Humber Health Partnership

Sponsorship SOP

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Hull University Teaching Hospitals NHS Trust
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This page details the version history and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 08.08.12	J H Pacynko & J Illingworth	Original SOP approved by R&D Committee on 01.08.12
Version 2, 29.01.14	J H Pacynko	- Internet links up-dated - Page 7 & 10 – The sponsor has 10 days to review sponsorship deleted. - Page 9 – A copy of the completed Delegation Log and signed off Monitoring Plan added to list of QA checks before R&D approval. - Science review of protocol added to Sponsorship Request Form
Version 3, 07.02.18	J H Pacynko	HRA approval added More detail on Risk Assessment and Sponsor greenlight process added Regulatory greenlight process added
Version 4, 12.02.19	J H Pacynko	- Added requirement for external auditing of trial. - Risk Assessment to be circulated to the CI/PI and all support service departments involved for their review and input. - Added Type A Notification Scheme. - Added, for single/double-blind trials, prior to Sponsor Green-light; ➢ to identify staff who should be blind/unblind to trial medication, ➢ to test un-blinding processes prior to Sponsor Green-light. -Added requirement for vendor assessments for 3rd party organisations. - Added requirement, for mult-site trial run by a CTU, that Sponsor green-light tasks and checks done by both the CTU and the Sponsor are to be documented, version controlled and signed off by both parties.
Version 5, 18.02.21	S Moffat	2.1 EU Directive replaced by UK Clinical Trials regs. 2.5 Clarification about the sponsor following the UK exit from the EU. 4.5.2 Addition of new process for seeking advice from MHRA whether trial is a CTIMP. 4.5.6 Addition of "Protocol guides are available from the R&D QA staff." 4.7.5 Replacement of R&D Director to Sponsor Oversight Group will make the final decision whether to sponsor the trial. 4.7.6 Addition of paragraph about feedback to the applicant of sponsorship decision. 4.7.7 Addition of note explaining the circumstances where the UoH may have to be considered for sponsorship rather than HHP. 4.7.8 Addition of "Costs for third party vendors will have to be included in any funding applications."
Version 6	S Moffat	Section 4 Procedure, page 6 • 4.4.1 R&D QA email address updated.

		• 4.5.2 Updated the process for deciding whether the trial is a CTIMP or non-CTIMP. • 4.5.3 Updated to read that R&D QA rather than the investigator, will ensure all correspondence regarding the CTIMP/non-CTIMP decision is filed in the TMF. Section 4.7 Protocol review and Risk Assessment, page 7 • 4.7.1 Addition of "The Protocol Review Checklist (WI 55) and the Study Review Checklist (WI 56) should be completed during the review." • 4.7.3 Updated to include the IRAS combined submission. Section 4.8 Sponsor Green-light process, page 9 • 4.8.7 Addition of Laboratory Site File (if required). Appendix 1, page 11 Rewording box 2 to include using MHRA algorithm and discussion with R&D QA regarding CTIMP status.
Version 7	L Cox	Updated to include new process for sponsorship request. Inclusion of Capacity and Capability within the new process Section 4.2 – Protocol Review and Risk Assessment • Added new subsection on identification of Critical-to-Quality (CtQ) factors to support ICH E6(R3) Quality-by-Design principles. • Added requirement to define Quality Tolerance Limits (QTLs) where appropriate. • Expanded collaborative risk review to explicitly include scientific, operational, data-related, and participant-related risks. Section 4.2 – Quality-by-Design (QbD) • Introduced explicit reference to QbD methodology, including proactive risk identification and proportionate mitigation strategies. Section 4.1 – Sponsorship Request Form and Verification • Added new subsection on digital system governance, requiring assessment of system suitability, audit trails, and data integrity controls for platforms such as Monday.com. Section 4.5 – Sponsor Green-light Process • Strengthened monitoring requirements to include a risk-proportionate monitoring strategy, incorporating central monitoring, adaptive oversight, and triggers for targeted monitoring. • Added requirement for monitoring plans to be informed by CtQ factors. Section 4.5.2 – Green-light Documentation Requirements • Added new bullets covering data integrity controls, including validation of data management systems, audit trails, and lifecycle documentation. Section 4.5.5 – Oversight of CTUs and Third Parties • Expanded expectations for risk-based oversight, including performance metrics, communication pathways, and escalation procedures for delegated activities. Section 3 – Responsibilities of HHP as Sponsor • Added new subsection describing the Sponsor's Quality Management System (QMS) and commitment to continuous improvement, CAPA processes, and proportionate oversight. Trust name changed from Hull University Teaching Hospitals NHS Trust (HUTH) to Humber Health Partnership (HHP- Hull University Teaching Hospitals NHS Trust and Northern Lincolnshire and Goole NHS Foundation Trust).

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HHP RDI GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

1 Purpose and who should use this SOP

1.1 This SOP describes the procedures for investigators to follow when applying for sponsorship by Humber Health Partnership (HHP).
1.2 The SOP also sets out the procedures that HHP Research and Development Department (RDI) QA staff are required to follow when an investigator applies for sponsorship.

1.3 This SOP also sets out the Sponsor green-light process. This is the final green-light needed before recruitment to the study can start.

1.4 Following these procedures will ensure compliance with the UK clinical trial regulations (Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments) and ICH GCP (International Conference on Harmonisation Good Clinical Practice for clinical research).

1.5 This SOP should be used by:

- All research staff involved with HHP-sponsored studies – Chief/Principal Investigator, co-investigators, research nurses, clinical trial assistants, project managers, clinical trial co-ordinators, data managers, administrators etc.
- Clinical trials pharmacy staff – technicians and pharmacists.
- All HHP RDI staff who manage the sponsorship of HHP-sponsored studies.
- Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for safety reporting. HHP RDI SOPs are defaulted to in this case.

2 Background

2.1 An investigational medicinal product (IMP) is defined as follows:

A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorization but is, for the purposes of the trial —
(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorization,
(b) used for an indication not included in the summary of product characteristics under the authorization for that product, or
(c) used to gain further information about the form of that product as authorised under the authorisation ***The Medicines for Human Use (Clinical Trial) Regulations 2004(SI 1031)*** *as amended.*

2.2 Medicinal products with a marketing authorization are IMPs when they are to be used as the test substance, reference substance or comparator in a clinical trial.

2.3 The Sponsor is the organisation that is responsible for ensuring that there are proper arrangements in place for the initiation, management, monitoring and financing (or arranging the financing) of a study.

2.4 A Sponsor can delegate any or all of its functions but cannot delegate responsibility for the study. Overall responsibility for the study always remains with the Sponsor.

2.5 It is a statutory requirement that all CTIMPs have a named Sponsor. For trials being conducted in the UK, the MHRA will continue to accept the Sponsor/Legal Representative being located in the UK or a country on the approved list of EU/EEA countries (this list may vary, please check at https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries).

2.6 It is important to identify a Sponsor as early as possible. Many funding bodies require a Sponsor to be agreed in principle prior to accepting a funding application.

2.7 The procedures described in this SOP enable HHP to fulfil its statutory requirements as Sponsor under the UK Clinical Trial Regulations and to have appropriate control over the sponsorship process.

2.8 Adhering to these procedures will avoid unnecessary work and delays for investigators.

3 Responsibilities of HHP as Sponsor

3.1 Humber Health Partnership (HHP) as a Sponsor for clinical research must be in a position to ensure the following requirements are met (list not exhaustive):

- The dignity, rights, safety and well-being of participants are given priority at all times by research teams.
- Research protocols are worthwhile, of high scientific quality and represent good value for money.
- Research trials meet all relevant standards.
- HHP will maintain a proportionate Quality Management System (QMS) that supports continuous improvement in trial conduct. This includes documenting quality issues, implementing corrective and preventive actions (CAPA), and reviewing quality performance to ensure ongoing compliance with UK Clinical Trial Regulations, ICH GCP, and ICH E6(R3) principles. Trials are conducted in accordance with appropriate regulatory approvals; MHRA clinical trial authorization, Research Ethics Committee (REC) favourable opinion, HRA approval, RDI confirmation of capacity and capability and Sponsor Green-light.
- Amendments to the study or protocol are reported according to the regulatory requirements.
- Notification of the end of trial is in accordance with the regulatory requirements.
- HHP puts and keeps in place arrangements to adhere to the UK CT regulations and GCP.
- HHP keeps records of all serious adverse events reported by investigators.
- HHP ensures the recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARS) to the MHRA and REC.
- HHP ensures that serious adverse events (SAEs), serious adverse reactions (SARs) and SUSARs are reported annually in a Developmental Safety Update Report (DSUR) to the MHRA and REC.
- HHP takes appropriate urgent safety measures with the Chief/Principal Investigator, if necessary.

3.2 HHP RDI department acts on behalf of HHP Trust to ensure that the above requirements are met.

4 Procedure

Sponsorship of CTIMPs represents a significant risk, cost and responsibility to HHP and therefore requires appropriate planning at the earliest opportunity. The protocol and all documentation and procedures associated with it must be developed in detail. Monitoring must be arranged and the monitor involved in the trial set-up. For large multi-site trials, external auditing of the trial systems must be arranged. All investigators must be trained and there must be sufficient financial and staff resources available for safe and effective conduct of the trial. Investigator teams will need to work with the RDI Office on all these matters (see R&D GCP SOP 04 -Trial set-up).

External auditing is an MHRA expectation. Auditors must be independent of Sponsor delivery staff (RDI QA staff). A risk-based audit plan should be developed to identify specific systems or areas and studies to focus on.

The following points lay out the process of requesting sponsorship and obtaining the Sponsor Green-light to start the trial. This is summarised in the flowchart in Appendix 1.

4.1 Sponsorship Request & Verification

4.1.1 All studies requesting sponsorship will complete an online 'sponsorship request form' on the Monday.com platform. This form asks for study details to be submitted. Accuracy of this submission is crucial by the investigator as further automatically generated risk assessments are conducted upon submission of the form. Once the Sponsorship Request Form is received R&D QA will send an email to the Principle Investigator to request copies of the Protocol and any other study related documents as part of the QA Verification.

4.1.2 RDI QA perform a verification on the submitted study to confirm accuracy in the submission (comparing the protocol received with the completed form) alongside the support of (HHP approved) AI tools to complete the review. A sense check is then completed along with ensuring the automatically generated risk score and trial category have been calculated correctly. Completed verification form to be completed by RDI QA and signed off within the department with any mitigating actions that are required and any dialogue necessary between the investigator and the QA team.

4.1.3 RDI QA team, when satisfied and any mitigating actions are to be put in place, generate a sponsorship in principle letter and send to the investigator. Included in the email with be the next steps for them to follow in terms of what needs to happen within the process before Sponsor Greenlight can be issued.

For ALL studies a sponsorship greenlight checklist will be generated on Monday.com (or equivalent paper alternative). The checklist will guide the RDI QA team through the checks required from submission to approval of the Sponsor Greenlight Letter.

4.1.4 Once submission to regulatory bodies (REC/HRA/MHRA) is completed, the investigator will need to wait for the Valid Submission notification and then complete the link on the email to request R&D Capacity and Capability.

4.1.5 Refer to Appendix 1.

4.2 Protocol review and Risk Assessment

4.2.1 The QA Manager (Clinical Trials Monitor or RDI Manager) will review the protocol and Sponsorship Request Form. Specifically for higher risk or medium risk studies, the Protocol Review Checklist (WI 55) and the Study Review Checklist (WI 56) should be completed during the review as well as a downloaded copy of the AI supported information. For all lower risk or nCTIMP studies any related AI support information should be downloaded and saved in the study folder as evidence of the review.

4.2.2 A Sponsor Risk Assessment will be started by the QA Manager or Monitor. The perceived risks associated with delivering the trial will be assessed and documented. Risks will be evaluated such as whether the research question is likely to be answered, whether there are adequate resources and whether the trial is safe and fully funded.

4.2.3 During the protocol review, the Sponsor, CI/PI, and relevant support departments will identify the Critical-to-Quality (CtQ) factors essential to ensuring participant safety, data integrity, and the reliability of trial results. CtQ factors will be documented during the QA Verification and will inform the design of monitoring, data management, vendor oversight, and operational controls

4.2.4 A Quality-by-Design approach will be applied during trial planning. This includes proactively identifying potential operational, safety, and data-related risks and implementing proportionate controls to prevent or mitigate these risks. Where appropriate, Quality Tolerance Limits (QTLs) will be defined and documented.

4.2.5 The Risk Assessment will also be circulated to the CI/PI and all relevant support service departments for review and input. This collaborative review ensures that scientific, operational, data-related, and participant-related risks are fully considered. Where possible, the Risk Assessment will be conducted face-to-face and will be documented by the QA Manager or Monitor.

4.2.6 Part of the Risk Assessment will involve the Sponsor and CI/PI deciding whether the trial is a Type A, B or C trial based on the type of IMP used.

- Type A trial is comparable to the risk of standard medical care.
- Type B trial is somewhat higher than the risk of standard medical care.
- Type C is markedly higher than the risk of standard medical care.

More detail on how to categorise the trial is given in the MRC/DH/MHRA's document 'Risk-adapted approaches to the management of CTIMPs' - MRC/DH/MHRA Joint Project

4.2.7 The Sponsor Risk Assessment Form is Working Instruction 12.

4.2.8 The Sponsorship Request Form and the Risk Assessment will be reviewed and discussed by the RDI Manager, QA Manager and RDI Monitor. In the event of irresolution regarding HHP sponsorship, this could be escalated to the SOG for confirmation of sponsorship if required.

4.2.9 If confirmation of Sponsorship is escalated to the SOG, the applicant will be informed of the outcome. In the event that sponsorship is declined, feedback will be given with an opportunity for the applicant to discuss further with the RDI QA team and SOG.

4.2.10 Please note:

- In the event that sponsorship is declined the CI/PI may be required to engage the University of Hull to sponsor the trial.
- In the event of capacity issues, Sponsorship will always be considered on a case by case basis.. Those employed by the University of Hull may need to have discussions with their employer about sponsorship.

4.2.11 At this point, it will also be discussed if vendor assessments are required for third party organisations such as a Clinical Trials Unit (CTU) who is managing a multi-site trial, an IMP manufacturing/preparation unit, a laboratory or randomisation service external to the Trust. Costs for third party vendors will have to be included in any funding applications.

4.2.12 The CI/PI will be notified by email of any concerns, vendor assessments and changes required.

4.3 Regulatory submissions

4.3.1 Regulatory submissions are all the documents submitted to the; REC for REC favourable opinion, the MHRA for the clinical trial authorisation and the HRA for approval.

4.3.2 If the trial is considered by the Sponsor and CI/PI to fall into the category of a Type A trial and as such involves an IMP or IMPs;

- licensed in the UK or any EU member state to be used according to the licensed indication, dosage and form
- or to be used off-label if the off-label use is established practice and supported by sufficient published evidence and/or guidelines.
  Then the trial can be submitted under the MHRA's Notification Scheme. The Notification Scheme has the advantages that a response will be received from the MHRA within 14 days of submission and there is no fee.

4.3.3 If sponsorship is agreed, the RDI QA Manager or Monitor will need to review all the documents for IRAS combined submission to REC, MHRA and HRA, including all IRAS forms, before the RDI Manager will confirm sponsorship by electronically signing the IRAS form. Refer to *R&D GCP SOP 21 Submissions*.

4.3.4 RDI QA staff will supply templates to the investigator for the PIS, ICF and GP letter.

4.3.5 Investigators must work closely with pharmacy to ensure that the correct labels and Summary of Product Characteristics or Investigator Brochures are submitted for each IMP.

4.3.6 Electronic copies of all documents submitted for combined review and all subsequent correspondence must be emailed to the RDI QA staff upon request in order to be saved in the eTMF.

4.4 Request for Confirmation of Capacity and Capability

4.4.1 Upon receipt of the ***Initial Assessment Letter from the HRA***, a request to RDU C&C should be made to the RDU speciality lead using the following link ; RDU C&C

4.4.2 Ensure that you include the SIP reference as this will be used to direct the study back to RDI QA to continue with the set-up of the study

4.4.3 Once the form is completed and submitted, this will be reviewed by the RDU Lead within 30 Calendar days.

4.5 Sponsor Green-light process

4.5.1 The trial cannot start recruiting before the Sponsor Green-light is sent to the CI/PI.

4.5.2 The following documents and reviews are required before the Sponsor Green-light is issued, the list is not exhaustive and there may be additional requirements for each trial:

- Protocol review and all actions addressed
- PIS, ICF, GP letter, patient invitation letter, advert review and all actions addressed
- Fully completed Sponsorship Request Form
- Fully completed Risk Assessment
- Fully signed Finance Agreement if required
- RDI finance review and sign off
- Approval of all service support departments involved
- Copy of REC, HRA and MHRA submission documents and correspondence received
- CRF and spreadsheet/database review
- Site initiation visit performed by RDI Monitor and all actions addressed
- Fully signed Protocol
- Fully signed CI/PI Sponsor Agreement
- Fully signed Contracts/Agreements with third party organisations (e.g. Lab Agreement with University of Hull labs, Funder Agreement, CTU Contract)
- Assessment of data management systems for data integrity controls, including audit trails, access controls, and validation appropriate to trial risk
- Finalised Data Management Plan
- Documentation of data lifecycle processes to ensure accuracy, completeness, and reliability of trial data
- Significant data/security incidents impacting trial data must be documented, escalated per relevant SOP, and filed in TMF/SSF along with maintenance of a register with computerised systems.
- Finalised Monitoring Plan
- Fully completed Training and Delegation Log
- Current GCP certificates, CVs and Honorary Contracts (if applicable) received for the research team
- Study-specific SAE forms QA checked
- Copies of finalised pharmacy dispensing procedure, prescription and drug accountability log
- REC favourable opinion
- MHRA clinical trial authorisation (CTA)
- HRA approval
- All conditions of approvals completed
- 'Technical Release' check (as part of Sponsor Greenlight checklist)
- RDI confirmation of capacity and capability (RDI C&C)
- Insurance/indemnity in place
- For double-blind trials, un-blinding procedures tested
- Pharmacy in receipt of all regulatory approvals and MHRA letter of non-acceptance and PI response (if applicable)
- Pharmacy Green-light
- Pharmacy final confirmation IMP checked and ready to dispense if not part of green light.
- Final review of Risk Assessment
- **Sponsor Green-light**

4.5.3 If the trial is single or double-blind, it will be necessary to identify and document which trial staff should remain blind to trial medication and which trial staff unblind. This will need to be circulated amongst all trial staff including pharmacy and statisticians prior to Sponsor Green-light. Testing of un-blinding processes will need to occur prior to Sponsor Green-light.

4.5.4 There may be other checks required depending on the trial. A green-light checklist is prepared by RDI QA staff and updated as documents and reviews are completed including the 'technical release review. The checklist template is completed on Monday.com. An equivalent paper version can be found as Working Instruction 05.

4.5.5 The Sponsor Green-light will be issued when RDI are happy that all the green-light checks have been completed.

4.5.6 Sponsor Green-light will be emailed to the CI/PI with the research team, statistician and all service support departments on copy.

4.5.7 If the trial is multi-site, the Sponsor must green-light each site before the site can start recruiting. The Sponsor Green-light process is given in the R&D GCP SOP 18 -Site Initiation of Multi-centre HHP-sponsored CTIMPs.

4.5.8 Any significant issues arising from this process that cannot be resolved with the RDI QA staff and Manager will be referred to SOG for discussion and action. Ultimately decisions where disputes cannot be resolved in this way will reside with the RDI Director (or Chief Medical Officer, as required).

4.5.9 For multi-site trials managed by a Clinical Trials Unit (CTU) or other third-party organisations, the Sponsor will implement a risk-proportionate oversight plan. This will include documented roles and responsibilities, performance metrics, communication pathways, and escalation procedures. All delegated activities must be monitored to ensure they are performed in accordance with the protocol, regulatory requirements, and CtQ factors.

4.5.10 The RDI Office will prepare and negotiate appropriate Contracts/Agreements with any external organisations. Contracts/Agreements should not be signed by the Chief or Principal Investigator prior to review by RDI. Agreement signatories should be parties (institutions or organisations) rather than individuals.

4.5.11 A site initiation visit (SIV) will be carried out by the RDI Monitor with the research staff involved with the trial. A separate SIV will be performed by the Monitor with the clinical trials pharmacy staff. The Monitor prepares the Investigator Site File, Pharmacy Site File and Laboratory Site File (if required) ahead of the visits. The purpose of the SIV is to check that all essential study documents are in place and research/pharmacy staff are trained in study procedures before the study starts. All actions as a result of the SIVs will need to be dealt with. More details on the SIV are in the R&D GCP SOP 15 - Monitoring.

4.5.12 Should the trial involve labs, then a lab monitoring visit will be performed by the RDI Monitor.

4.5.13 If the IMP is supplied by a third party organization, the Regulatory Green-light process described below will be followed, unless otherwise advised by the third party. If the IMP is

obtained from pharmacy stock or pharmacy sourced the Regulatory Green-light is not required.

5 Implementation

Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs.

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Appendix 1:

Flowchart showing the process for requesting sponsorship and Sponsor Green-light for HHP-sponsored clinical trials with CTIMP, Non CTIMP and Medical device studies.

Submit a request for Sponsorship through the Monday.com form (https://forms.monday.com/forms/d1eeba6d790d35559976e0a879edbd1b?r=use1).
↓
RDI QA perform a verification on the submitted study to confirm accuracy in the submission (comparing protocol submitted with the completed form) and sense check the automatically generated risk score and trial category have been calculated correctly. RDI QA Complete the Verification form and sign off within the department with any mitigating actions that are required and any dialogue necessary between the PI/ Research Team and the QA team. Completed Verification form is saved in the trial folder.
↓
RDI QA team, when satisfied that sponsorship of the trial is possible and any mitigating actions are put in place Sponsorship in Principle letter will be generated and sent to the PI / Research Team and the RDU Lead
↓
For **ALL** trials a Sponsorship Greenlight checklist will be generated on Monday.com (or equivalent paper alternative). The checklist will guide the RDI QA team through the checks required prior to submission.
↓
Before submission of the Trial the Principal Investigator will download and send a copy of the IRAS form to QA so that the IRAS Review Checklist (on Monday.com) can be completed. Once this has been reviewed and signed, R&D QA will confirm with the R&D Manager that the trial can be given 'Sponsor Authorisation' to submit. CTIMPs will be submitted to regulatory bodies via Combined Review as per *R&D GCP SOP 21 Submissions.*
↓
Upon receipt of the Valid Submission Letter, the PI / Research Team will make a request to the RDU Lead for Capacity and Capability review via the link - https://forms.monday.com/forms/18de92677cbea7ec1a8f22176d768cdf?r=use1 The C&C review for the study will aim to be completed within 30 calendar days
↓
For non-CTIMPS that receive regulatory approval within 10 days, R&D QA will contact the PI 4 days later to request REC/HRA Approval if not already received. For CTIMPS/Medical Device studies that receive regulatory approval within 30-60 days, R&D QA will contact the PI 4 days later to request Combined Approval (REC/MHRA/HRA) if not already received.
↓
SIV by RDI QA department where thought risk appropriate All issues resolved from SIV.
↓
All sponsor greenlight checks complete Sponsor Greenlight Letter and email sent to be PI / Research Team and RDU Lead to confirm approval to start the study.