsor.
    - The RMF or RPM will contact the researcher and ask them to suggest reviewers to peer review the research proposal. The reviewers should be independent and an expert in the research field of interest.
    - The RMF or RPM will contact the chosen reviewer(s) to ask them to review the research proposal and complete *TMPL_004 Scientific Review Form.*

Confirmation that there is capacity and capability to deliver the study within UH Bristol and at other sites (if relevant)

- For studies participating at UH Bristol, contact should be made with the relevant individuals as soon as possible for any studies that require support from a research team and/or one of the Trust's support departments (e.g. pharmacy, radiology, laboratory medicine or MEMO) to discuss requirements. This is to ensure there is the capacity and capability to deliver the research. Please refer to *SOP_17 Confirmation of Capacity and Capability to deliver research at UH Bristol* for further information on this process.
- For multicentre studies, The CI should confirm that sites are able to recruit the target number of patients and comply with the inclusion and exclusion criteria. For more complex studies, the CI should consider undertaking detailed feasibility activities using *TMPL_005 Site Identification and Selection*, for example requiring PIs at other sites to review existing patient databases and ensure recruitment can be achieved. The CI should also confirm that there are staff in place at all sites to screen, recruit and follow up study participants, complete and return the data, and that support departments can support the study at other sites.

Study Protocol

- The study protocol is the key document for a piece of research. It should be detailed enough to describe how the research should be conducted, and to the quality standards driven by the legislation and applicable guidelines.

- As sponsor, UH Bristol has a set of standards which it requires its protocols and the conduct of research to meet; these are described in *SOP_004 Writing a Research Protocol to Good Clinical Practice* and more information can be found on the R&I website.

6.2.1 The review process

- Once the documents to agree sponsorship (section 6.2) have been received, the allocated RMF or RPM will carry out the sponsorship assessment including a review of capability and capacity to deliver the research.
- This process is documented on the Research Management System EDGE using the R&D sponsorship workflow.
- During this process any identified risks will be documented and the study should be flagged for monitoring under the *SOP_010 Monitoring and Oversight of Research Activity.*

6.2.2 Risk assessment

- Developing and completing a risk assessment is an ongoing process. For CTIMPs it begins during grant development, and for non-CTIMPs it starts during the sponsorship process.

6.2.2.1 Risk assessment for complex interventional trials (incl. CTIMPs)

- If the grant for the proposed study is held by UH Bristol and it is a CTIMP or it has been assessed by the SMT to be a complex interventional trial, the R&I Research Grants Manager will, in conjunction with the CI, start to document the risks of the trial using the *TMPL_006 Risk Assessment Template* as soon as the grant is awarded.
- As the study passes through the sponsorship process the R&I RPM will continue to complete the risk assessment by arranging a multi-disciplinary meeting with the following personnel:

  Chief Investigator(CI), Principal Investigator (PI) (if different to CI at UH Bristol), Trial Co-ordinator, Research Nurse, Support department representatives and any other personnel deemed appropriate.
- All identified risks and mitigations will be agreed at this meeting and documented on the Risk Assessment Template. This will continued to be worked through until it is considered final by the CI and RPM as sponsor representative.
- The final version must be signed prior to issuing the green light, which must take place prior to any recruitment to the trial.
- Each time there are changes to the perceived risk and mitigating circumstances they must be agreed by the CI and sponsor representative. The Risk Assessment document must be updated, version controlled and re-signed by the appropriate signatories. This will be an ongoing process to document the risk throughout the life-cycle of the trial.

6.2.2.2 Risk assessment for all other research

- The RMF allocated to the study will document any risks identified during the sponsorship or capacity and capability review process on the applicable workflow on EDGE. Examples of these risks include; new investigators with limited experience, complex consenting procedures, challenging protocol design or a vulnerable patient population. This is not an exhaustive list. The RMF will (as applicable) discuss any identified risks during the weekly operations meeting in R&I and agree the appropriate mitigating action e.g. any monitoring required in line with SOP_010 Monitoring & Oversight of Research Activity UH Bristol.

6.2.3 Study Set Up & Management Plan

- For **CTIMPs and complex interventional trials**, a *TMPL_007 UH Bristol Sponsor Study Set Up & Management Plan (SUMP)*, will be prepared by the RPM alongside the completion of the risk assessment. If it is not possible to complete the SUMP during the multi-disciplinary review meeting, the RPM will arrange to meet the trial co-ordinator and complete it as soon as possible.

- The purpose of the SUMP is to document the management arrangements for the study and to ensure that it will be conducted in accordance with GCP and other relevant legislation. The ongoing activities for the management of the study will be discussed, assigned as appropriate, and documented, covering the period from the initial set-up to the close down of the study. The meeting is an opportunity to ensure that all parties are aware of their responsibilities before the study starts recruitment.

6.3 Issuing sponsorship

- On completing the review process, a sponsorship letter is issued.
- For **CTIMPs and complex interventional trials,** *TMPL_008 Sponsorship IMP study* should be sent to the CI, accompanied by *TMPL_023 Statement of Responsibilities for CTIMPs and Complex non-CTIMP Sponsored Studies*, which requires the CI's signature to indicate agreement with the content, and must then be returned to the R&I office.
- For **non CTIMPs and non-complex interventional trials**, *TMPL_009 Sponsorship non-IMP study single site* or *TMPL_010 Sponsorship non-IMP Study Multi site* will be issued depending upon the number of sites involved.
- It is at this stage, that the Trust may be named as the sponsor on subsequent applications to the MHRA, HRA and NRES. Requests for electronic authorisation by the sponsor on the IRAS system must be sent to R&DSponsorship@uhbristol.nhs.uk.
- UH Bristol's agreement to act as sponsor is not the green light for the study to commence, and is **conditional** on HRA approval and, where applicable, MHRA approval being in place.

6.4 Gaining and maintaining authorisations.

- A minimum of 6 weeks for non CTIMPs should be given from initial request for sponsorship before submitting an application to the HRA. For CTIMPs a longer period of time should be allowed. Please note that if your research has been fully supported by the UH Bristol Research Grants Manager and team prior to grant submission, you should still apply for sponsorship; it may, however, be possible to shorten the 6 week lead time in these cases.
- For information about the application through IRAS for REC, HRA and MHRA approval, please refer to *GD_001 Gaining & Maintaining Authorisations*. All documents to be submitted must be reviewed by the allocated sponsor representative prior to submission.
- Since September 2013 it has been a condition of REC approval that all clinical trials are registered on a publically accessible database. Accepted databases and further guidance can be found in the protocol template and guidance document produced by the HRA as referred to in the *SOP_004 Writing a Research Protocol to Good Clinical Practice*.
- If a multicentre study, local packs should be submitted to other sites for capacity and capability review after a joint decision to proceed has been made with those sites in accordance with HRA guidance. Further guidance on this process will be provided by the applicable personnel in R&I taking the study through sponsorship. Local capacity and capability review will be conducted in accordance with *SOP_017 Confirmation of capacity and capability to deliver research at UH Bristol*.

6.5 Green light process to commence recruitment

- Once HRA approval has been issued for the study and the study site(s) have issued capacity and capability confirmation then the allocated sponsor representative will ensure that all necessary approvals and checks have been completed prior to issuing the green light for site(s) to open to recruitment as described below.

6.5.1 Green light process to commence recruitment for CTIMPs and complex interventional trials at UH Bristol site

- The R&I RPM will review progress of completion of each applicable item on the SUMP. Any outstanding tasks requiring completion before trial commencement will be followed up by the RPM in conjunction with the research team and support departments.
- When all conditions have been met and all required tasks completed, the RPM will issue the sponsor's green light for UH Bristol as a site using *TMPL_011 Greenlight for sponsored CTIMP studies at UHB* in line with *SOP_017 Confirmation of Capacity and Capability to deliver research at UH Bristol.*

6.5.2 Green light process to commence recruitment for CTIMPs and complex interventional trials at other sites

- A *Site Initiation Checklist (TMPL_015)* must be completed by the research team for each participating site and returned to the RPM.
- On receipt of the checklist the RPM will ensure the required approvals are in place for that site (e.g. REC and Capacity and Capability confirmation) and once satisfied, the green light will be issued for the site to open to recruitment using *TMPL_012 Greenlight for sponsored CTIMP studies at external sites.*

6.5.3 Green light process to commence recruitment for all other research studies

- The RMF will check that all required regulatory approvals are in place and where applicable, confirmation of capacity and capability has been received for the relevant site. The RMF will issue green light using the appropriate template:
    - For single site studies (UH Bristol only) green light is provided in the confirmation of capacity and capability email (*TMPL_013 Confirmation of C&C with green light for UHB sponsored single site study*)
    - For multi-site studies green light is provided using *TMPL_014 Greenlight for sponsored non CTIMP studies at external sites* for all participating sites (including UH Bristol).
- Please note that accredited clinical trials units may have their own green light processes. If a trial is under a trials unit's management, and agreement is in place to do so, the unit's green light processes may be followed instead.

6.6 Investigator oversight of UH Bristol sponsored studies

- Where UH Bristol is sponsor of a study the expectation is that the CI and PI(s) will maintain oversight as described in *SOP_008 Investigator Oversight of Research*. Although certain roles and duties within the trial may be delegated (e.g. to trials units and research nurses), the CI retains responsibility for those roles and duties and must maintain oversight of the delivery of the trial.
- For **CTIMPs and complex interventional trials** the CI will be required to document their training in *SOP_008 Investigator Oversight of Research to* confirm they understand and accept their responsibilities. Further information on this process can be found in *SOP_007 Research Training* and *SOP_008*.

6.7 Monitoring, oversight and safety reporting of UH Bristol sponsored studies

- Under the UK Policy Framework for Health and Social Care Research, UH Bristol has a responsibility to monitor research conducted on its premises (including sponsored and hosted studies). Furthermore, in accordance with GCP, UH Bristol has a duty to monitor studies which it sponsors. Please refer to *SOP_010 Monitoring and Oversight of Research* for further details.

- There are a number of mechanisms for maintaining sponsor oversight of research. These include, but are not limited to, sponsorship representation at management and steering groups, routine communication with CIs, PIs and research teams, monitoring of the Study Management Plan (SUMP) and monitoring recruitment activity on EDGE. For UH Bristol sponsored studies, each study will be assessed on a case by case basis to determine whether a sponsor representative should attend oversight meetings (as defined above), and how regularly. This should be documented in the protocol and the SUMP as applicable.
- In accordance with the UKPF (for all studies) and the clinical trials regulation (for CTIMPs), UH Bristol must have systems in place to record, investigate and report adverse incidents arising from any research undertaken within the Trust. Please refer to *SOP_009 Research Safety Reporting* for further guidance.
- For all UH Bristol sponsored studies annual progress reports and annual safety reports should be submitted to the REC annually. Furthermore, development safety update reports should be submitted annually to the MHRA for all UH Bristol sponsored CTIMP studies. These documents should be reviewed by a sponsor representative prior to submission. For further information about this, please refer to *GUI_001 Gaining & Maintaining Authorisations* and *SOP_009 Research Safety Reporting.*

6.7.1 Sponsor review meetings

- In order to monitor progress and compliance with applicable regulations, sponsor review meetings for active UH Bristol CTIMPs may be carried out. These will be led by the RPM and will involve the CI, PoC and any other appropriate personnel. Further detail of the processes involved in arranging and conducting a sponsor review meeting is provided in the *WI_001 Work Instruction for Sponsor Review meetings*.

6.8 Sponsor assessment of amendments:

- In line with the information described in *GD_001 Gaining and Maintaining Authorisations* and *SOP_019 UH Bristol sponsored research amendments*, all amendments for UH Bristol sponsored research must be submitted to R&DSponsorship@UHBristol.nhs.uk for sponsor assessment prior to submission to HRA/REC/MHRA. Full details on the amendment process are described in *SOP_019 UH Bristol sponsored research amendments.*

6.9 Study Close down and Archiving

- For **CTIMPs and complex interventional trials,** a *Sponsor close out checklist (TMPL_016)* will be completed between the RPM and the trial manager.
- The archiving process described in *SOP_015 Archiving of research documentation* will be followed for UH Bristol sponsored studies.
- The MHRA (where applicable) and the REC must be notified that a trial has ended, within 90 days of the end of the trial, using a *Declaration of End of Trial Form*. Following that, an *End of trial study report* must be submitted to the MHRA (where applicable) and the REC within a year of the end of the study.
- Each of these forms must be agreed by UH Bristol R&I department prior to submission. A minimum of two weeks prior to the submission deadline, the report/form must be submitted to R&Dsponsorship@uhbristol.nhs.uk, so that the sponsor can agree and authorise submission.
- See:https://www.gov.uk/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#end-of-trial and http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/ for details of both of these processes.

6.10 Dissemination of the Research Findings

- All research sponsored by UH Bristol must have a plan for disseminating the findings of the study which must be written into the research protocol; further guidance on this can be found in *SOP_004 Writing a Protocol to GCP*.

- Transparency, registration and publication of research are core priorities to the HRA. More information on legal requirements as well as best practice can be found on the HRA website.
- For CTIMPs, in accordance with the commision's guidelines it is mandatory for the sponsor to post trial results in EudraCT http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf. For UH Bristol sponsored CTIMPs, preparing these results will be delegated to applicable personnel within the research team and the RPM will provide support as required.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP 007 Research Training*.

8. References and related documents

- ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996) http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
- Medicines and Healthcare products Regulatory Authority (MHRA), 2014. Good Clinical Practice Guide. 3rd impression. TSO (The Stationary Office). Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf
- UK Policy Framework for Health and Social Care Research (UKPF)
- GD_001 Gaining & Maintaining Authorisations
- SOP_003 Developing and designing your study
- SOP_004 Writing a research protocol to good clinical practice
- SOP_007 Research Training
- SOP_008 Investigator Oversight of Research
- SOP_009 Research Safety Reporting
- SOP_010 Monitoring and oversight of research activity
- SOP_015 Archiving of research documentation
- SOP_017 Confirmation of capacity and capability to deliver research at UH Bristol
- SOP_019 UH Bristol sponsored research amendments
- TMPL_003 Request for UH Bristol to be research sponsor form
- TMPL_004 Scientific review form
- TMPL_005 Site Identification and Selection
- TMPL_006 Risk Assessment Template
- TMPL_007 UH Bristol Sponsor Study Set Up & Management Plan
- TMPL_008 Sponsorship IMP study
- TMPL_009 Sponsorship non-IMP study single site
- TMPL_010 Sponsorship non-IMP Study Multi site
- TMPL_011 Greenlight for sponsored CTIMP studies at UHB
- TMPL_012 Greenlight for sponsored CTIMP studies at external sites
- TMPL_013 Confirmation of C&C with green light for UHB sponsored single site study
- TMPL_014 Greenlight for sponsored non-CTIMP studies at external sites
- TMPL_015 Site initiation checklist
- TMPL_016 Sponsor close out checklist
- TMPL_022 Short CV template

- TMPL_023 Statement of Chief Investigator Responsibilities
- WI_001 Work Instruction for Sponsor Review meetings.