Standard Operating Procedure (SOP)

# RESEARCH SPONSORSHIP AT UHBW

**SETTING** Trustwide

**FOR STAFF** Research staff including Chief Investigators (CI) and Principal Investigators (PI) and those involved in study design and co-ordination for studies requesting sponsorship by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

**ISSUE** To describe the process for applying, authorising and retaining UHBW sponsorship for research studies.

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| **SOP number** | SOP 002 | **SOP Version** | 5.0 |
| **Effective Date** | 14/NOV/2024 | **Review Date** | 14/NOV/2026 |

**Document History**

| 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 |
| V3.0 | Updated in line with new SOP template |
| V3.1 | Minor updates and clarifications as part of biennial review. |
| V4.0 | Major updates in line with regulatory changes taking effect from 1 January 2021 after end of the EU transition period and clarifications |
| V4.1 | Minor updates to remove reference to UHBW update to section 6.2.2.1 to clarify sponsor process for CTIMPs and other minor corrections. |
| V4.2 | Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment. |
| V5.0 | Major revision to sponsorship process to include new processes for non CTIMPs, expand on existing processes and to provide timelines. |

| Review date | Version number | Version date | Effective date | Author/ Reviewer | Authorised by |
|---|---|---|---|---|---|
| N/A | V1.0 | 21/DEC/2015 | 03/NOV/2015 | Diana Benton | Diana Benton |
| 13/MAY/2016 | V2.0 | 07/APR/2016 | 13/MAY/2016 | Jess Bisset | Diana Benton |
| NOV/2016 | V2.1 | 23/DEC/2016 | 17/JAN/2017 | Jess Bisset | Diana Benton |
| 23/NOV/2017 | V3.0 | 22/JAN/2018 | 14/FEB/2018 | Trusha Rajgor & Jess Bisset | Diana Benton |
| SEPT/2020 | V3.1 | 21/JUL/2020 | 21/SEP/2020 | Elinor Griffiths, Katharine Wale & Sarah Bishop | Jess Bisset |
| JAN/2021 | V4.0 | 13/JAN/2021 | 22/NOV/2021 | Katharine Wale | Diana Benton |
| JUL/2022 | V4.1 | 27/JUL/2022 | 27/JUL/2022 | Jess Bisset | Elinor Griffiths |
| FEB/2023 | V4.2 | 15/FEB/2023 | 01/APR/2023 | Lucy Riddolls | Jessica Bisset |

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| JULY 2024 | V5.0 | 01/AUG/2024 | 14/NOV/2024 | Sandra Mulligan<br>Jess Bisset | Diana Benton |

## 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 (2012) 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 UHBW sponsorship in order to ensure that UHBW sponsorship requirements are and continue to be met throughout the duration of the research.

## 3. Scope

**In Scope:** UHBW sponsored research.
**Out of scope:** Research sponsored by other organisations.

## 4. Responsibilities

The Chief Investigator is responsible for applying to UHBW 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), Research Management Team Leader 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 |
| **CIMD** | Clinical Investigation of a Medical Device |
| **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 |
| **PI** | Principal Investigator |
| **PoC** | Point of Contact |
| **REC** | Research Ethics Committee |
| **RMF** | Research Management Facilitator |
| **RMO** | Research Management Office |
| **RPM** | Research Projects Manager |
| **RSS** | Research Support Services |
| **SMT** | Senior Management Team (R&D) |
| **SoECAT** | Schedule of Events Cost Attribution Template |
| **SOP** | Standard Operating Procedure |
| **UKPF** | UK Policy Framework for Health & Social Care |
| **UHBW** | University Hospitals Bristol & Weston NHS Foundation Trust |

| 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 UHBW sponsorship

- The substantive employer of the CI usually takes on the role of sponsor. For clinical research, it may be appropriate for UHBW to sponsor a study led by clinical academics practising in UHBW who 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 UHBW, it is reviewed to determine whether UHBW is the most appropriate sponsor.
- Prior to applying for UHBW 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 and grant submission through UHBW*, *SOP_004 Writing a Research Protocol to Good Clinical Practice* UHBW and to the R&D website for more information.

- In order to apply for sponsorship, researchers should complete the appropriate *TMPL_003a or TMPL_003b "Request for UHBW to be Research Sponsor" form* and submit it with a copy of the draft study protocol or research proposal via e-mail to R&DSponsorship@uhbw.nhs.uk.
- On receipt of a sponsorship application the WI_007 *Work Instruction for sponsorship requests received into the R&DSponsorship inbox* will be followed.
- Where sponsorship has already been discussed as part of grant submission, e.g. for NIHR, upon notification of award, the UHBW Grants Manager will complete the sponsorship form and send by email to R&DSponsorship to trigger the Sponsorship process; copying in the CI and other relevant study contact(s) and highlighting any risks identified. The Grants Manager or Research Projects Manager will bring the study to SMT. The process will then bbe the same as for other sponsorships.
- Completed forms will be discussed at the weekly R&D Senior Management Team (SMT) meeting in order to assess whether it is appropriate for UHBW 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 UHBW is not the most appropriate sponsor, the UHBW R&D 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 UHBW R&D will lead on:
  (i) Agreement that UHBW 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 UHBW to sponsor the research, members of SMT will complete the following during the meeting:
- the initial risk assessment as part of the sponsorship form, including whether a further full risk assessment is required. For CTIMPs this is always a requirement and TMPL_006 Risk Assessment will be used, for non CTIMPs this is agreed on a case by case basis. If it is required, then TMPL_016 non CTIMP risk assessment is used).
- Decide who the study should be allocated to within the R&D department as sponsor representative. This decision is based on study type and what may require more senior oversight. CTIMPs, Clinical Investigations of Medical Devices (CIMDs) or complex interventional trials will be allocated to the Research Projects Manager (Sponsored trials) (RPM).
- Decide whether a Study Set Up and Management Plan will require completion using TMPL_007 UHBW Sponsor Set Up and Management Plan or TMPL_122 UHBW SUMP non CTIMP-CIMD
- Decide whether TMPL_041 Template Data Management Plan or TMPL_131 Template Abridged Data Management Plan require completion.

A member of SMT will then email the R&D Sponsorship inbox confirming their decision and attaching the risk assessment as required. If the study is to be allocated to the RPM, the Research Operations Manager will liaise directly with the RPM. If the study is to be allocated to another member of the R&D department (e.g. a Research Management Facilitator (RMF) or RMF Team Leader) the Research Projects Assistant will pick up the email from SMT in the sponsorship inbox and liaise with the RMF Team leader to allocate the study accordingly.

Of note, in some instances it may be necessary for a member of SMT to liaise with the researcher if any aspects of the application are unclear before a decision can be made by SMT whether the study is able to proceed through sponsorship.

- Once agreed to take through sponsorship and within 7 days from the date of the SMT meeting the sponsor representative (RMF or RPM) from R&D willintroduce themselves andwill send the researcher an email containing the following information:
  - Confirmation that a study record has been created on the EDGE research management system.
  - The R&D 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 SMT review.

The sponsor representative will follow up with a more detailed email with specific queries relating to sponsor review within 14 days of being allocated the study.

### 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 provide a current copy of their CV and GCP certificate 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 and grant submission through UHBW*.

**Evidence of funding** If UHBW did not sign off the grant submission or where there is no external funding the following need to be provided:

- A copy of the funding award letter (if applicable) to provide 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 funded 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, plus a copy of the SoECAT if one was submitted with the grant application. 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 Research Delivery Network for NIHR portfolio studies (from October 2024), or via the funder (e.g. 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.nihr.ac.uk/documents/eligibility-criteria-for-nihr-clinical-research-network-support-for-commercial-studies/11635

**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. This will normally have been received by the Research Grants Manager, and saved in the study folder. The RMF should check before requesting this from the researcher.
- If the study has not been reviewed by an external funder, then R&D SMT will decide on the level of peer review necessary and document on the sponsorsip form, and the RMF/RPM will arrange for this as part of the sponsorship process. Note that any concerns of reviewer(s) will need to be addressed prior to agreeing to sponsor.
    - The RMF, RMF Team Leader or RPM will refer to *WI_006 Work Instruction for RMF Peer Review* for guidance.
    - The RMF, RMF Team Leader or RPM will contact the researcher and ask them to suggest reviewers to peer review the research proposal after checking whether any potential reviewers have been identified on the Sponsor request form. The reviewers should be independent and an expert in the research field of interest.
    - The RMF, RMF Team Leader 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 UHBW and at other sites (if relevant)**

- For studies participating at UHBW, 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 UHBW* for further information on this process.
- For multicentre studies, the CI should confirm that sites are able to recruit the target number of patients, comply with the protocol and recruit to time and target. 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 past and current numbers of potentially eligible patients to ensure recruitment can be achieved. The CI should also ascertain whether 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 as set out in the legislation and applicable guidelines.
- As sponsor, UHBW 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&D website.

### 6.2.1 The review process

- Once the documents to agree sponsorship (section 6.2) have been received, the allocated RMF, RMF Team Leader or RPM will carry out the sponsorship assessment using *TMPL_116 Sponsorship tracker and guidance* (as applicable) and will review capability and capacity to deliver the research at UHBW site.
- 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 if applicable the study should be flagged for monitoring under the *SOP_010 Monitoring and Oversight of Research Activity UHBW.*

### 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 UHBW and it is a CTIMP or it has been assessed by the SMT to be a complex interventional trial, the R&D Research Grants Manager will, in conjunction with the CI, start to document the risks of the trial using the *TMPL_006 Risk Assessment Template* during the grant submission and award processes.
- Due to the level of risk involved in CTIMPs, the complexity of trial management arrangements and to ensure compliance with the regulations, UHBW will only sponsor a CTIMP if it will be run through an experienced trials unit. Please speak to R&D prior to submitting a grant application or request to sponsor if you are planning a CTIMP.
- As the study passes through the sponsorship process the R&D RPM will continue to complete the risk assessment with input from the following personnel:

  Chief Investigator (CI), Principal Investigator (PI) (if different to CI at UHBW), Trial Manager/Trial Co-ordinator, and any other personnel deemed appropriate including Research Nurse and Support department representatives.
- All identified risks and mitigations will be agreed at a risk assessment meeting and documented on the risk assessment template. This will continue 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 types of research

- The SMT, will determine whether a Risk Assessment is required for the study at the review meeting. This will be documented on the appropriate *TMPL_003A or TMPL_003B "Request for UHBW to be Research Sponsor"* form. 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
- If a Risk Assessment is required, the RMF will complete *TMPL_115 Non CTIMP_Risk Assessment* with input from the following personnel:
  - Chief Investigator (CI), Principal Investigator (PI) (if different to CI at UHBW), Trial Manager/ Trial Co-ordinator, and any other personnel deemed appropriate.
- The final version must be signed prior to issuing the green light, which must take place prior to any recruitment to the trial
- If a Risk Assessment is not required, 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.
- The RMF or RMF Team Leader will also (as applicable) discuss any identified risks during the weekly operations meeting in R&D and agree the appropriate mitigating action e.g., any monitoring required in line with SOP_010 Monitoring & Oversight of Research Activity UHBW.

### 6.2.3 Study Set Up & Management Plan

#### 6.2.3.1 For CTIMPs and complex interventional trials

a *TMPL_007 UHBW 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.

#### 6.2.3.2 For all other types of research

- At the review meeting, the SMT will determine whether a SUMP is required and document on the sponsorship form.
- If applicable, a *TMPL_122 UHBW SUMP Non CTIMP-CIMD* should be completed. The purpose of this, is the same as outline above for CTIMPs and complex interventional trials.Issuing sponsorship
- On completing the review process, a sponsorship letter is issued.
- For **CTIMPs, CIMDs and complex interventional trials,** *TMPL_008 Sponsorship IMP study* should be sent to the CI, accompanied by *TMPL_023 Statement of Responsibilities for CTIMPs, CIMDs 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&D 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/TMPL_096 Sponsorship non-IMP Study MULTI-SITE_Greenlight delegated* 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, Health Research Authority (HRA) and Research Ethics Committee (REC). Requests for electronic authorisation by the sponsor on the IRAS system must be sent to R&DSponsorship@uhbw.nhs.uk.
- UHBW'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.

### 6.3 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.
- For information about the application through IRAS for REC, HRA and MHRA approval, please refer to *GD_001 Gaining & Maintaining Authorisations UHBW*. 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 publicly 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 UHBW*.
- If a multicentre study, local packs should be submitted to other sites for capacity and capability review in accordance with HRA guidance. Further guidance on this process will be provided by the sponsor representative in R&D taking the study through sponsorship. Local capacity and capability review at UHBW will be conducted in accordance with *SOP_017 Confirmation of capacity and capability to deliver research at UHBW*.

### 6.4 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.

#### 6.4.3 Green light process to commence recruitment for CTIMPs and complex interventional trials

- The R&D 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.
- UHBW as sponsor will delegate greenlighting of trial sites to the trial management team. Therefore, once all applicable outstanding tasks from the SUMP have been completed, the RPM will issue sponsor's permission for the trial team to issue green light at participating sites, using *TMPL_012 Greenlight for Sponsored CTIMP Studies at External Sites*
- A *Site Initiation Visit Checklist (TMPL_015)* must be completed by trial management teams for each participating site and returned to the RPM. If the trial management team wishes to use their own checklist this will be agreed with the RPM in advance.
- The trial management team must copy the sponsor into the greenlight confirmation email/letter and simultaneously provide the sponsor with a copy of the completed site initiation checklist.

#### 6.4.4 Green light process to commence recruitment for all other research studies

- The RMF/RMF Team Leader 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.
- If the study set-up involves a SUMP, then the RMF/RMF Team Leader will review progress of completion of each applicable item on the SUMP. Any outstanding tasks requiring completion before study commencement will be followed up by the RMF/RMF Team Leader in conjunction with the research team and support departments as applicable.
- The RMF/RMF Team Leader will issue green light using the appropriate template:
    - For single site studies (UHBW only) green light is provided in the confirmation of capacity and capability email (*TMPL_013 C&C and green light for UHBW 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 UHBW).
      For multi-site studies where UHBW as sponsor has delegated greenlighting to the CI it is the responsibility of the CI to ensure that confirmation of capacity and capability has been received for the relevant site before issuing the green light to commence recruitment

Please note that 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.

### 6.5 Investigator oversight of UHBW sponsored studies

- Where UHBW 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 sign the 'Statement of Chief Investigator Responsibilities' document (TMPL_023) to confirm they understand and accept their responsibilities. Further information on this process can be found in SOP_008 Investigator Oversight of Research Training.

### 6.6 Monitoring, oversight and safety reporting of UHBW sponsored studies

- Under the UK Policy Framework for Health and Social Care Research (UKPF), UHBW has a responsibility to monitor research conducted on its premises (including sponsored and hosted studies). Furthermore, in accordance with GCP, UHBW has a duty to monitor studies which it sponsors. Please refer to *SOP_010 Monitoring and Oversight of Research UHBW* 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, formal and informal communication with CIs, PIs and research teams, monitoring of the Study Management Plan (SUMP) and monitoring recruitment activity on EDGE. For UHBW 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. In some cases, the grant funders will dictate which committees the sponsor must attend and this will be adhered to. This should be documented in the SUMP or risk assessment as applicable.
- In accordance with the UKPF (for all studies) and the clinical trials regulations (for CTIMPs), UHBW 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 UHBW* for further guidance.
- For all UHBW sponsored studies annual safety reports should be submitted to the REC annually. Furthermore, development safety update reports should be submitted annually to the MHRA for all UHBW sponsored CTIMP studies. For CTIMPs which were approved by combined review safety reports should be submitted to the MHRA only. These documents should be reviewed by a sponsor representative prior to submission. For further information about this, please refer to *GD_001 Gaining & Maintaining Authorisations* and *SOP_009 Research Safety Reporting.*

#### 6.6.1 Sponsor review meetings

- In order to monitor progress and compliance with applicable regulations and guidelines sponsor review meetings for active UHBW sponsored studies may be carried out. These will be led by the R&Dsponsor representative and will involve the CI, PoC and any other appropriate personnel. Outcomes of these meetings will be fully documented and retained in the sponsor files. Meetings will take place as needed.

#### 6.6.2 Sponsor assessment of amendments:

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

### 6.7 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.

- **For all studies** the archiving process described in *SOP_015 Archiving of research documentation* will be followed for UHBW sponsored studies.
- For CTIMPs 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 (available on the MHRA website)*. For trials submitted through combined review, the form should be completed and submitted in the new part of Integrated Research Application System (IRAS). This automatically submits notification to the MHRA and REC. If the trial was not submitted through combined review, the *Declaration of End of Trial Form* should be submitted to the MHRA through the MHRA Submissions portal and a copy emailed to REC.
- An *End of trial study report* must be submitted to the REC within a year of the end of the study using the webform on the HRA website. The MHRA must be notified (where applicable) within a year of the end of the study, and within six months for paediatric trials. If you submitted via combined review, you should complete and submit the final report form in the new part of Integrated Research Application System (IRAS). For all other CTIMPs the MHRA should be informed via email that the end of trial results information has been uploaded to the public database/s where it was registered and be provided with a link.
- If a study has HRA approval but no REC approval was required, notification of the end of study should be emailed to the HRA (following the processes outlined on their website).
- Different notifications may also be required depending on study type (e.g. MHRA for CIMDs) or Confidentiality and Advisory Group (CAG). Please refer to the HRA website for guidance: Ending your project - Health Research Authority (hra.nhs.uk). The R&D sponsor contact will support the CI through these processes.
- Any required notification/end of study forms/reports must be agreed by UHBW R&D department prior to submission. A minimum of two weeks prior to the submission deadline, the report/form must be submitted to the sponsor representative via R&Dsponsorship@uhbw.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 the HRA website for details of both of these processes.

### 6.8 Dissemination of the Research Findings

- All research sponsored by UHBW 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 UHBW*.
- Transparency, registration, and publication of research are core priorities to the HRA and the NIHR. More information on legal requirements as well as best practice can be found on the HRA website and the NIHR website https://www.nihr.ac.uk/documents/nihr-policy-on-clinical-trial-registration-and-disclosure-of-results/12252#:~:text=Policy%20review-,Introduction%20and%20background,of%20results%20from%20clinical%20trials.&text=Prospective%20study%20Registration%20and%20timely,Clinical%20Trials%20funded%20by%20NIHR..
- For CTIMPs, results should be published on the register (or registries) where the clinical trial was registered. Results should continue to be uploaded to EudraCT for all trials which completed before 1 January 2021. The results of trials completing after 1 January 2021 do not need to be uploaded to EudraCT but they must be made available on another public register, such as ISRCTN. For UHBW sponsored CTIMPs, preparing these results will be delegated to applicable personnel within the research team and the RPM will provide support as required.
- For other types of study, results should be posted on the relevant registry website if registered, otherwise published through peer-reviewed scientific publications. A summary of fundings may be posted on the UHBW website if there are no publications a year after study closure (or grant ending). Otherwise the link to the main study publication(s) will be added.

## 7 Dissemination and training in the SOP

This SOP will 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>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>All updates (major and minor to the SOP) will be:<br>1. Updated on the trust Document Management System<br>2. Updated on the R&D website<br>3. Cascaded in the R&D e-bulletin |
| **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* |

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|---|---|
| **REFERENCES** | 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<br><br>Medicines and Healthcare products Regulatory Authority (MHRA), 2014. Good Clinical Practice Guide. Medicines and Healthcare products Regulatory Authority (MHRA) 2012. 4th impression 2015. TSO (The Stationery Office).<br><br>Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 |

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|---|---|
| | http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf<br><br>The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019<br>https://www.legislation.gov.uk/uksi/2019/744/contents/made?view=plain<br><br>UK Policy Framework for Health and Social Care Research (UKPF) |
| **RELATED DOCUMENTS AND PAGES** | GD_001 Gaining & Maintaining Authorisations UHBW<br>SOP_003 Developing and designing your study UHBW<br>SOP_004 Writing a research protocol to good clinical practice UHBW<br>SOP_007 Research Training UHBW<br>SOP_008 Investigator Oversight of Research UHBW<br>SOP_009 Research Safety Reporting UHBW<br>SOP_010 Monitoring and oversight of research activity UHBW<br>SOP_015 Archiving of research documentation UHBW<br>SOP_017 Confirmation of capacity and capability to deliver research at UHBW<br>SOP_019 UHBW sponsored research amendments<br>TMPL_003A Request for UHBW to be research sponsor form (charity funding)<br>TMPL_003B Request for UHBW to be research sponsor form (student, BRC, ARC, unfunded projects)<br>TMPL_004 Scientific review form<br>TMPL_005 Site Identification and Selection<br>TMPL_006 Risk Assessment Template<br>TMPL_007 UHBW Sponsor Study Set Up & Management Plan<br>TMPL_008 Sponsorship IMP study<br>TMPL_009 Sponsorship non-IMP study single site<br>TMPL_010 Sponsorship non-IMP Study Multi site<br>TMPL_011 Greenlight for sponsored CTIMP studies at UHBW<br>TMPL_012 Greenlight for Sponsored CTIMPStudies at External sites<br>TMPL_013 C&C and green light for sponsored single site study<br>TMPL_014 Greenlight for sponsored non-CTIMP studies at external sites<br>TMPL_015 Site Initiation Visit checklist<br>TMPL_016 Sponsor close out checklist<br>TMPL_022 Short CV template<br>TMPL_023 Statement of *Responsibilities for CTIMPs and Complex non-CTIMP Sponsored Studies*<br>TMPL_041 Template Data Management Plan<br>TMPL_096 Sponsorship non-IMP Study MULTI-SITE_Greenlight delegated<br>TMPL_115 Non CTIMP_Risk Assessment<br>TMPL_116 Sponsorship tracker and guidance<br>TMPL_122 UHBW SUMP Non CTIMP-CIMD<br>TMPL_131 Template Abridged Data Management Plan<br>WI_006 Work Instruction for RMF Peer Review<br>WI_007 Work Instruction for sponsorship requests received into the R&DSponsorship inbox |

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| | Latest versions of external facing documents can be found on the Research & Development section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/ |
| **AUTHORISING BODY** | Trust Research Group |
| **SAFETY** | N/A |
| **QUERIES AND CONTACT** | Research & Development (R&D) department on 0117 34 20233 or research@uhbw.nhs.uk |
| **AUDIT REQUIREMENTS** | R&D departmental Quality Management System audits are undertaken annually. |