Standard Operating Procedure

# RESEARCH CONTRACTS AND VENDOR SELECTION

**SETTING** Trustwide

**AUDIENCE** Research & Development (R&D) 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&D department via research@uhbw.nhs.uk

**Document History**

| | | | |
|---|---|---|---|
| **SOP number** | SOP 016 | **SOP Version** | 4.0 |
| **Effective Date** | 28/APR/2026 | **Review Date** | 28/APR/2028 |

| Review date | Version number | Version date | Effective date | Author/ Reviewer | Authorised by |
|---|---|---|---|---|---|
| - | 1.0 | 19/OCT/2015 | 03/NOV/2015 | Jake Harley | Diana Benton |
| NOV/2016 | 1.1 | 25/NOV/2016 | 12/DEC/2016 | Jess Bisset | Diana Benton |
| DEC/2017 | 1.2 | 22/DEC/2017 | 20/FEB/2018 | Elinor Griffiths | Jess Bisset |
| SEP/2020 | 1.3 | 14/SEP/2020 | 16/SEP/2020 | Elinor Griffiths/Jess Bisset | Jake Harley |
| JAN/2021 | 2.0 | 13/JAN/2021 | 22/NOV/2021 | Katharine Wale | Diana Benton |
| FEB/2023 | 2.1 | 16/FEB/2023 | 01/APR/2023 | Lucy Riddolls | Elinor Griffiths |
| SEP/2023 | 3.0 | 27/SEP/2023 | 23/NOV/2023 | Elinor Griffiths | Diana Benton |
| SEP/2025 | 3.1 | 29/SEP/2025 | 30/SEP/2025 | Elinor Griffiths<br>Sarah Bishop | Jess Bisset |
| DEC/2025 | 4.0 | 20/JAN/2026 | 28/APR/2026 | Sarah Bishop<br>Margie Pavey | Diana Benton (on behalf of TRG) |

| 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. |
| 2.1 | Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment. |
| 3.0 | Biennial review. Major update due to clarification of collaboration agreements and addition to vendor selection assessment criteria. Also some other minor clarifications and updates in line with Trust SOP template. |
| 3.1 | Minor updates and clarifications as part of biennial review. |
| 4.0 | Major update to align with Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 and further clarification on collaboration agreements. |

## 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.

The sponsor may delegate a number of sponsor functions to external vendors but retains ultimate responsibility for the trial. Therefore, it is important to ensure that oversight is maintained of all vendors.

Vendor oversight begins with the assessment and selection of a suitable vendor. The sponsor should implement processes for the assessment of any vendors to be used, prior to the signing of contacts.

## 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 of scope:** Research sponsored by organisations other than UHBW.

## 4. Responsibilities

R&D are responsible for identifying and selecting suitable external vendors to carry out research related activities on behalf of UHBW.R&D are responsible for ensuring that appropriate contractual arrangements are put in place with other organisations as required.

## 5. Abbreviations and Definitions

| Abbreviations | |
|---|---|
| **BHP** | Bristol Health Partners |
| **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&D** | Research & Development department |
| **SFI** | Standing Financial Instructions |
| **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 locations . |

## 6. Procedure

### 6.1 Contractual Arrangements (other than funding agreements)

- For all research sponsored by UHBW, an assessment should be made in R&D as to what type of contracts and agreements are 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 should 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 should 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

A template NIHR collaboration agreement, based on one used for NIHR grants is available as a starting point for contracts with other funders. This template, has been developed between organisations in Bristol Health Partners (BHP), is owned and regularly maintained by the BHP contracts group and so it sits outside the R&D Quality Management System. The UHBW R&D contracts advisor is a member of this group and updates the latest version of the template with input and agreement from other members of the BHP contracts group. The template includes optional sections that are used or removed depending on the nature of the work included in the agreement.

- 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 should be reviewed and agreed within R&D, with a further legal review on behalf of UHBW if appropriate. R&D should 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 should be assessed on a case-by-case basis.
- UHBW's existing long term 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 should start on that project until the appropriate agreement is in place with the funder. If the funder is delayed issuing a contract, there must be agreement from the relevant UHBW finance manager to start before contracts have been issued. To note in these instances once issued the contract will be backdated.
- Where agreements are needed with collaborators or subcontractors for an externally funded study, every effort should be made to ensure these are in place before the study commences. However, 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 agreement is reached on a case-by-case basis with that partner organisation whether the study can start before contracts have been finalised. Additionally, if the new collaborator is employed by a UK university or NHS organisation, or Trials centre based in a UK university R&D might agree to commence the study before contracts are in place after assessing any risk.

- Most research agreements and contracts should be signed by appropriate personnel in R&D 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&D 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&D may sign the agreement and 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 sponsor functions to other organisations.
- For the avoidance of doubt the functions of the sponsor include functions in relation to:

  (i) the development and maintenance of trial specific computerised systems, and

  (ii) the selection and oversight of a laboratory in relation to the analysis or evaluation of human samples collected as part of the clinical trial. (Part 4 Regulation 28 Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025)

- R&D should 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 should be used when assessing the suitability of a vendor, including but not limited to:

    - Assessment of expertise
    - Prior experience of working with the vendor
    - Recommendation from a member of BHP that has direct experience working with that vendor and has undertaken an assessment
    - 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 should be determined on a case-by-case basis and should follow UHBW procurement processes where applicable, identifying if a Single Tender Action (STA) is required. The process of assessment and selection decision should 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 should be maintained by the R&D department. Accompanying this should 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 exceeds a certain amount as defined in UHBW Standing Financial Instructions (SFIs), the process described in UHBW SFI 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 is the result of a grant application to an external funder, usually the NIHR or a partner charity.
- The funder should have either a contract or terms and conditions that need to be adhered to or in some cases negotiated before UHBW can accept.
- R&D should lead on agreeing the funding contracts and terms and conditions, with appropriate legal, financial or specialist input, for example around exploitation terms.
- NIHR grants require sign off by R&D including R&D finance 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 should be disseminated to applicable research staff (including R&D) and will be available on the R&D website.

| **Plan Elements** | **Plan Details** |
|---|---|
| **The Dissemination Lead is:** | Research Operations Manager |
| **Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:** | A – replacing the same titled, expired SOP |
| **If answer above is B: Alternative documentation this SOP will replace (if applicable):** | N/A |
| **This document is to be disseminated to:** | All applicable research staff (including R&D) |
| **Method of dissemination:** | For major updates to the SOP dissemination will be:<br><br>1. To Chief Investigators of UHBW Sponsored CTIMPs<br>2. Research Unit leads across UHBW<br>3. Head of Research Governance at UoB (where SOP is applicable)<br><br>All updates (major and minor to the SOP) will be:<br><br>1. Updated on the trust MyStaff App<br>2. Updated on the R&D website |

| | |
|---|---|
| | 3. Cascaded inR&D communications |
| **Is Training required:** | 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 UHBW* |

| | |
|---|---|
| **RELATED DOCUMENTS AND PAGES** | • Medicines and Healthcare products Regulatory Authority (MHRA), 2012. Good Clinical Practice Guide. 4th impression (2015). TSO (The Stationery Office).<br>• SOP_002 Research Sponsorship at UHBW<br>• SOP_007 Research Training<br>• TMPL_049 UHBW Service Level Agreement Template<br>• TMPL_042 UHBW Material Transfer Agreement Template<br>• TMPL_051 UHBW Amendment to Contract Template<br>• TMPL_052 UHBW Confidential Disclosure Agreement Template<br>• GD_001 Gaining & Maintaining Authorisations UHBW<br>• GD_021 Preferred Providers: Vendor Selection<br>• Standing Financial Instructions https://www.england.nhs.uk/publication/standing-financial-instructions/<br>• The Public Contract Regulations 2015 https://www.legislation.gov.uk/uksi/2015/102/contents/made |
| **AUTHORISING BODY** | Trust Research Group |
| **SAFETY** | N/A |
| **QUERIES AND CONTACT** | Research & Development department via email: research@uhbw.nhs.uk |
| | |

| | |
|---|---|
| **AUDIT REQUIREMENTS** | R&D departmental Quality Management System audits are undertaken annually. |