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.

SOP number	SOP 002	**SOP Version**	6.0
Effective Date	28APR2026	**Review Date**	28APR28

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.
V6.0	Major revision to sponsorship application process to include new online sponsor request form as well as updates to align with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

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
JULY 2024	V5.0	01/AUG/2024	14/NOV/2024	Sandra Mulligan Jess Bisset	Diana Benton
NOV 2025	V6.0	13/JAN/2026	28/APR/2026	Sarah Bishop Jess Bisset	Diana Benton (on behalf of TRG)

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". ["Clinical Trials Regulations" as amended by United Kingdom Statutory Instrument 2025/538 (The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025]

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 2004 1031) and its amendments

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 (CI) is responsible for applying to UHBW for sponsorship and fulfilling obligations delegated by sponsor to CI throughout the research.

The Senior Management Team in the Research & Development (R&D) core team are responsible for reviewing all applications for sponsorship and maintaining oversight of UHBW sponsored studies.

The Research Management Facilitator (RMF), Research Management Team Leader or Research Projects Manager (RPM) in R&D is responsible for acting as nominated sponsor representative, liaising with the CI, and managing risk..

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
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
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 Research
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.
Sponsor representative	The individual within the sponsoring organisation who acts on behalf of the sponsor to ensure that the sponsor's legal, regulatory, governance and oversight responsibilities for a research study are fulfilled
CI	The investigator with overall responsibility for the research. In a study conducted at more than one study location, the CI has co-ordinating responsibility for research at all locations . All applications for ethical review should be submitted by the CI.

6. Priorities for UHBW Sponsorship

UHBW will prioritise studies for sponsorship as follows, due to having limited resources, but also because we need to ensure that all research is of good quality, appropriately designed, funded, and has undergone peer-review. See *SOP_003 Developing and Designing your study and grant submission through UHBW*

- NIHR and partner project and programme grants
- Grants awarded through the UHBW Research Funding Committee, e.g hospital charity
- Studies associated with NIHR infrastructure hosted at UHBW

The following are unlikely to be of a high priority

- Unfunded or inadequately funded research
- Research which is not eligible for adoption onto the NIHR portfolio

Other studies should be considered for sponsorship on a case by case basis, for example Investigator Initiated studies that are fully funded by other funders. This includes commercial grants.

Note also that studies done as an undergraduate or postgraduate qualification should be sponsored by the awarding university.

7. Procedure

7.1 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 academics practising clinically 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 sponsor request form located on the R&D website.
- 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 or Research Grants Post-Award manager should email R&DSponsorship to trigger the Sponsorship process. The email should be copied to the CI and other relevant study contact(s), a copy of the grant application should be attached to the email, and the email should highlight any risks already identified. The

Grants Manager, Research Grants Post-Award manager or Research Projects Manager should bring the study to the R&D SMT, who will decide if a meeting with the CI is needed. The study should then follow the same process as for other sponsorships.

- The CI should be invited to a meeting with members of the R&D Senior Management Team (SMT) to discuss the study, including any risks and whether it is appropriate for UHBW to sponsor. Providing that there are no significant issues to be addressed, the CI should be informed within seven working days who the nominated sponsor representative will be and the next steps for proceeding through the sponsorship application process.. If UHBW is not the most appropriate sponsor, the UHBW R&D staff should liaise with partner organisation research management offices before proposing that they may be a more suitable sponsor.
- Members of SMT who were in attendance at the meeting should complete the following actions:
  - (i) Complete an initial risk assessment, identifying whether a further risk assessment is required. For CTIMPs this is always a requirement, using TMPL_006 Risk Assessment. For non CTIMPs this is agreed on a case-by-case basis. If it is required, then *TMPL_115 non CTIMP risk assessment* should be used
  - (ii) Decide who is appropriate within the R&D department to act 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).
  - (iii) Decide whether a Study Set Up and Management Plan is required using TMPL_007 UHBW Sponsor Set Up and Management Plan or *TMPL_122 UHBW SUMP non CTIMP-CIMD*
  - (iv) Decide whether TMPL_041 Template Data Management Plan or TMPL_131 template Abridged Data Management Plan require completion.

- A member of SMT should 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 should 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 should pick up the email from SMT in the sponsorship inbox and liaise with the RMF Team leader to allocate the study accordingly within 3 working days.

- Within 7 days from the date of the meeting the sponsor representative (RMF or RPM) from R&D should:
  - (i) for studies funded through a UHBW grant, discuss the study with the Research Grants Manager or Research Grants Post-Award Manager to become familiar with the study and avoid requesting duplicate information.
  - (ii) Introduce themselves to the CI and any key contacts via 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 initial queries on the proposed research not addressed during the meeting.

7.2 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 Curriculum Vitae (CV)

- The CI should provide a current copy of their CV and Good Clinical Practice (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, or copy of the grant award (see evidence of funding section below).
- Study 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 should be 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 should be provided or confirmed:

- A copy of the grant application and award letter (if applicable) to provide evidence of which costs 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 with their line manager 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 (again, line manager approval is needed).
- Evidence that arrangements are in place to meet excess treatment costs, plus a copy of the SoECAT if one was submitted with the grant application.
- 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. Eligible funders are listed on the NIHR Non-commercial Partner list.

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 should normally have been received by the Research Grants Manager, and saved in the study folder. The RMF or RPM should check before requesting this from the researcher.
- If the study has not been reviewed by an external funder, R&D SMT should decide on the level of peer review necessary and confirm via email to the sponsor representative; they should arrange for this as part of the sponsorship process. Note that any concerns of reviewer(s) should be addressed prior to agreeing to sponsor.
    - The sponsor representative should refer to *WI_006 Work Instruction for RMF Peer Review* for guidance.
    - The sponsor representative should contact the researcher and ask them to propose 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 sponsor representative should 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 taking place at UHBW, the PI or delegated other should make contactwith 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.

7.2.1 The review process

- Once the documents to agree sponsorship (section 6.2) have been received, the allocated sponsor representative should carry out the sponsorship assessment using *TMPL_116 Sponsorship tracker and guidance* (as applicable) and should 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 should be documented, and if applicable the study should be flagged for monitoring under the *SOP_010 Monitoring and Oversight of Research Activity UHBW.*

7.2.2 Risk assessment

- Developing and completing a risk assessment is an ongoing process. For CTIMPs and CIMDs it begins during grant development, and for other studies it starts during the sponsorship process.

7.2.2.1 Risk assessment for complex interventional trials (incl. CTIMPs and CIMDs)

- 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 should, 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**. CIMDs should be reviewed on a case by case basis.

- As the study passes through the sponsorship process the R&D RPM should 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, sponsor pharmacist and any other personnel deemed appropriate including Research Nurse and Support department representatives.

- All identified risks and mitigations should be agreed at a risk assessment meeting and documented on the risk assessment template. This is an iterative process that continues until the risk assessment is considered final by the CI and RPM as sponsor representative.
- The final version must be signed prior to the sponsor 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. Where applicable 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

- If a full Risk Assessment is required for other research this should be documented by SMT. 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 required, the sponsor representative should 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 sponsor representative should document any risks identified during the sponsorship or capacity and capability review process on the applicable workflow on EDGE.
- The sponsor representative should also (as applicable) discuss any identified risks during the monthly sponsor 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.

7.2.3 Study Set Up & Management Plan

- **6.2.3.1 For CTIMPs, CIMDs and complex interventional trials** *TMPL_007 UHBW Sponsor Study Set Up & Management Plan (SUMP)*, should 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 should arrange to meet the trial co-ordinator/manager and complete it as soon as possible.
- The purpose of the SUMP is to document the management and delegation 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 should 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

- If required, a *TMPL_122 UHBW SUMP Non CTIMP-CIMD* should be completed. The purpose of this, is the same as outlined above for CTIMPs and complex interventional trials.

6.3 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/MHRA Notice of no objection 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 and CIMDs 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 should 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 CIMDs and complex interventional trials

- The R&D RPM should review progress of completion of each applicable item on the SUMP. Any outstanding tasks requiring completion before trial commencement should 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 should 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*

- ***For CTIMPs or CIMDs not run by an experienced trials unit the R&D RPM should determine during study set-up if it is appropriate to delegate greenlight of trial sites to the trial management team. This should be documented in the SUMP.***
- 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 should 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 should 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 Sponsor Representative should review progress of completion of each applicable item on the SUMP. Any outstanding tasks requiring completion before study commencement should be followed up by the Sponsor Representative in conjunction with the research team and support departments as applicable.
- The Sponsor Representative should 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, CIMDs and complex interventional trials** the CI is 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 should 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 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), the clinical trials regulations (for CTIMPs) and the medical devices regulations (for CIMDs): 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.
- Annual safety reports (DSURs) for all CTIMPs (whether they were submitted via Combined Review or not) should only be reported to the MHRA only . If any ethical issues are identified by the MHRA when they receive these reports, they will liaise with the REC directly. 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.*
- As a condition of MHRA approval for a clinical investigation (CIMDs), in addition to reporting individual serious adverse events as detailed in the protocol, you must send quarterly summary reports providing an update on the latest overall safety profile for the investigation. Further guidance can be found on the MHRA website.

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 should be led by the R&D sponsor representative and will involve the CI, PoC and any other appropriate personnel. Outcomes of these meetings should be fully documented and retained in the sponsor files. Meetings should 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, notifications and Archiving

- **For CTIMPs, CIMDs and complex interventional trials,** a *Sponsor close out checklist (TMPL_016)* should be completed between the RPM and the trial manager.
- **For all studies** the archiving process described in *SOP_015 Archiving of research documentation* should be followed for UHBW sponsored studies.

  For CTIMPs and CIMDs 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/CIMDs 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 it is a legal requirement that clinical trials are published in a public registry, a summary of trial results is published within 12 months of the end of trial and that sponsors offer to share a summary of results with participants (or their representative) in a format they

can easily understand. Further details of research transparency requirements for CTIMPs can be found on the HRA website.

- For CTIMPs, results should be published on the register (or registries) where the clinical trial was registered. Results should continue to be uploaded to the European Union Drug Regulating Authorities Clinical Trials Database (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 -The UK's Clinical Study Registry . 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 findings 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: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust Document Management System 2. Updated on the R&D website 3. Cascaded in R&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*

REFERENCES	ICH Harmonised Tripartite Guideline for Good Clinical Practice (2025) ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf 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). Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 https://www.legislation.gov.uk/uksi/2019/744/contents/made?view=plain The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 https://www.legislation.gov.uk/uksi/2025/538/contents UK Policy Framework for Health and Social Care Research (UKPF)
RELATED DOCUMENTS AND PAGES	GD_001 Gaining & Maintaining Authorisations UHBW SOP_003 Developing and designing your study UHBW

	SOP_004 Writing a research protocol to good clinical practice UHBW SOP_007 Research Training UHBW SOP_008 Investigator Oversight of Research UHBW SOP_009 Research Safety Reporting UHBW SOP_010 Monitoring and oversight of research activity UHBW SOP_015 Archiving of research records UHBW SOP_017 Confirmation of capacity and capability to deliver research at UHBW SOP_019 UHBW sponsored research modifications TMPL_004 Scientific review form TMPL_005 Site Identification and Selection TMPL_006 Risk Assessment Template TMPL_007 UHBW Sponsor Study Set Up & Management Plan TMPL_008 Sponsorship IMP study TMPL_009 Sponsorship non-IMP study single site TMPL_010 Sponsorship non-IMP Study Multi site TMPL_011 Greenlight for sponsored CTIMP studies at UHBW TMPL_012 Greenlight for Sponsored CTIMP Studies at External sites TMPL_013 C&C and green light for sponsored single site study TMPL_014 Greenlight for sponsored non-CTIMP studies at external sites TMPL_015 Site Initiation Visit checklist TMPL_016 Sponsor close out checklist TMPL_022 Short CV template TMPL_023 Statement of *Responsibilities for CTIMPs and Complex non-CTIMP Sponsored Studies* TMPL_041 Template Data Management Plan

	TMPL_096 Sponsorship non-IMP Study MULTI-SITE_Greenlight delegated TMPL_115 Non CTIMP_Risk Assessment TMPL_116 Sponsorship tracker and guidance TMPL_122 UHBW SUMP Non CTIMP-CIMD TMPL_131 Template Abridged Data Management Plan WI_006 Work Instruction for RMF Peer Review WI_007 Work Instruction for sponsorship requests received into the R&DSponsorship inbox 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 via research@uhbw.nhs.uk
AUDIT **REQUIREMENTS**	R&D departmental Quality Management System audits are undertaken annually.