About the Site Signature and Delegation log

The site signature and delegation log documents:

* The names of staff working on the study along with an example of their signature and initials
* The staff member’s trial specific role
* The specific tasks each individual member of staff is authorised to carry out
* The authorisation from the PI for individuals to carry out these delegated tasks

It is the responsibility of the PI to ensure that each individual on the delegation log is appropriately qualified for the role they are to undertake and have received GCP and study specific training commensurate to the task(s) they have been delegated.

* An individual must be added to the delegation log and signed off by the PI prior to undertaking any study specific tasks

Completing the delegation log

* The delegation log can be pre populated electronically however signatures, initials, PI signature and PI date must be wet ink
* Hand written information must be legible. Any changes made to the log should be made using a GCP compliant correction (see CR004).
* Tasks in the footer should be made study specific and reflect tasks required by the protocol and other study specific documents.
  + Tasks in **Bold** should not be removed without prior agreement by the ACCORD Clinical Trials Monitor.
  + Clinician only tasks in red can only be performed by a qualified clinician. Clinician only tasks in black may be performed by other clinical members of staff on a study specific basis depending on clinical setting, if you wish to remove clinician only from these tasks please confirm with the ACCORD Clinical Trials Monitor.
  + When listing ‘Other’ please specify the task
  + For trials of medical devices please add adverse device effects (ADEs), device deficiencies and serious adverse device effects (SADEs) assessment as tasks
* The ‘from’ date for an individual should state the date they began working on the study. The ‘to’ date should not be completed until the individual has left the study team or the study ends at site.
* The PI signature at the bottom of each page should be completed once the study site has closed and the delegation log is complete.
* For tasks which are delegated to whole departments, e.g IMP dispensing to pharmacy, only one member of the department, e.g the lead pharmacist, should be added to the study signature and delegation log. The delegated department should then hold a separate signature log to record members of staff authorised to perform the task at a departmental level.
* Members of staff performing tasks as part of their routine job function with no study specific role, e.g NHS Haematology laboratory staff processing routine FBC, need not be added to the delegation log. Individuals completing any form of study specific paperwork, e.g CRFs or logs, must be added to the delegation log regardless of if they are performing a routine job function.

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