

Standard Operating Procedure

RESEARCH CONTRACTS AND VENDOR SELECTION

- SETTING** Trustwide
- AUDIENCE** Research & Innovation (R&I) staff involved in setting up and conducting research sponsored by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW). Research staff to note.
- ISSUE** Contractual arrangements and the process for selection of third party vendors to conduct research activities for research sponsored by UHBW.
- QUERIES** Contact R&I department : Ext 20233 or research@uhbw.nhs.uk

Document History

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Review date	Version number	Version date	Effective date	Author/Reviewer	Authorised by
-	1.0	19/OCT/15	03/NOV/15	Jake Harley	Diana Benton
November 2016	1.1	25/NOV/16	12/DEC/16	Jess Bisset	Diana Benton
December 2017	1.2	22/DEC/17	20/FEB/18	Elinor Griffiths	Jess Bisset
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January 2021	2.0	13/JAN/2021	22/NOV/21	Katharine Wale	Diana Benton

Version Number	Reason for change
Original V1.0	N/A – original
1.1	Minor updates and clarifications
1.2	Annual review. Funding agreements section added.
1.3	Clarifications on collaboration agreements and signatories. Other minor updates as part of biennial review.
2.0	Major update to vendor selection section and minor clarifications.

1. Introduction

Research may require different contractual arrangements to be put in place between the organisations involved in the sponsorship, funding, management and delivery of a study, depending on the study type and the research activities being undertaken.

2. Purpose

The purpose of this document is to describe the type of contracts UHBW will use when acting as sponsor for research and the process by which third party vendors will be selected to undertake any contracted research related activities.

3. Scope

In Scope: UHBW sponsored research or where UHBW holds the funding.

Out scope: Research sponsored by organisations other than UHBW.

4. Responsibilities

R&I are responsible for identifying and selecting suitable vendors to carry out research related activities on behalf of UHBW.

R&I are responsible for ensuring that appropriate contractual arrangements are put in place with other organisations as required.

5. Abbreviations and Definitions

Abbreviations	
MTA	Material Transfer Agreement
mNCA	Model non-commercial agreement
NBT	North Bristol NHS Trust
NHS	National Health Service
NIHR	National Institute for Health Research
R&I	Research & Innovation department
SLA	Service Level Agreement
SOP	Standard Operating Procedure
STA	Single Tender Action
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UoB	University of Bristol
Definitions	
Collaborator	An institution (e.g. hospital or university) whose employees are collaborating on a project and/or are co-applicant on a grant application
Vendor	An organisation to which research-related activities have been contracted or sub-contracted, other than other NHS Trusts recruiting patients which should be considered research sites.

6. Procedure

6.1 Contractual Arrangements (other than funding agreements)

- For all research sponsored by UHBW, an assessment will be made in R&I as to what type of contracts and agreements will be required with the other organisations involved in the study, including but not limited to:
 - Site agreements, with other NHS organisations recruiting patients into the study
 - Collaboration Agreements

- Material Transfer Agreements (MTA)
 - Data sharing agreements
 - Service Level Agreements (SLA)
 - Confidentiality Agreements
 - Supplier contracts
- Where possible UHBW will utilise national templates and guidance for contractual arrangements for research (<http://www.ukcrc.org/regulation-governance/model-agreements/>), for example the model non-commercial agreement (mNCA) developed by the UK Clinical Research Collaboration.
 - Where national templates do not exist, UHBW has developed a suite of template agreements which will be used and adapted as required:
 - TMPL_049- UHBW Service Level Agreement Template
 - TMPL_042 UHBW Material Transfer Agreement Template
 - TMPL_051 UHBW Amendment to Contract Template
 - TMPL_052 UHBW Confidential Disclosure Agreement Template
 - TMPL_053 UHBW template for research collaboration agreements where funding has been provided by NIHR or partner charity.
 - In instances where a template for a particular agreement does not exist or the other party to the agreement is unwilling to accept the relevant UHBW template, UHBW may review a template provided by another organisation.
 - Any amendments requested from other organisations to national or UHBW templates will be reviewed and agreed within R&I, with a further legal review on behalf of UHBW if appropriate. R&I will request this further legal review using either the UHBW legal department or appropriate personnel contracted to UHBW to carry out this activity.
 - Where existing overarching research agreements exist between UHBW and its partner organisations, study specific research contracts may not be required. These will be assessed on a case by case basis.
 - UHBW's existing overarching agreements are listed below; a process of regular review of these documents is in place:
 - Framework Agreement, NBT, original dated 7th August 2013 (reviewed annually)
 - Service Level Agreement, UoB, original dated 24th July 2012 (reviewed annually)
 - Framework Agreement for Collaborative Research, UoB, original dated 14th October 2014 (reviewed every 5 years or sooner if required)
 - Where research is being funded by an external body, e.g. the NIHR or a charity, no work will start on that project until the appropriate agreement is in place with the funder.
 - Where agreements are needed with collaborators or subcontractors for an externally funded study, every effort will be made to ensure these are in place before the study commences. However, in reality these are often signed at a later date due to the volume of contracts organisations have to review. If the collaborator is a partner organisation we have worked with before, and is listed as one of our preferred providers (in GD_021), then we agree on a case by case basis with that partner organisation whether the study can start before contracts have been finalised, and taking into account the level of risk. .
 - The majority of research agreements and contracts will be signed by appropriate personnel in R&I on behalf of UHBW in accordance with UHBW's standing financial instructions, delegation of authority and budget managers responsibilities. There may be exceptions to this where a signature is delegated by R&I to a CI for example to sign on UHBW's behalf as sponsor. The reason for the exception would be fully documented.

- In some circumstances UHBW R&I may sign the agreement and also request that the CI acknowledge/confirm they have read the agreement e.g. Pharmacy Technical Agreements.

6.2 Vendor selection

- As sponsor UHBW may be required to delegate certain research related activities to other organisations.
- R&I will assess the suitability of a vendor, to ensure that the vendor can perform the services to applicable standards and regulations prior to signing the research contract. This does not apply to academic/NHS collaborations.
- A variety of assessment methods will be used when assessing the suitability of a vendor, including but not limited to:
 - Assessment of expertise
 - Prior experience of working with the vendor
 - Pre-qualification questionnaires (in accordance with UHBW's Procurement processes)
 - Obtaining appropriate references where applicable
 - Assessment of the vendor's quality system and/or written procedures
 - Cost/budget
- The type of assessment undertaken will be determined on a case by case basis and will follow UHBW procurement processes where applicable, identifying if a Single Tender Action (STA) is required. The process of assessment and selection decision will be clearly documented.
- Some services may already be provided for UHBW by external organisations in the clinical setting. Where this is the case, a separate assessment of suitability may not be required for the same organisation to provide the same services for research purposes.
- A list of vendors who have previously provided research services will be maintained by the R&I department. Accompanying this will be a list of vendors who have met the defined assessment criteria. These lists will be used by UHBW for future vendor selection. Full reassessment will not be required unless the vendor is offering different services or has changed its SOPs significantly. New vendors may also be approached.
- If the cost of the services to be contracted with an organisation is £5000 or greater, the process described in UHBW Standing Financial Instructions and Scheme of Delegation SOP and Single Tender Action (STA) Requests SOP (if only one appropriate supplier) must be followed (these are available on UHBW intranet).

6.3 Funding agreements

- In many cases UHBW sponsored research will be the result of a grant application to an external funder, usually the NIHR or a partner charity.
- The funder will have either a contract or terms and conditions that need to be adhered to or in some cases negotiated before UHBW can accept.
- R&I will lead on agreeing the funding contracts and terms and conditions, with appropriate legal or specialist input, for example around exploitation terms.
- NIHR grants will require sign off by R&I as described in 6.1 above, or for non-NIHR grants by an appropriate Divisional representative.

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. Related documents

RELATED DOCUMENTS AND PAGES	<ul style="list-style-type: none"> • Medicines and Healthcare products Regulatory Authority (MHRA), 2012. Good Clinical Practice Guide. 4th impression (2015). TSO (The Stationery Office). • SOP_002 Research Sponsorship at UHBW • SOP_007 Research Training • TMPL_049 UHBW Service Level Agreement Template • TMPL_-42 UHBW Material Transfer Agreement Template • TMPL_051 UHBW Amendment to Contract Template • TMPL_052 UHBW Confidential Disclosure Agreement Template • TMPL_053 UHBW template for research collaboration agreements where funding has been provided by NIHR or partner charity. • GD_001 Gaining & Maintaining Authorisations UHBW • GD_021 Preferred Providers: Vendor Selection • Standing Financial Instructions https://www.england.nhs.uk/publication/standing-financial-instructions/ • The Public Contract Regulations 2015 https://www.legislation.gov.uk/ukxi/2015/102/contents/made
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Innovation department on 0117 342 9873 or email research@uhbw.nhs.uk