



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester Research Governance Office
SOP S-1007 UoL**

Version 7.0, February 2021

Monitoring of Research Sponsored by the University of Leicester

OFFICE BASE

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Definitions

ADE	Adverse Device Effect
AE	Adverse Event
CI	Chief Investigator
CIP	Clinical Investigation Plan (medical device studies)
CRF	Case Report Form
CRO	Contract Research Organisation
CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
DPA	Data Protection Act
GDPR	General Data Protection Regulation
HRA	Health Research Authority
HTA	Human Tissue Authority
ICF	Informed Consent Form
ICH GCP	International Conference of Harmonisation Good Clinical Practice
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISF	Investigator Site File
PI	Principal Investigator
PIS	Participant/Patient Information Sheet
REC	Research Ethics Committee
REGI	Research Ethics Governance and Integrity
RGO	Research Governance Office
SADE	Serious Adverse Device Effects
SAE	Serious Adverse Events
SDA	Source Data Agreement
SDV	Source Data Verification
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UoL	University of Leicester

1. Introduction

This Standard Operating Procedure (SOP) describes the procedures for monitoring research sponsored by the University of Leicester (UoL) and defines the conduct and frequency of monitoring visits.

The UoL, when acting as Sponsor of research, has an obligation to ensure that research activity is conducted in accordance with the relevant legislation and guidelines.

A Sponsor is required to regularly review the progress of research and to ensure that Investigators comply with the relevant guidelines and legislation appropriate to the individual research activity. It is expected that all Trial Master Files (TMF) and Investigator Site files (ISF) are 'inspection ready' at all times.

A clear line of communication between the Sponsor representative and the Chief Investigator (CI), Principal Investigator (PI) and/or Trial Manager (as appropriate) must be maintained throughout the duration of the trial. This can be achieved through site visits and regular communication to ensure that:

- The rights and well-being of human subjects are protected.
- The reported study data are accurate, complete and verifiable from source documents.
- The conduct of the study is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and/or with the applicable regulatory requirement(s), directives and guidelines and with the applicable version of the Declaration of Helsinki.

2. Purpose and Scope

This document provides guidance for CIs, PIs and research staff on the risk based procedures used by the UoL to monitor and maintain oversight of the research that it sponsors.

The SOP applies to:

- Clinical Trials of Investigational Medicinal Products (CTIMPs),
- Studies using Non-CE Marked Devices,
- Non-CTIMP studies where applicable and determined by a Sponsor Risk Assessment, and
- UoL sponsored research selected for monitoring

This SOP does not describe monitoring procedures carried out by a vendor on behalf of UoL as Sponsor.

3. Procedures to Follow

3.1 Monitoring Plan

The UoL operates a risk-based monitoring programme to which all sponsored research is subject. A Monitoring Plan will be developed for all Clinical Trials of Investigational Medicinal Products (CTIMPs) and studies using Non-CE Marked Devices. A Monitoring Plan will be developed for non-CTIMP studies on a case-by-case basis where applicable and determined by a Sponsor Risk Assessment.

The Sponsor Risk Assessment facilitates the development of the Monitoring Plan (Appendix 1) and the Sponsor will discuss the monitoring requirements with the CI and relevant research staff at the initial Sponsor Review and Risk Assessment meeting. The Monitoring Plan itself will be discussed in detail at the Site Initiation Visit.

Adequate funding provision must be available to provide appropriate levels of monitoring proportionate to the phase, study complexity or anticipated recruitment rate. The method of monitoring, the frequency and the focus of monitoring visits will be determined by the risk rating allocated to ensure that monitoring approaches are targeted, justified and that a risk-adaptive approach is implemented. In addition, the Monitoring Plan will be further informed with the use of Monitoring Strategy Tables (Appendix 2) and should be tailored to the specific subject population, data integrity risk of the research, and the experience of the CI, PI and research staff at each site.

The Sponsor Monitoring Plan will be reviewed at least annually at the same time that the Development Safety Update Report (DSUR) is submitted. It may also be reviewed following a Substantial Amendment or a Monitoring Visit if required.

Further information concerning risk rating and the risk assessment process can be found in the Sponsor Risk Assessment SOP S-1003 UoL.

Where external vendors are providing monitoring on behalf of the UoL, the vendor(s) will be responsible for developing the monitoring plan and may utilise their own documentation subject to agreement by the Sponsor. Any Monitoring Plans must be reviewed and agreed by Sponsor prior to their implementation and the Sponsor retain the right to conduct monitoring and view reports upon request in order to maintain oversight. There is an expectation that all monitoring personnel must have evidence of qualification, training and experience.

Further information concerning Sponsor oversight of vendors can be found in the Vendor Selection and Oversight for Research Studies SOP S-1037 UoL.

3.2 Monitoring Frequency

The initial monitoring visit following Sponsor Green Light (SGL) for a site will be detailed in the Monitoring Plan. If the site does not enroll any patients, or enrolment is slow, has paused or stopped, regular monitoring visits will not be scheduled and issues around recruitment will be discussed with the relevant site and trial staff. If there is an extended gap in activity or a major change in site personnel, the Sponsor will communicate with the relevant site and trial staff to ensure that site staff are appropriately trained when activity recommence. This

may include extended gaps between the Site Initiation Visit and Sponsor Green Light or activity at that site. Where this is the case, it is expected that relevant and appropriate site initiation activities are repeated and that if required, refresher training is completed.

The frequency of subsequent Monitoring Visits will be determined initially by time, number of participants recruited, and the agreed number of Monitoring Visits as per the monitoring quote. This frequency will be detailed in the Monitoring Plan and is subject to revision based on a number of factors, including but not limited to, concerns over the management or conduct of the trial at a site, Serious Adverse Events (frequent and/or the nature of), Protocol Deviations (frequent and/or the nature of), and/or previous Monitoring Visit findings.

Monitoring Visits should also be scheduled between phases of trials (i.e., where there is a dose finding phase followed by a subsequent dose efficacy phase(s)) to ensure that data is monitored prior to any review by Data Monitoring Committee(s) and subsequent phases of the trial.

3.3 Remote Monitoring

Remote monitoring may be utilised as a method of maintaining oversight of a trial. The format of remote monitoring will be discussed between the Sponsor and site prior to commencing, as some methods may be dependent on the site's information governance requirements and local trust policy.

Remote monitoring includes: regular communication with the site by email or telephone; regular status updates to the Sponsor from the site regarding recruitment, operational issues (such as key staff changes, key document amendments, deviations and non-compliances), sharing of operational group and oversight group meeting minutes (such as Trial Management Group (TMG) and Trial Steering Committee (TSC)) and the completion of the Remote Monitoring Report (Appendix 8) and the Remote Pharmacy Monitoring Report (Appendix 9). Where necessary, telephone calls should be followed-up via email to provide a written record. Evidence of all remote monitoring correspondence and pertinent issues should be retained within the site file.

When a site is select for a remote monitoring visit the Sponsor will populate the relevant sections of the Remote Monitoring Report/Remote Pharmacy Monitoring Report and send to the PI/delegate/Pharmacy representative. Site/Pharmacy research staff will be expected to work through Part B, confirming the presence of the listed documents in the site file and providing additional information/documents where required. Any sections marked as 'N/A' do not require completing and can be left blank. Unless specified, sites will have 28 days to complete the report and return it to the Sponsor along with all requested supporting documents. The Sponsor will review the completed report and supporting documentation within 21 days and issue any outstanding actions on Part C. The site must address the outstanding actions, record the action taken and return the final signed document to the Sponsor for report closure within the timelines specified on the report and in email correspondence. Copies

of the completed and closed report and all associated correspondence should be retained in the Site File.

Where applicable, the following remote monitoring methods may also be utilised and fully documented in the Remote Monitoring Report:

3.3.1 Screen-sharing via video-conference

A suitable and secure video conferencing platform should be used in accordance with any local trust SOP on remote monitoring. This should be agreed with the site in advance of the meeting. The following should also be adhered to:

- Patient consent for the Sponsor (or their delegate) to access identifiable information for monitoring purposes on the Consent Form
- Screenshots 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
- Location of access will be agreed prior to the video-conference and a private location will be used
- The 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

3.3.2 Remote access to clinical systems

The Sponsor (or their delegate) may be able to obtain remote access to electronic clinical records, but this will depend on the site procedures and systems available.

3.3.3 Remote IMP reconciliation

Where necessary and applicable, remote investigational medicinal product (IMP) accountability will be conducted. For example, where a site is difficult to travel to, there are travel restrictions in place, or recruitment rates make it difficult and/or unfeasible to travel to the site.

The monitor will populate the relevant sections of the Remote Pharmacy Monitoring Report (Appendix 9) and send to Pharmacy staff to complete Part B and return along with any relevant documentation to aid the reconciliation of IMP.

This may include but is not limited to:

- Confirmation of shipment and receipt of IMP; including verification that IMP arrived within acceptable conditions according to the IB/manufacture/Pharmacy manual
- Confirmation of the available stock and its expiry dates
- Evidence of temperature monitoring and/or records of temperature deviations
- Accountability logs (with participant identifiable information redacted)
- Records of IMP returns (with participant identifiable information redacted) and any quarantined stock

- Total number/amount of IMP waiting destruction, and destruction records

The Sponsor will verify the information and authorise IMP destruction once there is agreement that the records and available information are accurate. Copies of pharmacy destruction logs for remotely reconciled IMP should be forwarded to Sponsor. All reports, records and associated communication regarding remote drug reconciliation must be retained in the Pharmacy Site File for review at the next on-site monitoring visit.

3.4 Central Monitoring

Central monitoring may be used in large studies with multiple sites and be managed through a central coordinator. The coordinating centre, will receive information from the investigator sites.

Central monitoring may consist of remote review of:

- Informed Consent Forms
- Case Report Forms (CRFs)
- A data review
- Investigator site file
- Site staff qualifications and training

It may also employ statistical techniques that allow identification of patterns and trends within large studies.

When using central monitoring, other legislative requirements must also be considered. If documentation with subject identifiers or contact details for telephone follow up/questionnaires are required, a formal system must be in place that complies with the relevant Information Governance legislation to ensure access to confidential information is restricted and that subjects of the clinical study are aware that the Sponsor, or third party may have access to their data. This must be explicitly detailed in the subject information sheet/consent form and be approved by the HRA and Research Ethics Committee (REC).

Central monitoring (including plans, documentation to be used and processes) will be discussed as part of the Sponsor risk assessment and included in the monitoring plan.

3.5 Triggered Monitoring

A Monitoring Visit may be triggered and a more in-depth assessment of a site be required, if this occurs a Monitoring Visit will be arranged.

Triggers may include:

- Sponsor concerns about the management or conduct of a trial
- Previous Monitoring Visit findings
- Whistleblowing

- When pre-defined thresholds are met (such as number of participants, interim database locks, Data Safety Committee meetings, primary endpoints etc)
- Protocol compliance
- Data compliance
- Notably high adverse event rates
- Notably low adverse event rates
- Lower than expected recruitment
- Higher than expected recruitment
- Lack of compliance with regulatory requirements
- IMP management issues
- Dosing errors

A targeted monitoring strategy will identify sites that require additional support to resolve procedural and compliance issues. Full documentation of the identified trigger, the subsequent visit and actions taken must be documented in the monitoring report and CAPA and retained in TMF and ISF.

3.6 Preparation for On-site Monitoring Visits

The Sponsor will provide adequate notice to the relevant site staff.

Prior to a Monitoring Visit, the Sponsor must review the following in order to develop a clear list of objectives for the visit:

- Protocol
- Risk Assessment
- Data Management Plan (where available)
- Relevant Standard Operating Procedures (SOPs)
- Monitoring Plan
- Previous Monitoring Visit Reports if relevant, paying particular attention to any action points recorded
- Correspondence with the site
- Pharmacovigilance Reports (if applicable)
- Annual and Safety Reports
- Approved documents

In addition, the monitor should:

- Request latest study recruitment figures
- Arrange appropriate appointments with support services (i.e. Pharmacy/Labs/Tissue Bank) and site staff
- Request relevant documentation to aid the preparation of the Monitoring Visit Report
- Request the documentation to be made available during the visit

The site staff must make available all files relating to the research activity. This includes the following:

- Trial Master File(s)/Investigator Site File(s)
- Consent Forms

- CRFs
- Medical notes

3.7 During On-Site Monitoring Visits

The Sponsor will sign the Monitoring Visit Log (Appendix 3). The date on the log must correspond with the Monitoring Visit Report.

Monitoring Visits will be conducted in accordance with the Monitoring Plan and may include the activities listed below however, when applying a risk-based approach and according to the time and information available, it may be necessary to adapt each visit.

3.7.1 Site and site staff:

- Discuss the trial status and any issues that may have been identified
- Seek assurance that the site continues to have adequate resources and facilities for the duration of the study
- Seek assurance that all site staff involved are qualified for their role within the study and are adequately trained in order to meet the study requirements
- Ensure that all site staff have signed, dated and completed the Delegation of Authority and Signature Log. Ensuring also that the CI/ PI has countersigned the log
- Check that there are: up to date study training logs; GCP (or equivalent) certificates; CV's; and completed SOP read records (or equivalent as agreed by the Sponsor) for each member of staff listed on the Delegation of Authority and Signature Log and that these documents cover the duration of their involvement in the study
- Confirm that the site staff are performing the specified study functions in accordance with the Protocol and any other written agreement.

3.7.2 Essential documentation:

The Trial Master File/Investigator Site File will be checked to ensure that all relevant copies of essential documentation are up to date and present, and that there is no personal identifiable data of participants.

3.7.3 Participant recruitment and status:

- Review participant screening, enrolment and recruitment
- Ensure that any barriers or problems with expected recruitment are discussed with the relevant site staff and documented in the monitoring report
- Check that all withdrawn and lost to follow up participants are reported and explained (where appropriate) in the CRF and documented on the enrolment log

3.7.4 Informed consent:

- Ensure that the correct versions of Participant/Patient Information Sheets (PIS) and Informed Consent Forms (ICF) have been used, including where it has been necessary to re-consent a participant
- Check that the ethically approved process is being followed for informing patients about the research, including that they have had adequate time to consider participation
- Check that consent is being appropriately documented in the medical records/CRFs
- Confirm that members of staff obtaining informed consent are adequately qualified and that this task has been delegated to them by the PI on the Delegation of Authority and Signature Log
- Verify that ICFs have been correctly completed and that all participants that sign a Consent Form are listed on both the enrolment log and the screening log
- Confirm that no personnel listed on the Delegation of Authority and Signature Log have been enrolled
- Document non-compliance with the correct consent procedure in the Monitoring Visit Report

3.7.5 Adverse and safety events:

- Review the CRFs and source documents for Adverse Events (AEs)/Adverse Device Effects (ADEs)
- Ensure the current version of the Serious Adverse Event (SAE)/Serious Adverse Device Effect (SADE)/device deficiency reporting form(s) is being utilised
- Determine that all initial and follow-up/final safety reports have been reported to the Sponsor and Chief/Principal Investigator, and where applicable, to any third party organisation
 - Check that the events have been appropriately reported
 - Evidence that Expectedness and Causality are appropriately and accurately assessed and recorded by the relevant and delegated individual
 - Ensure all documentation and associated correspondence is filed in the TMF/ISF and that there is evidence of acknowledgement for all reportable safety events by the Sponsor
 - Evidence that the applicable safety reports have been sent to the Competent Authority (i.e., the MHRA) and the REC
 - Check that there is adequate oversight of safety events by the PI, the CI and Data Safety Monitoring Committee (where relevant)
- Confirm all required safety event data are recorded in the CRF and are consistent with the source data and associated safety reports

- Evidence that periodic and annual safety updates and summaries are sent to the Competent Authority (i.e., the MHRA), REC and third party organisation(s), as required

3.7.6 Pharmacy and IMP accountability:

The key aspects to be assessed and verified for Investigational Medicinal Product(s) (IMPs) within Pharmacy include, but are not limited to, the following:

- Verify, for IMP(s):
 - 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 the receipt, use, and return of the IMP(s) is controlled and documented
 - That the destruction of unused IMP(s) complies with applicable regulatory requirements and is in accordance with the protocol and third party agreements
 - Sufficient supplies are in place throughout the study and expiry dates are acceptable
 - A risk assessment of storage conditions has been carried out where IMP is stored outside of Pharmacy
 - Appropriate labelling (in accordance with Annex 13) and handling of IMP according to manufacturer's requirements is in place
 - Unblinding procedures are in place and working (i.e. a test has been carried out)
- Review storage conditions of IMP(s) and check any deviation from the requirements of the Protocol/Investigator Brochure (e.g. temperature deviations) have been appropriately reported
- Review expiry dates, stock levels held at site, dispensing and accountability records
- Check that participant compliance is acceptable. Where possible, this should be determined from quantities of returned IMP
- Any compliance issues should be brought promptly to the attention of the Investigator

3.7.7 Protocol adherence:

- Verify that the Investigator follows the approved protocol and all subsequent approved amendments to the protocol and associated documentation
- Check the transportation and storage arrangements for any samples taken as part of the protocol
- Ensure that randomisation is being performed in accordance with the Protocol and that the blinding is maintained (if applicable)
- Ensure that Protocol Deviations are reported in the CRF (if a comments section has been provided) and in a Site File Note. Protocol Deviations should also be recorded on the Protocol Deviation Tracking Log and remedial actions should be documented

- The monitor will verify that remedial actions have been implemented and that there are no more (unjustified) Protocol Deviations of the same nature
- A record of the Protocol Deviations will be obtained
- Where applicable report Serious Breaches as per SOP S-1013 UoL Reporting Serious Breaches.

3.7.8 Regulatory Compliance:

- Ensure that all amendments have been correctly notified to the Sponsor and appropriate regulatory review bodies and that all necessary and applicable approvals are in place

3.7.9 Source Data Verification (SDV):

Prior to the Sponsor Green Light, the source of data to be verified should be agreed and documented on the in the Source Data Agreement (SDA; Appendix 4) which should be kept in the TMF. The monitoring of source data will also be explained in the Monitoring Plan.

Source data is comprised of records where subject information is first recorded. It includes, but is not limited to, medical records, lab results, scan results, questionnaires, and where agreed, the CRF or trial worksheets.

- Confirm that enrolled participants meet the inclusion/exclusion criteria.
- Check that source data records are adequately maintained
- Inform the relevant site staff via the monitoring report of any CRF entry error, omission or illegibility
- Check the accuracy and completeness of the CRF entries, source documents and other study related records against each other. For example, 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
 - Safety events, 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 and as Protocol Deviations (where required)
 - All withdrawals of enrolled participants from the study are reported and explained on the CRFs
- Check the process by which changes should be made, and whether this process has been followed. This includes ensuring changes are made, explained (if necessary), that the original entry has not been obscured and that changes have been initialled and dated by the individual and checked by an authorised member of the research team. An audit of changes made in any electronic database should be available also

- Check systems are in place to ensure compliance with data protection requirements
- SDV will be performed for the following data:
 - Participant ID number and initials
 - Date of initial approach and written informed consent
 - Participant eligibility against the inclusion and exclusion criteria
 - Past medical history and demographic data
 - Visit dates
 - Key efficacy variables
 - Safety events
 - Concomitant medications
 - Laboratory results
 - Other safety and efficacy variables

Where there is a SDA, any items defined as being entered directly into the CRF cannot be verified.

3.7.10 Device accountability:

- Review storage conditions of the medical device (if applicable) and identify and report any deviation from the requirements of the Protocol/Investigator Brochure/manufacturer's instructions.
- Review component/device expiry dates, stock levels held at site, dispensing and accountability records (as applicable).
- Check that participant usage/compliance is acceptable.
 - Any usage/compliance issues should be brought promptly to the attention of the Investigator.

3.7.11 Randomisation and Unblinding:

- Check that there is a documented randomisation and unblinding procedure and verify that this is being followed.
- Confirm that there is 24-hour access to the unblinding (or code break) system (where appropriate) and that this has been tested.
- In the event of unblinding/code break, the monitor must check that the reasons are appropriately documented (i.e. the opened code is signed and dated and the treatment assignment and reasons for unblinding are documented in the subject's medical records and CRF, or that the randomisation system has produced a report that shows an audit trail for the event and the reason for unblinding). This documentation should only be reviewed to the extent that it does not compromise the blind of other members of the research team/blinded personnel.
- Details of any unblinding, including the reason, must be documented on the Monitoring Visit Report.

- Check that the Sponsor has been informed of the unblinding/code break within 1 working day.

3.7.12 Laboratory and Clinical procedures:

The key aspects to be assessed and verified within Labs include, but are not limited to:

- Checking that consent for sample collection is in place
- Checking appropriate labelling of samples
- Ensuring destruction of samples complies with ethical approval and appropriate procedures are in place for this
- Checking validation of methods and calibration of equipment has taken place
- Checking that clinical procedures, samples handling and storage are in accordance with the Protocol and laboratory SOPs/procedures.
- Checking that all results are being reviewed, signed and dated in a timely manner by an appropriately qualified and delegated member of the research team.
 - If results fall outside of the normal ranges, clinical significance must be reported and any follow-up actions must be documented.

3.7.13 Biological Samples (blood, tissue and urine):

- Confirming that the Protocol requirements for timing of collection, storage, shipping and documentation have been met
- Checking that temperature monitoring and recording of stored samples (where applicable) have been adhered to
- Checking that the appropriate SOP/procedures for the retention and destruction of biological samples have been followed

At the end of the Monitoring Visit, the monitor will discuss a summary of their findings with the relevant site staff, and any major concerns or issues identified will be discussed with the Principal Investigator (or their delegate) as appropriate.

4. Reporting Timelines

Monitoring Visit Report forms (Appendix 5, Appendix 7 and Appendix 12) must be completed/reviewed by the monitor and submitted to the relevant site staff within 21 calendar days of a visit. Remote Monitoring Visit forms (Appendix 8 and Appendix 9) will be emailed to sites. All Monitoring Visit report forms are published as complete documents however they are intended to be adapted and sections separated out where required to facilitate clear documentation of a monitoring visit.

For all types of Monitoring Visit, unless otherwise specified, the site will have 28 calendar days to respond to the findings using the appropriate document. If the site fails to respond within the specified time, a reminder will be sent giving the site an additional 14 calendar days to respond. Other response timelines may be agreed upon discussion with the Sponsor. Failure to respond after the reminder or agreed

time will result in the non-compliance SOP S-1016 being implemented with a minimum of a major finding.

Monitoring Visit Reports will be escalated within 5 working days if non-compliance and/or areas of concern have been identified in accordance with the non-compliance SOP S-1016. All actions required will be followed-up until satisfactory resolution. All discrepancies that cannot be resolved will be documented in a Site File Note and signed by the CI/PI, relevant site staff and the Monitor (if required).

5. Non-CTIMP Monitoring

The UoL operates a risk-based monitoring programme for non-CTIMP studies. As such, not all sponsored studies or every non-CTIMP site can be monitored. Remote Monitoring by the site, or the Sponsor may be undertaken by utilising the Non-CTIMP Interim Site Monitoring Checklist (Appendix 7) or the Remote Monitoring Report (Appendix 8), respectively. This will enable the Sponsor/CI to have oversight of the management and conduct of the study at that site(s).

The Non-CTIMP Interim Site Monitoring Checklist (Appendix 7) should be utilised at time points throughout the study dependent on study timeline and Sponsor requirement. The Remote Monitoring Report (Appendix 8) should be utilised should a triggered monitoring event occur.

6. Monitoring of External Vendors

External Vendors will be visited as stated in the External Vendor Selection SOP S-1037.

7. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Sponsor	Monitor	Establish a clear list of objectives prior to each monitoring visit.
2.	Sponsor	Monitor	Request that all site staff and documentation required are available for the monitoring visit.
3.	Sponsor	Monitor	Ensure that, as appropriate, the objectives of a monitoring visit are met by following the procedures in section 3.
4.	Sponsor	Monitor	Complete all appropriate documentation as detailed in section 3.
5.	CI/PI	CI/PI or delegate	Provide all requested documentation as detailed in section 2.
5.	Sponsor	Monitor	Develop Monitoring Plan.
6.	Sponsor	Monitor	Review the Monitoring Visit Report and initiate any necessary actions.

	Responsibility	Undertaken by	Activity
7.	CI/PI	CI/PI or delegate	Complete the Monitoring Visit Report Response Document and return within timeline specified detailing action taken and planned.
8.	Sponsor	Monitor	Follow up on the Monitoring Visit Report Response Document requesting update of outstanding corrective action.

8. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
Where required, studies have a Risk Assessment and a Monitoring Plan is developed in accordance with the Risk Assessment	Where applicable, research is included on the monitoring schedule	Where applicable, monitoring is conducted in accordance with the Monitoring Plan. Otherwise, risk-based monitoring conducted according to the risk profile of a study.	Research Governance Manager or their Delegate

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Author:	Dr Cat Taylor	Job Title: Research Governance Manager
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REVIEW RECORD		

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Oct 2013	2	Wendy Gamble	Version 1 revised following review of Sponsor Processes
March 2014	3	Wendy Gamble	Version 2 amended to clarify reporting requirement timelines, now version 3
June 2015	4	Wendy Gamble	Version 3 amended to update appendices, add reference to dose escalation studies and minor amendment to responsibilities table.
March 2016	5	Diane Delahooke	Version 4 amended to include non CTIMP monitoring/audit checklist.
Nov 2016	6	Diane Delahooke	HRA additions, corrections to numbering.
February 2021	7.0	Cat Taylor	Review for proportionality and emphasis on Risk Adaptation, updated address details, UoL logo/branding updated, revision of the document in its entirety, moved to new accessibility template and updated in line with current legislation. Appendix 6 UoL Contact Monitoring Log removed from use. Addition of Appendices 8, 9, 10, 11 and 12. Title of SOP updated.