Standard Operating Procedure

MONITORING & OVERSIGHT OF RESEARCH ACTIVITY

SETTING Trust-wide

AUDIENCE All staff involved in research

ISSUE To describe UHBW R&D department's monitoring process for research

QUERIES Contact Research Operations Manager via research@uhbw.nhs.uk

Document History

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Version Number	Reason for change
V1.7	Annual review of SOP and minor updates made
V2.3	Major update to previous monitoring SOP
V2.4	Annual review of all SOPs and minor updates made
V3.0	Major update to remove redundant sections and restructure SOP
V4.0	Major update to include monitoring processes during a pandemic and other updates and clarifications as part of biennial review.
V4.1	Minor amendment to include new self-monitoring templates and UHBW sponsored non CTIMP risk assessment process.
V4.2	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
V5.0	Major update to include monitoring of electronic Trial Master Files and Investigator Site files. Other minor amendments and clarifications as part of biennial review.
V5.1	Minor updates to align to the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 including terminology changes.

1. Introduction

UHBW has a responsibility for oversight of research conducted on its premises, and research which it sponsors. These responsibilities are driven by the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. Consequently, the Research & Development Department (R&D) undertakes to monitor research conducted at UHBW where a risk has been identified in an externally sponsored study, where UHBW is acting as a research sponsor or where it has been contracted to undertake monitoring on behalf of another organisation.

The purpose of monitoring is to ensure:

That the dignity, rights, safety and wellbeing of the participants in the study are protected

- The conduct of the study is in compliance with the current approved protocol/protocol modification(s), with Good Clinical Practice (GCP) aligned with ICH R6 E3 and with the applicable regulatory requirements
- The reported trial data are accurate, complete and verifiable from the source.

2. Purpose

The purpose of this document is to describe the risk-based procedures that will be used by UHBW R&D to monitor and maintain oversight of research sponsored by UHBW, conducted on Trust premises or which fall under a Service Level Agreement with other organisations.

3. Scope

In Scope: This SOP applies to:

• UHBW and University of Bristol (UoB) sponsored research selected for monitoring by R&D and/or UoB.

• Research conducted at UHBW which requires monitoring but does not have sufficient external monitoring in place. An assessment of whether monitoring is required is made by the R&D department.

Out of scope: This SOP does not apply to externally sponsored research which already has sufficient monitoring in place as assessed by a member of the R&D department. This SOP does not describe monitoring procedures carried out by personnel outside of R&D on behalf of UHBW as sponsor (e.g., where a study is managed and monitored by a Clinical Trials Unit).

4. Responsibilities

All staff within the R&D operations team have a responsibility to flag any studies requiring monitoring.

The Research Management Facilitators (RMFs) with a monitoring speciality, the Research Governance and Quality Officer (RGQO) and the RMF Team leader (referred to as R&D monitors) have a responsibility to ensure that all studies identified for monitoring are monitored in accordance with this SOP.
Research staff (both internal to UHBW and external) have a responsibility to make all documentation available for monitoring and respond to monitoring reports in a timely manner until monitoring is complete.

5. Abbreviations and Definitions

Abbreviations	
AE	Adverse Event
ATIMP	Advanced Therapy Investigational Medicinal Product
C&C	Capacity & Capability
CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
PIS	Patient Information Sheet
PoC	Point of Contact
PI	Principal Investigator
REC	Research Ethics Committee
RGT	Research Governance Team
RGQO	Research Governance and Quality Officer
RMF	Research Management Facilitator
R&D	Research & Development Department
SAE	Serious Adverse Event
SLA	Service Level Agreement
SUMP	Study set Up and Management Plan
SUSAR	Suspected Unexpected Serious Adverse Reaction
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UoB	University of Bristol
UKPF	UK Policy Framework for Health & Social Care Research

Definitions	
Sponsor	The Sponsor is defined in two ways: **UKPF:** "The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project" **Clinical Trials Regulations:** "'sponsor' means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial." http://www.legislation.gov.uk/uksi/2004/1031/regulation/3/made

6. Procedure

6.1 Risk Assessment and Risk Management

- For hosted and sponsored studies prior to commencement at UHBW, all research is reviewed and assessed by UHBW R&D team in accordance with current national requirements. This is in order to support sponsor processes and ensure research can be delivered within the trust. The areas reviewed include, but are not limited to, the following:
    - Regulatory and contractual requirements
    - Sponsorship arrangements
    - Essential documents
    - Consent
    - Study type
    - Data and tissue
    - Research team
    - Recruitment and retention
    - Financial arrangements
    - Resource use
    - Organisational responsibilities
- Please note for externally sponsored studies some of these areas will be reviewed by the Health Research Authority (HRA) as part of HRA assessment rather than within R&D, for example, data and tissue, essential documents etc.
- **For UHBW Sponsored CTIMPs, CIMD's and selected complex interventional trials,** the Research Projects Manager (Sponsored Trials) will undertake a full risk assessment of the trial which will inform a study specific monitoring plan (*TMPL_029*). The Research Projects Manager (Sponsored Trials) will also organise a Study Set Up and Management Plan (SUMP) meeting. The purpose of the meeting is to review, document and agree the risks identified, agree any actions required to mitigate identified risks and document the study management plan for oversight of the research. Further details can be found in *SOP_002 Research Sponsorship at UHBW*.
- **For other UHBW sponsored research** an assessment will be made in the Senior Management Team prior to allocation of the sponsorship to an RMF whether a non CTIMP risk assessment is required (TMPL_115 Non CTIMP Risk Assessment). If it is, all risks will be documented using this template and any subsequent monitoring requirements to mitigate risk. If no risk assessment is required, the assessed risk for the study is very low and the RMFs will capture any concerns using the EDGE sponsorship and C&C workflows and *TMPL_116*

Sponsorship tracker and guidance. Any identified monitoring as a consequence will be flagged to the R&D monitors to be added to the monitoring database.

- **For all other research**, an assessment will be carried out by an allocated Research Management Facilitator (RMF) in R&D, at the time of Capacity and Capability (C&C) review, to identify risks of conducting the research. Further details on C&C review can be found in *SOP_017 Capacity & Capability review at UHBW.* The RMF completing the C&C review should consider whether any monitoring of the study is required by reviewing the identified risks and referring to the R&D Monitor(s) and Research Operations Manager for guidance. Any monitoring requirements should be captured in the monitoring section of the C&C Review Workflow on EDGE. If applicable, the RMF should flag the study to the R&D Monitor(s) who, in consultation with the Research Operations Manager, should add the study and type of monitoring to be conducted to the monitoring record database which is located on the R&D shared drive in the monitoring folder. If the RMF is unclear whether a study should be identified for monitoring, they should raise the issue at the weekly R&D Operational meeting where a member of the senior management team should confirm requirements.

Examples of major risks which would flag the study for potential monitoring (not exhaustive)

- ATIMP (Advanced Therapy Investigational Medicinal Products) trial
- Highly invasive clinical intervention– e.g. surgical techniques, radiotherapy & cytotoxic drugs
- UHBW/UoB Sponsored CTIMP
- UHBW/UoB Sponsored CIMD
- UHBW/UoB Sponsored study
- Hosted CTIMP with risk of harm and no clear monitoring arrangements
- UHBW lead site with no clear monitoring arrangements
- Large scale research studies (200-250)
- Participants with poor prognosis
- Participants with incapacity
- Participants are children
- Significant change from standard care/withholding care
- Inexperienced research team
- High risk of protocol non-compliance due to challenging study design or participant pathway

- During the course of a study there may be other reasons to flag the study for monitoring. For example, the research team in liaison with an RMF regarding study progress may highlight an issue relating to conduct, recruitment, governance or other reasons. New risks may also be identified during planned monitoring visits which require additional monitoring.

- For UoB sponsored studies, a member of University of Bristol Research Governance Team (UoB RGT) will highlight a study for monitoring to the Research Operations Manager.

- Whenever a study is flagged for monitoring, the R&D monitor should add the study to the monitoring database which documents identified risks and proposed monitoring. This database is reviewed bi-monthly by the R&D monitor(s) with the Research Operations Manager. In addition, if not identified by UoB RGT (i.e. identified by a member of the R&D department) the UoB RGT should be alerted when a UoB study has been identified for monitoring. Then once the monitoring has taken place they will receive copies of monitoring reports and responses.

- A pragmatic risk-based monitoring approach will be put in place for each study as applicable. The level of monitoring required will therefore be dependent on the study type as well as the risks identified, for example; there will be a greater level of monitoring required for a Clinical Trial of an Investigational Medicinal Product than for a non-interventional study.

6.2 Monitoring Plan

For UHBW and UoB Sponsored CTIMPs, CIMDs and complex interventional trials

- A study specific monitoring plan (*TMPL_029*) should be developed by the Research Projects Manager (Sponsored studies), (for UHBW only) and R&D monitors (for UHBW & UoB) during study set-up. The purpose of the monitoring plan is to describe the proposed monitoring to be undertaken throughout the course of the trial based on the risks identified. The first version of the monitoring plan will detail the risks identified from the initial risk assessment. If an assessment does not exist), risks which have been identified/raised by the sponsor, and the mitigating actions addressing those risks will be documented as part of the monitoring plan by the R&D Monitor(s).
- Where a trial is complex and monitoring requirements are unclear an initial meeting may take place with the Chief Investigator (CI) and Point of Contact (PoC) to discuss monitoring and inform the monitoring plan.
- As a study progresses and monitoring is carried out, the monitoring plan should be updated regularly by the R&D monitor(s) in order to document any monitoring undertaken, identification of new risks and subsequent proposed monitoring. The initial monitoring plan and any subsequent versions (where new risks and new monitoring visits have been identified) should be sent to the CI and sponsor (where the sponsor is not UHBW) by the R&D monitor(s). The monitoring plan should be version controlled.
- Monitoring responsibilities may be delegated to a Clinical Trials Unit, if appropriate. This should be documented on the monitoring plan.

- For **UHBW and UoB Sponsored non-CTIMPs** the proposed monitoring should be recorded on the R&D monitoring database stored on the R&D shared drive. When the monitoring has been completed, or as the proposed monitoring requirements change, the record should be updated by the R&D monitor(s) on the database. The monitoring record should be held confidentially by the R&D department. The Research Operations Manager should update the Head of Research Governance or the Research and Human Tissue Manager at UoB on the planned monitoring of non CTIMPs sponsored by UoB within the upcoming quarter; the UoB RGT should be alerted by UHBW R&D once monitoring has taken place and updated about monitoring findings and responses.

6.3 Types of Monitoring

- The monitoring conducted by R&D will be targeted to specific elements of the study requiring review. For example, where a risk is identified during study setup whereby a research team is unfamiliar with required data management processes, a monitoring visit will take place to review data management and carry out source data verification.
- In order to use monitoring resources effectively and efficiently, various monitoring visit types have been developed as follows:

6.3.1 Self-monitoring

- The R&D monitor should email a self-monitoring form to check recruitment, safety and overall study progress, including changes to the research team, training needs and study document updates. For UoB/UHBW sponsoredmultisite studies conducted at more than one study location which are co-ordinated by a central team the monitor will initially email the Trial Manager/Co-ordinator and CI with *TMPL_108 Central Study Team self-monitoring form.* Following the responses received the monitor may select one or more site(s) to send

the *TMPL_030 Self-Monitoring Form.* Where the study is single site or a UHBW hosted study identified for monitoring *TMPL_030* will be used.

- The form should be returned to the monitor **within two weeks of being sent to the PoC;** the R&D monitor should chase a response if the completed form is not received on time.
- This form of monitoring is an opportunity for the research team to identify any issues with the study which need addressing. If any issues are identified, follow up via telephone calls or emails will be made by the R&D monitor until the issues are resolved. All actions will be documented. If the self-monitoring raises any concerns for the R&D monitor a site visit may be arranged.

6.3.2 Study set up visit

- For new and inexperienced UHBW Chief Investigators (CI) or Principal Investigators (PI) a study set up monitoring visit may be offered prior to or at the point of the study starting.
- During the visit the R&D monitor should provide to the investigator/ PoC a copy of UHBW's *Investigator Site File Contents* (*TMPL_044*) with an explanation of what documentation is required to be kept within an Investigator Site File (ISF), referring to *SOP_014 Essential Research Documents UHBW*. Depending on the study type and identified risks, the R&D monitor should discuss key elements of the research, e.g. informed consent, how to document PI oversight, data collection and verification etc, the principles of GCP The PI should use this visit as an opportunity to raise any queries with the R&D study monitor prior to the study start.

6.3.3 Site File Review

- A site file review may be conducted to ensure the ISF is being maintained in accordance with ICH GCP. This may take place at any time during the study depending on the identified risk.
- A site file review will also ensure essential documentation is being maintained and filed in accordance with UHBW SOPs (as relevant). A site file review is not required at every study location visit.
- The decision to conduct a site file review should be determined by the risks identified during R&D assessment in accordance with section 6.1 and/or where issues raised at a first study location visit have not been adequately addressed. *TMPL_031 Site File review Visit* UHBW which should be used for a paper ISF is based on the essential documentation checklist (Section 8) of ICH GCP E6.
- A site file review may involve review of a paper ISF or an e-ISF or a combination of both. Where an e-ISF review is undertaken *TMPL_127 eISF review* will be used.

6.3.4 Eligibility review

- An eligibility review should be carried out on a sample of participants (at least 10% of total recruited) if there is a risk identified and documented in the study assessment around the eligibility review process - e.g., CTIMPs with inexperienced investigators or complex eligibility processes.
- The R&D monitor should use *TMPL_032 Eligibility review monitoring* as the monitoring report. During the visit a member of the research team may be asked to describe how eligibility is reviewed, assessed and documented.
- For **CTIMPs**, the eligibility review should include ensuring that the decision regarding a participant's eligibility was made by an appropriately qualified doctor or dentist (if applicable), unless other arrangements have been agreed and documented in advance by the sponsor.

6.3.5 Informed consent review

- An 'informed consent review' monitoring visit should be carried out for studies which have identified risks around consent e.g. complex arrangements for informed consent such as, parental consent/carer consent/incapacitated adults, inexperienced research team in taking consent etc., or where other risks have been identified in the study assessment.
- The whole process of informed consent should be reviewed using *TMPL_033 Informed consent review* and may include, but not limited to;
  - checking the correct and current REC approved versions of the participant information sheet (PIS) and informed consent form (ICF) are in use,
  - that the ethically approved process is being followed for informing participants about the research, including ensuring they have adequate time to consider participation,
  - that consent is being appropriately documented,
  - that members of staff taking informed consent are adequately qualified and that this task has been delegated to them by the PI.

6.3.6 First Participant First Visit

- For high risk trials e.g. using Advanced Therapy Investigational Medicinal Products (ATIMPs) it may be necessary to conduct a monitoring visit as soon as the first participant is recruited.
- During this visit the following monitoring elements should be conducted for the first participant, eligibility review, informed consent review data management review and where identified a site file review. This should allow any issues identified to be rectified prior to further recruitment into the trial. The applicable templates should be amalgamated and used as the monitoring report.

6.3.7 Protocol Compliance

The risks identified and documented during set up and assessment of a study will be used to guide the protocol compliance review. *TMPL_034 Protocol compliance* should be used.

- The key aspects to be assessed during this type of monitoring visit include, but are not limited to the following:
  - Verifying, for Investigational Medicinal Product(s) (IMPs):
  - That the IMP(s) is/are supplied only to the participants who are eligible to receive it and at the dose(s) specified in the protocol
  - That participants are provided with necessary instructions on proper use, storage, and return of the IMP(s) (as applicable)
  - Verifying that the Investigator follows the approved protocol and all subsequent approved modifications to the protocol and associated documentation
  - Checking the accuracy and completeness of the Case Report Form (CRF) entries, source documents and other study related records against each other, e.g. that:
  - The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents
  - Any dose and/or therapy modifications are adequately documented for each of the study participants
  - Adverse Events (AEs) (including serious AEs), concomitant medications and illnesses are reported in accordance with the protocol and applicable SOPs
  - Visits that the participants fail to attend, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs
  - All withdrawals of enrolled participants from the study are reported and explained on the CRFs
  - Reviewing CRF entry error, omission or illegibility.
  - Checking the process by which changes should be made, and whether this process has been followed. This includes ensuring changes are made, explained (if necessary), and initialled by the Investigator or an authorised member of the research team

- Checking systems are in place to ensure compliance with data protection requirements
- Checking the transportation and storage arrangements for any samples taken as part of the protocol

6.3.8 E-TMF monitoring

As the majority of Trial Master Files have moved to electronic means, an e-TMF monitoring visit will be conducted if it has been identified in the risk assessment or flagged through another route. These visits can be carried out remotely as long as monitor(s) are provided with appropriate access and given instructions how to use the e-system. The monitoring visit will use *TMPL_126 e-TMF review* which focuses on ensuring all documentation is available to reconstruct the research and provide evidence of adherence to applicable regulations, guidelines and the protocol.

6.3.9 Pharmacovigilance

- For UHBW and UoB sponsored studies this type of monitoring may be carried out within the R&D department to audit compliance with *SOP_009 Research Safety Reporting*.
- Where any risks or issues are identified with pharmacovigilance a visit may also be undertaken with the study team to assess relevant paperwork including, but not limited to the process for assessing AEs (including SAEs), PI and CI oversight and Data Monitoring Committee reviews.
- This visit should also review whether all SAEs that are known to have happened have been reported, and whether all events documented in the source data that meet the definition of an SAE have been recorded and reported in accordance with the approved protocol. *TMPL_035 Pharmacovigilance Monitoring Visit* will be used for this type of monitoring.

6.3.10 Data Management

- If risks have been identified concerning data management (e.g. an inexperienced research team in data management, multi-centre trials, high volume of data, complex database design/validation) a 'data management monitoring' visit should be carried out.
- The R&D monitor should refer to the Data Management Plan (if in place for a study) and decide in consultation with the R&D Operations Manager the percentage of data that should be reviewed. The R&D monitor should, depending on the risk identified, carry out source data verification, computer system validation procedures and/or review of the whole life cycle of data management within the study. *TMPL_036 Data management review* and *TMPL_037 Quality control monitoring spreadsheet* should be used.

6.3.11 Laboratory and Pharmacy

A lab or pharmacy monitoring visit using *TMPL_038 Pharmacy Monitoring Template and TMPL_039 Laboratory monitoring* may be carried out either to review systems and processes within the departments and how they apply to a collection of studies or specifically to monitor a particular study.

The key aspects to be assessed and verified for Investigational Medicinal Product(s) (IMPs) during this type of monitoring visit within **Pharmacy** include, but are not limited to, the following:

- storage temperature and conditions are acceptable and comply with manufacturer requirements

- sufficient supplies are in place throughout the study
- a risk assessment of storage conditions has been carried out where IMP is stored outside of Pharmacy
- appropriate labelling (in accordance with Annex 13[1]) and handling of IMP according to manufacturer's requirements is in place
- IMP accountability
- unblinding procedures are in place and working (i.e. a test has been carried out)
- the destruction of unused IMP(s) complies with applicable regulatory requirements and is in accordance with the protocol

The key aspects to be assessed and verified during this type of monitoring visit within **Labs** include, but are not limited to, the following:

- Consent for sample collection is in place
- Appropriate sample labelling is in place
- Sample storage and handling are appropriate and documented
- Destruction of samples is in compliance with ethical approval and procedures are in place for this
- Validation of methods and calibration of equipment has taken place

6.3.12 Close out visit

- If a close out visit is included within the Monitoring Plan, the R&D monitor should record the expected study end date on the monitoring database. Within 2 months prior to the expected date of closure or if requested earlier by UoB RGT, the R&D monitor should book a visit and review arrangements for study closure and archiving. *TMPL_040 Close out visit* should be used.
- For UHBW sponsored CTIMPs the Research Projects Manager will complete a close out checklist. A discussion will take place between the Research Projects Manager and R&D monitor whether a close out visit is also required based on either the outcome of the close out checklist or if previously identified as a risk.

6.4 Remote Monitoring

- In some instances it may be necessary or preferable for monitoring visits to be completed remotely. Any remote monitoring should therefore be conducted in a secure manner and participant confidentiality must be maintained at all times.

- There are several options to conduct remote monitoring:
  a) Screen-sharing via video-conference
  - A suitable and secure video conferencing platform should be used and agreed with the study location (e.g. for UHBW participants use UHBW's agreed IT platform such as MS Teams), however the following should also be in place:
    - Participant consent for UHBW monitors to access identifiable information for monitoring purposes.
    - Screen-shots must not be taken.
    - The video-conference should not be recorded.
    - Equipment/devices used for the video-conference must be secure, e.g. have appropriate firewalls, security setting, and should not be left unattended.

[1] EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 13 Investigational Medicinal Products
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2009_06_annex13.pdf

- Location of access will be agreed prior to the video-conference and a private location will be used.
- The UHBW monitor will confirm they are alone in the room/area to ensure their screen can't be seen or the conversation can't be overheard by anybody else.

b) Redaction of source documents and sending to UHBW monitor

- Redaction of source documents is acceptable, it can be done on paper or electronically, and these along with other non-identifiable study documents can be sent to the UHBW monitor. However, there are certain requirements that should be met:
  - Redaction should be done in accordance with the guidance on redaction published by the National Archives.
  - Documents sent electronically should be done so via a secure email, e.g. NHS address.
  - Documents sent in hard copy should be done so via a secure postal service e.g. recorded delivery.
  - Should redaction not be possible study participants will need to consent to any identifiers leaving the study location and be assured that their confidentiality will be protected.

c) Remote access to clinical systems

- UHBW monitors may be able to obtain remote access to electronic clinical records, but this will depend on the study study location and sponsor and systems available.

- The format of any remote monitoring will be discussed with the study sponsor and research study location prior to commencing, as the preferred method will be dependent on the study location's information governance requirements.

E-ISF and E-TMF monitoring may be carried out remotely and the research point of contact will provide the monitors with appropriate access to the e-system with instructions on its use. The e-system must have an in built audit trail. A video conference with the point of contact will be made prior to the visit and again afterwards if there are queries or any issues with accessing the e-systems.

6.5 Monitoring process and required response from research teams

- The template forms to be used by the R&D monitor(s) are part of the R&D standalone templates and are found in the Quality Systems Documents folder on the electronic shared R&E drive in R&D. Any queries regarding the standalone templates need to be referred to the Research Operations Manager.

The monitoring process is as follows:

Before the visit

- Identify study for monitoring
- R&D monitor(s) adds study to the monitoring database. The R&D monitor(s) should regularly review this with the R&D Operations Manager to prioritise studies to monitor in the upcoming quarter.
- R&D monitor(s) email or phone the PoC/PI to arrange a suitable date for the visit. In setting up the visit, the R&D monitor(s) should make a request that any paperwork or resources to be reviewed during the visit are available e.g., medical notes, CRFs, databases, site file etc. If the monitor requires access to any electronic medical records (e.g. EVOLVE as used in UHBW) they will follow the research study location's procedure for monitors accessing

electronic records. For example, this may involve selected study participantt's records being downloaded onto a suitable device or tablet or the monitor being provided with a temporary login for access during the visit.

- If the study is co-ordinated by a trial co-ordinator the R&D monitor(s) will inform them if the monitor will require a meeting with the Research Nurse and/or PI on the day of the visit.
- Correspondence regarding the visit will be documented electronically in the applicable R&D study folder on the shared drives (R&D Group for UHBW sponsored/hosted studies and R&E for UoB sponsored studies)

During the visit

- A suitable space should be made available for the R&D monitor to carry out the monitoring (not applicable for any remote monitoring visits).
- A PoC in the research team should be available ideally throughout the visit or if necessary after the visit to answer any queries.
- The PI should also be available at some agreed point during the visit as required (or where this is not possible, soon after the visit).
- Verbal feedback should be provided by the monitor to the PoC at the end of the visit where this is practical.
- The PoC should be informed of the next steps and any further monitoring required.

After the visit

- R&D monitor writes the report and sends to the PoC and PI within 3 weeks (15 working days) of the monitoring visit. UoB RGT will also be sent a copy of the report by R&D monitor if it relates to a UoB sponsored study.
- PoC/PI has 20 working days in which to respond.
- If there are any queries from the visit report these must be raised with the R&D monitor within 10 working days of receipt of the report.
- If no response is received from the PoC/PI within 20 working days the monitor should send a reminder email for the report to be returned within 5 working days.
- If a response is still not received, the monitor shall escalate the issue to the Research Operations Manager and the study may be halted at this study location. For studies monitored on behalf of UoB, the Head of Research Governance will be informed in order to agree further actions. Following receipt of responses to the monitoring report, the monitor should either request further information and enter into correspondence until all issues are resolved or send a final email confirming that responses received are acceptable and that the report is closed.
- The monitor should update the monitoring record in the database to document that the monitoring has been fully completed. If any further monitoring is required a new record will be created in the database detailing the risks identified and the proposed monitoring. For studies monitored on behalf of UoB, the UoB RGT will be updated accordingly.
- Staff who undertake monitoring on behalf of UHBW or UoB sponsored studies must be appropriately trained. UHBW R&D will determine whether the monitoring staff are appropriately trained, either through line management and training of their own staff, or, for external staff, by review of qualifications and assessment of whether further training is required. Prior to monitoring by non-R&D staff, sponsor agreement must be gained.
- If any monitoring is undertaken for UHBW or UoB sponsored studies by personnel other than UHBW R&D, a copy of the monitoring report must be provided to the R&D department. The R&D monitor will review the contents of the report and decide whether any follow up or future monitoring is required. This excludes any external monitoring carried out on UHBW or UoB sponsored studies by host organisations for their own purposes.

Monitoring during a Pandemic

- Where monitoring of research is required during a pandemic, the safety of participants, research staff and monitors is paramount. Where monitoring is required at the study location (i.e. for vaccine research, urgent safety review of CTIMPs etc.) the study location's safety policies with regards to PPE and other guidance on infection control must be adhered to at all times. R&D monitors must agree any arranged monitoring with R&D managers prior to visits taking place.
- Where practical remote monitoring will be encouraged at all times to minimise risk. The steps described in 6.4 will be followed.
- Monitoring visits may also be delayed or postponed where appropriate.

6.6 Quality Assurance of UHBW monitoring processes

- In order to ensure delivery of high quality effective monitoring at UHBW, the following quality assurance checks will be undertaken;
    - Every quarter a selection of monitoring reports should be reviewed by the Research Operations Manager or another member of the Senior Management Team. Content, accuracy, completeness and timeliness of the reports will be checked.
    - Ad hoc reviews of the monitoring process may also be carried out by a member of the Senior Management Team. The purpose of these reviews is to check whether the processes described within this SOP are being followed. If the SOP is not being followed, feedback should be provided to the line manager of the R&D monitor(s), who will address the issues. One potential outcome is that the SOP requires review, and the appropriate mechanisms will be followed to enact changes.

- The R&D Quality Management System will also be monitored for compliance by the R&D monitors. Any areas of non-compliance will be reported to the Research Operations Manager who will act accordingly (e.g. re-train staff, revise procedural documents if appropriate).

6.7 Research at UHBW

- Although studies should be monitored and managed in different ways according to the type of study and the agreed monitoring plan (as applicable), all studies at UHBW should be:
    - Managed throughout their lifetime
    - Have a named individual in R&D (an allocated RMF) assigned to support management of the research as applicable. For UHBW sponsored CTIMPs, Clinical Trials of Investigational Medical Devices (CIMD's) and selected complex interventional trials the Research Projects Manager (Sponsored Trials) will carry out this role
    - Assessed for risk during sponsorship (where applicable) and during approval or confirmation of C&C (as required according to national guidelines). These assessments should identify study risks (to participant safety, data integrity and success to study delivery)

6.8 Research Sponsored by University of Bristol (UoB)

- The University of Bristol holds a Service Level Agreement (SLA) with UHBW. Under the Agreement the Trust undertakes to monitor and carry out pharmacovigilance for certain UoB sponsored studies. These activities should be carried out in accordance with the SLA, the identified risks, subsequent proposed monitoring and where applicable the study's specific Monitoring Plan.

6.9 Research Sponsored by Other Organisations

- Monitoring should be carried out according to risks identified where sufficient external monitoring is not in place and in accordance with any agreement in place with the sponsor.

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 MyStaffApp 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	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2009_06_annex13.pdf The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
RELATED DOCUMENTS AND PAGES	• SOP_002 Research Sponsorship at UHBW • SOP_ 007 Research Training UHBW • SOP_009 Research Safety Reporting UHBW • SOP_014 Essential Research Documents UHBW • SOP_017 Capacity & Capability review UHBW • TMPL_029 Monitoring plan

	• TMPL_030 Self-monitoring form • TMPL_031 Site File Review Visit UHBW • TMPL_032 Eligibility review monitoring visit • TMPL_033 Informed consent review • TMPL_034 Protocol compliance visit • TMPL_035 Pharmacovigilance monitoring visit • TMPL_036 Data management review • TMPL_037 Quality control monitoring spreadsheet • TMPL_038 Pharmacy Monitoring Template UHBW • TMPL_039 Laboratory monitoring UHBW • TMPL_040 Close out visit • TMPL_044 InvestigatorSite File Contents • TMPL_108 Central Study Team self-monitoring form • TMPL_115 Non CTIMP_Risk Assessment • TMPL_116 Sponsorship Tracker and Guidance • TMPL_127 e-ISF review UHBW These are available on the R&D section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development Department on 0117 34 20233 or research@uhbw.nhw.uk
AUDIT REQUIREMENTS	R&D departmental Quality Management System audits are undertaken annually.