Quality Control Document:

Site Signature and Delegation Log

# Purpose

One of the principles of Good Clinical Practice is that each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s). In addition, the principal investigator (PI) is responsible for the conduct of the trial at a trial site. They may however delegate trial-specific duties to staff members. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

The purpose of the site signature and delegation log (SS&DL) is to identify site staff members who have taken on trial tasks during the lifetime of the trial. The SS&DL will capture staff members’ names, initials and signatures as needed for identification purposes. It also contains a delegation section to clarify which tasks the PI has delegated to the site staff member. For each trial a SS&DL must be set up, however the design is optional. This template can be used to generate a trial-specific SS&DL but could also be used for studies to meet the requirements of UoB-SMA-SOP-001 Investigator Site Management.

If using a local, site-specific pharmacy signature log, it is expected that the site will retain this for the required duration after the trial’s completion, and that copies are archived for the required period. Where an in-house review of drug accountability forms is performed, it is also expected that copies of the (site-specific) pharmacy signature log are obtained to allow crosschecks to be performed.

# Instructions

1. Remove this first instruction page.
2. Update identifier in header e.g. trial identifier or research group.
3. Update footer; keeping reference information to this quality control document (QCD).
4. Amend the template’s red example text to make it trial specific. If needed, add additional tasks to the ‘responsibilities, descriptions and restrictions’ table and ensure the same numerical code is added to the list of codes on the bottom of the actual SS&DL.
5. It is possible to use a local, site-specific pharmacy signature log alongside the site- or trial-specific SS&DL. In that event, ensure the pharmacist tasks as described under code 15 include ‘ensure pharmacy staff members involved in the clinical trial complete a (site- or trial-specific) signature log’.
6. File completed versions of this record and all related correspondence in the investigator site file (ISF), and where required/applicable, update the coordinating centre of any changes made to this document.
7. Ensure this record remains up to date through regular review

# Related documents

* UoB-SMA-SOP-001 Investigator Site Management
* UoB-SMA-QCD-002 Site-Initiation Checklist

Note the UoB QMS documents can be found on the [Clinical Research Compliance Team (CRCT) website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

| Code | Responsibility  | Restrictions  | Description |
| --- | --- | --- | --- |
| 1. | Obtain local approval for trial  |  | Deal with application for local ethical and research & development approval on behalf of principal investigator, including amendments. |
| 2. | Inform participant of trial (with the purpose of obtaining consent) |  | Inform participant of trial, including visit schedule, medication intake and (trial-specific) assessments. |
| 3. | Obtain participant’s informed consent  | Trial specific – e.g. investigators or medically qualified staff members only | Obtain written informed consent and sign informed consent form. Other members of the research team (e.g. research nurse) may assist with this process (see ‘inform participant of trial’). |
| 4. | Confirm participant’s eligibility  | Investigators only (note for CTIMPs this must be a medically qualified individual)  | Ensure the participant is eligible for trial. Other members of the research team (e.g. research nurse) may assist with this process but responsibility remains with the investigator.  |
| 5. | Participant registration/randomisation |  | Register/randomise participant. This may involve randomisation via telephone, computer systems etc. |
| 6. | Overseeing participant’s medical care (Investigator) | Investigators only | Ensure participant is treated in accordance with the protocol unless this is not in the best interest of the participant. Ensure appropriate tests are performed and deviations from protocol documented. Other members of the research team (e.g. junior doctors, research nurse) may assist with this process, but responsibility remains with the investigator.  |
| 7. | Participant’s medical care (physician) |  | Treat participant in accordance with the protocol unless this is not in the best interest of the participant. Ensure appropriate tests are performed and deviations from protocol documented. Final responsibility remains with the investigator. |
| 8. | Participant’s medical care (nursing) |  | Treat participant in accordance with the protocol unless this is not in the best interest of the participant. Ensure appropriate tests are performed and deviations from protocol documented. Final responsibility remains with the investigator. |
| 9. | Prescribe trial medication  | Investigators or supplementary prescribers only | Prescribe trial medication based on the participant’s current medical condition (laboratory values, weight, adverse events etc.) and dose adjustment schedules stipulated in the protocol.  |
| 10. | SAE reporting |  | Report serious adverse events to the appropriate institution, in accordance with the protocol, and notify other bodies in accordance with local NHS/R&D policy. |
| 11. | Perform causality assessment on SAEs | Investigators only  | Ensure information provided on SAE form is accurate, perform causality assessment, and countersign completed form. |
| 12. | CRF and DCF completion |  | Complete, modify, sign CRF and data queries (e.g. data clarification forms (DCFs)). |
| 13. | Trial-specific sample collection | Trial specific | Collection and shipment of trial specific samples (e.g. pathology tissue samples) according to the protocol. |
| 14. | Investigator site file maintenance |  | Keep investigator site file documentation up to date, including maintaining site signature and delegation log, participant screening/enrolment log and participant identification log, filing completed informed consent forms, case report forms (CRFs), correspondence etc. (as applicable). |
| 15. | Overseeing trial-medication handling | Pharmacist only | Ensure pharmacy staff members involved in the clinical trial complete a (site-specific or trial-specific) signature log that includes their name, function, signature and initials. Ensure pharmacy staff members involved in the clinical trial are appropriately trained to order, receive, appropriately store, dispense and destroy trial medication. Ensure pharmacy file is maintained, including, drug accountability log, drug destruction record etc. as applicable. Ensure trial-specific instructions (e.g. as captured in the pharmacy manual) are followed.  |
| 16. | Trial-medication handling |  | Order, receive, appropriately store, dispense and destroy trial medication. Maintain pharmacy file including (if applicable), drug accountability log, drug destruction record etc.  |
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| --- | --- |
| Site: | PI: |
| Research Team Members | Principal Investigator |
| Name(use block capitals) | Trial role | Tasks(enter codes from list below) | Signature | Initials | Involved in trial | PI initials \* | Date of PI agreement(dd/mon/yyyy) |
| From(dd/mon/yyyy) | To(dd/mon/yyyy) |
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By initialising an entry, I confirm that the person completing the entry is authorised to perform the trial procedures documented in the tasks section and that the person is qualified to undertake these tasks. I also confirm that the person is appropriately informed about the trial protocol and relevant trial procedures.

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| --- | --- | --- | --- |
| 1. Obtain local approval for trial
2. Inform participant of trial
3. Obtain participant’s informed consent
4. Confirm participant’s eligibility
5. Patient registration/randomisation
 | 1. Oversee participant’s medical care (investigator)
2. Participant’s medical care (physician)
3. Participant’s medical care (nursing)
4. Prescribe trial medication
5. SAE reporting
 | 1. Perform causality assessment on SAEs
2. CRF and DCF completion
3. Trial-specific sample collection
4. Investigator site file maintenance
5. Overseeing trial-medication handling
 | 1. Trial-medication handling
2. Other:………………………………………
3. Other:………………………………………
4. Other:………………………………………
5. Other:………………………………………
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