Guideline on completion of the Sponsorship Application and Study Assessment

Introduction

According to the UK Policy Framework for Health and Social Care Research 2017, all health and social care research has a sponsor. 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.

UHS is able to act as sponsor for research studies subject to review and approval by the R&D office. In order for UHS NHS FT to provide sponsorship in principle for a research study, the Chief Investigator is required to complete a Sponsorship Application and Study Assessment Form. This provides the R&D Office with information on the considerations which have been made in the development of the protocol in a number of areas to help assess the level of risk to the Trust and how this can be mitigated. Upon review, further assessment may be needed and the CI will be expected to be available to assist.

Conditions of Sponsorship

UHS NHS FT may act as sponsor, subject to the conditions below and the receipt and evaluation of a UHS Sponsorship Request and Study Assessment Form, for research where:

- The study has an experienced Chief Investigator or if an inexperienced Chief Investigator they are willing to be mentored by an experienced UHS (or UoS) Chief Investigator/carry out CI training.

- CI is based in Southampton and is a substantive employee of UHS NHS FT or holds an honorary clinical contract with UHS NHS FT and is a substantive employee of University of Southampton.

- The study is due to be performed in an acute hospital setting and UHS NHS FT is a planned recruitment site.

- The study is a student project where the lead investigator is an employee and/or student of University of Southampton and UHS is a planned recruitment site.

N.B. Supervisors on student projects will need to meet the requirements of substantive employment/honorary contract with UHS NHS FT detailed above.

- CI has demonstrated the ability and resources to support the research, including, but not limited to, that trial management arrangements have been considered.

N.B. Trial management and sponsor oversight may be in the form of a Clinical Trials Unit (CTU)/Clinical Research Organisation (CRO) / trial management team funded in the study budget as appropriate.

- UHS can appropriately indemnify the activities under the NHS Litigation Authority Indemnity Scheme.

N.B. The Trust does not routinely sponsor internationally or enter into co-sponsorship arrangements.

N.B. Sponsor would need to determine in collaboration with the CI if appropriate

insurance cover can be arranged and any additional costs for such insurance cover are covered by the study funding.

- The study has received the appropriate peer review assessed by risk to confirm the scientific robustness and clinical safety of the study. This may be as part of a grant funding application or using the UHS Peer Review form (R&D/Forms028).

- The study has appropriate funding levels for the resources required to conduct the study.

The purpose of this document is to assist in the completion of the Sponsorship Application and Study Assessment Form to avoid confusion and delays.

Section 1

- Please enter the study title,

- Q1 – Proposed start and finish dates. Please be realistic with these dates, taking into account the length of time for obtaining regulatory approvals and study set-up. Please also enter the length of time a patient will be followed up, if no follow-up is required please mark as 0.

- Q2 – Please indicate whether the application is for grant application or whether funding has already been granted. If neither of these options is appropriate then please explain, e.g. No funding secured.

- Q3 – Please indicate if the study is an educational project. NB: Undergraduate student projects are usually sponsored by the University so please contact the appropriate Divisional Research Manager if sponsorship cannot be arranged with the University for any reason.

- Q4 – Please complete the CI details with the best contact information. E.g. If only a soton email account is regularly checked then please put this. If the CI primary employer is not UHS then please indicate whether the CI has an honorary contract with UHS.

- Q5 – Please indicate if the CI will also be PI for the study at UHS. NB this can be the same or different.

- Q6 – No has been answered to Q5, please indicate who the PI will be at UHS if known.

- Q7 – Please indicate whether the study is a Device study, a CTIMP/ATIMP or involves interventional techniques.

- Q8 – Please indicate how many participants it is intended will be recruited to the study and if not patients, staff or healthy volunteers please explain e.g. School children, notes review etc.

- Q9 – Please indicate which UHS resources will be used in the study e.g. clinic rooms, nursing staff etc.

Section 2

- Q10 – Please indicate if the study is in receipt of funding and if not please indicate how the costs of the study will be covered. You will be asked to elaborate in the Study assessment section.

- Q11 – Please indicate what type of organisation is funding the study and what type of peer review has been performed.

  NB: For adoption onto the NIHR portfolio the peer review must be independent and high quality. This means independent of the organisation as well as the study. If in doubt please email sponsor@uhs.nhs.uk for assistance.

- Q12 – Please indicate if the study has been costed by UHS R&D Finance.

- Q13 – Please indicate if funding will cover all delivery activities at UHS and if not please specify how costs will be covered.

- Q14 – If multi-site please indicate if funding is available to support delivery activity at other sites.

- Q15 – Please indicate the type of scientific peer review the study has received.

- Q16 – Please indicate whether the study is single or multi-centre, if the study is multi centre, please complete section 3.

- Q17 – Please specify whether study management involves a CTU or CRO. If a CTU or CRO is involved then please enter the name and contact details. You will be asked to elaborate in the Study Assessment.

Section 3

This section only needs to be completed if the study has more than one site.

- Q18 – Please indicate whether UHS is to be lead site and if not which organisation will be lead site. Please also indicate why the lead site will not be acting as Sponsor.

- Q19 – Please indicate how many sites are to be involved in the study (please do count UHS) and please list the proposed sites and their locations.

Study Assessment

In order to assist with the sponsorship decision, the risks associated with carrying out the protocol and managing the study have to be considered. Please complete the study assessment sections as set out taking into consideration the below points. These points are not exhaustive but should be used to assist you. **Please note, we will work with you to mitigate any risk concerns.**

A: Study Legal and Regulatory Needs

The MHRA is the competent authority in the UK and they are responsible for ensuring the regulations are enforced for certain types of study involving drugs and devices.

- To determine if your drug study needs MHRA approval please refer to the MHRA Algorithm. For drug studies requiring MHRA approval please indicate the MHRA risk category (Appendix 1)
- To determine if your device study needs MHRA approval please refer to the MHRA guidance and speak to your Divisional Research Manager for further assistance.

NB: Applications to the MHRA will incur a fee.

The majority of studies will require a favourable opinion from a Research Ethics Committee. However there are some exceptions so please refer to the Governance Arrangements for Research Ethics Committees (GafREC) for further guidance.

The Health Research Authority is the body that ensures studies are fit to run within the NHS and as such perform an assessment and approval on the majority of studies prior to them being able to open. There are a few studies which do not fall under the HRA and guidance can be found on the HRA website.

The Confidentiality Advisory Group (CAG) are able to set aside the common law duty of confidentiality for medical purposes where it is not possible to use anonymised information and where seeking individual consent is not practicable. Approval of applications will only be considered where anonymised data will not suffice and consent is genuinely not practicable. For guidance please see the IRAS website.

UHS does not normally sponsor studies that require additional insurance outside of NHS indemnity e.g. non UK sites, pathogen challenge studies. If your study has non-UK sites or has an unusual design which may mean it falls outside the NHS indemnity scheme then please discuss with your Divisional Research Manager in the first instance as UHS may not be able to act as Sponsor.

B: Local Alignment

If the study involves a drug then the protocol will need to have been considered by clinical trials pharmacy. Please indicate if this has been the case and who your point of contact was for this.

If the study involves the use of any equipment being supplied to the Trust or devices being used in the study then the Medical Equipment Management Service should be contacted and are able to advise on supply and maintenance arrangements. Please indicate if this has been the case and who your point of contact was for this.

If the study involves imaging for research purposes then the appropriate department should have been involved in advising on the protocol. Please indicate if this has been the case and who your point of contact was for this.

If the study involves any other clinical services performing activities for research purposes in the Trust such as pathology and microbiology etc then they should be involved in protocol development. Please indicate if this has been the case and who your point of contact was for this.

If the study is being carried out on inpatient wards then please indicate which wards and if you have been in contact with the ward matron please give contact details.

C: Investigator Team

Please give an indication of the number of studies for which you have acted as CI and what category these were i.e. CTIMP/ATIMP, Device, Novel Intervention, Observational. Please indicate how many of these were multi-site studies i.e. where more than one NHS organisation was recruiting participants.

Please give an indication of the number of studies for which you have acted as PI and what category these were i.e. CTIMP/ATIMP, Device, Novel Intervention, Observational.

D: Research Team

Consideration should be made as to how the study will be delivered and what type of support might be required. Please indicate if any discussions have happened with the research nursing teams as to whether research nurses, clinical coordinators or clinical trials assistants will be needed to help deliver the protocol. Please indicate who was involved in these discussions.

Please consider whether there are any special techniques, procedures or indications that staff will require training in.
Please consider how the study team will be made aware of adverse event reporting requirements and procedures and how staff will be kept updated with amendments and new information on the study or intervention.

E: Science Design

Studies to be considered for sponsorship by UHS must have undergone peer review, either as a standalone process or as part of the funding application. If the peer reviewers have made comments then these should have been taken into consideration before submission of the protocol for sponsorship review.

In order to ensure the study is able to definitively answer the research question and achieve its outcomes it is important that consideration has been made to the statistical aspects of the study. This will include power calculations, analysis plan and sample size calculations. Please indicate if there been a statistician involved in the study design.

In order to deliver the study efficiently and ensure that funding flows to the appropriate recipients, it is important that there is a distinction between what is the standard patient pathway and what is additional research activity. Please indicate if this has been taken into account when designing the protocol and ensure it is clear in the protocol where the research pathway differs from that of standard care.

F: Patient Safety Design

The protocol should clearly state how potential participants are to be identified, together with the inclusion and exclusion criteria. Please indicate whether informed consent will be received from the potential participants and if not please explain why.

Some interventions require close monitoring of participants for safety reasons e.g. 15 minute observations. Please indicate if any additional safety monitoring procedures over standard care are required. Please give details or refer to the section in the protocol where these procedures are documented.

Some interventions, particularly early phase studies, have additional safety precautions that need to be in place for the study to be delivered e.g. emergency resuscitation equipment, notification of high dependency units, specialist personal protective equipment. Please indicate if any additional safety precautions are required. *NB: This can be for patients or staff. Please give details or refer to the section in the protocol where these precautions are documented.*

Participant safety is one of the most important aspects of clinical research and therefore needs to be closely monitored. One of the main mechanisms for ensuring safety data is considered is to convene a safety/oversight committee. This committee should include a chair who is independent not only of the study but also of the institution. Please indicate if such a committee has been convened or is planned. Please indicate if a chair has been identified and how often the committee is likely to meet.

G: Patient Group Design

The recruitment process for participants should be clearly set out in the protocol, including how potential participants will be identified. Please indicate how long it is planned that recruitment onto the study will take.

Please indicate if the participants are considered to be a rare patient group. A rare disease in Europe is defined by EURORDIS as a disease affecting less than 1 in 2,000 citizens. The NIHR considers a very rare disease as one that affects less than 1 in 100,000 of the general population. Please indicate the incidence of the disease area being studied.

Please indicate if you are planning to recruit participants who are unable to consent for themselves. If you are including this group of participants then please be aware that the condition you are studying must be related to the reason why the participants lack capacity e.g. a dementia study or critical care study. Please ensure that the protocol sets out the procedure for assessing capacity and for gaining consent if the participant regains capacity prior to the end of the study. The protocol should also document the recruitment procedure this group of participants.

H: Management and Monitoring

Studies sponsored by UHS need to be managed appropriately and, as Sponsor, UHS delegate a number of duties to the CI and study teams. It is therefore important that someone is identified who will take on the management/coordination of the study. For simple studies it could be the CI themselves, a research fellow, a research nurse or CTA. Please indicate if a person has been identified and if they have please provide their contact details. If no dedicated resource has been identified then please indicate how the study will be managed.

For more complex studies, and especially for multi-centre studies and early phase studies, a more specialised and dedicated resource for managing/coordinating the study will be needed. This is usually in the form of a clinical trials unit or a clinical trials organisation. These organisations do require specific funding and so this should have been considered when applying for funding for the study. If a CTU/CRO has been identified please provide contact details. If a CTU/CRO has not been identified then please discuss with your Divisional Research Manager in the first instance.

Please indicate how much time the CI can dedicate to the study in work time

equivalent (e.g. 1 day per week is 0.2WTE). It is important that the CI can demonstrate oversight of the study as a whole and if the study is multi-site then they need to be able to demonstrate oversight of the associated PIs at the other sites in addition. This oversight is not without its time commitment and therefore the CI needs to be able to dedicate the time needed to the study.

To ensure that the study is causing no harm to participants' safety monitoring/reporting is an essential part of study activity. Reporting time frames must be adhered to according to the leglisation, therefore please indicate who will responsible for safety reporting/monitoring. Please indicate if UHS sponsor team or an external organisation will be expected to conduct this. Please provide contact details.

In order to ensure the study is running smoothly, according to the legislation and the protocol, monitoring of the study may be required during its lifetime. Monitoring ensures any problems are picked up quickly and actioned appropriately and is one of the mechanisms by which the Sponsor can demonstrate oversight of both patient safety and data quality. A monitoring plan will usually be produced based on the inherent risks of the study but may require specialist monitors e.g. for early phase studies, or more intense monitoring e.g. for a multi-site CTIMP study. Please indicate if monitoring will be provided by an external organisation or will be expected of the UHS Sponsor team. Please provide contact details.

Studies usually generate a lot of data in order to answer the research question and to monitor patient safety throughout the study. To enable the efficient and effective analysis of that data a data management plan can help. There are a number of ways in which data can be managed, including electronic databases and eCRFs and dedicated data managers. The more complex a study the more important it is to have plans in place to manage the volume of data generated by the study and to ensure that it is accurate and clear. Please indicate if a data management plan is in place or is planned and if not please indicate how data will be managed. E.g. for a simple questionnaire study this may be a member of the study team collating the questionnaires and manually checking them for completeness.

I: Finance

It is the expectation of UHS as sponsor that every effort will be made to have every eligible study adopted onto the NIHR portfolio. Please speak to your Divisional Research Manager if you need assistance with this. If the study is adopted onto the NIHR portfolio then service support costs are made available to the Trusts recruiting patients. This funding is to support the recruitment process and patient safety. Therefore, if the study is not on the NIHR portfolio the study support costs will need to be covered by other means. Please indicate how these costs will be covered.

Some studies can generate Excess Treatment Costs. In simple terms these are costs that would be incurred if the treatment or intervention became standard care. They are covered by the Care Commissioning Groups and have to be applied for in advance of study opening. Please indicate if you believe your study will incur these costs and if you are not sure please discuss with your Divisional Research Manager.

N.B. All financial implications must be considered and agreed before study start and may require approval from the R&D Steering Group.

J: Third party arrangements

All external arrangements for IMP supply, equipment supply or movement of tissue and data must be in place prior to study start and it is therefore key to identify these as early as possible so any contract negotiation does not delay study opening.

For studies involving drug and/or devices, a supplier of these products needs to be identified. Please indicate if you have identified a supplier and the contact details of the person you have been in communication with. If a supplier has not yet been identified, please contact Sponsor@uhs.nhs.uk for assistance

If other supplies are needed for the study then please do make a note of this here and if any suppliers have been identified.

Whilst the UHS sponsor team will identify agreements that need to be in place regarding the supply and control of drug and/or devices that are the subject of the study, there are other external agreements that may need to be in place.

Please indicate if any equipment is being loaned or given to the Trust by a third party. Please answer no if UHS is purchasing the equipment.

Please indicate if tissue and/or data is being imported or exported outside of the NHS. This can be for any purpose but may need to be detailed in an agreement.

Submission

Once you have completed your Sponsorship application and Study Assessment form please return it, together with your protocol (version controlled), peer reviews (unless performed by funder) and funding letter, to sponsor@uhs.nhs.uk and one of the Divisional Research Managers will be in contact with you.

If you have any questions or queries or are struggling with the forms then please email sponsor@uhs.nhs.uk for assistance.

Appendix 1

Taken from the MHRA Guidance

Trial Categories based upon the potential risk associated with the IMP	**Examples of types of clinical trials**
Type A: no higher than that of standard medical care	Trials involving medicinal products licensed in any EU Member State if: • they relate to the licensed range of indications, dosage and form or, they involve off-label use (such as in paediatrics and in oncology etc) if this off-label use is established practice and supported by sufficient published evidence and/or guidelines
Type B: somewhat higher than that of standard medical care	Trials involving medicinal products licensed in any EU Member State if: • such products are used for a new indication (different patient population/disease group) or • substantial dosage modifications are made for the licensed indication or • if they are used in combinations for which interactions are suspected Trials involving medicinal products not licensed in any EU Member State if • the active substance is part of a medicinal product licensed in the EU (A grading of TYPE A may be justified if there is extensive clinical experience with the product and no reason to suspect a different safety profile in the trial population)*
Type C: markedly higher than that of standard medical care	Trials involving a medicinal product not licensed in any EU Member State (A grading other than TYPE C may be justified if there is extensive class data or pre-clinical and clinical evidence)*

*If a grading other than those indicated is felt to be justified the rationale and evidence should be presented in the CTA application