



Monitoring Clinical Trials
305-00

1. Purpose

The purpose of this operating procedure is to outline the monitoring procedures performed by the methods centre for research studies.

2. Responsibilities

Qualified Investigator (QI):

Methods Centre (MC):

3. Procedures

3.1 Monitoring is *“the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements.”*

-ICH GCP section 1.38

3.2 As per ICH GCP section 5.18.1, monitoring is performed to verify:

3.2.1 The rights and well-being of human participants are protected

3.2.2 The reported trial data are accurate, complete, and verifiable from source documents.

3.2.3 The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable governing regulations.

Qualification and Selection of Monitors

3.3 Monitors should be appointed by the MC and the study principal investigator.

3.4 Individuals delegated the responsibility of conducting study monitoring should have their qualifications documented.

3.4.1 Monitors should be appropriately trained to conduct monitoring activities.

3.4.2 Monitors should possess scientific and/or clinical knowledge relevant to the indication under study.

3.5 The monitor should be familiar with the investigational product, written informed consent form (and any other written information provided to participants), MC SOPs, GCP and any governing regulations.

Extent and Nature of Monitoring

3.6 The MC should ensure research studies are adequately monitored.

3.7 The MC should ensure the extent and nature of monitoring is proportionate to the following:

3.7.1 Objectives and purpose

3.7.2 Design and sample size

3.7.3 Complexity

3.7.4 Blinding

3.7.5 Associated risks

3.7.6 Endpoints



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- 3.8 In general, on-site monitoring should be conducted before, during and after the study. However in the context of academic (Investigator initiated) studies, the Principal Investigators (PI) and the MC may decide central monitoring supplemented with training, meetings, written guidance is sufficient to ensure compliance with GCP and governing regulations.
- 3.9 The specific details concerning monitoring activities for a particular research study will be documented in a study specific work instruction (WI). The WI will include the following details:
- 3.9.1 Selection of data elements to be verified
 - 3.9.2 Frequency of monitoring
 - 3.9.3 Scheduling monitoring visits (including requests for access to source documentation)
 - 3.9.4 Communications with research sites
 - 3.9.5 Monitoring queries and follow-up
 - 3.9.6 Monitor documentation
 - 3.9.7 If applicable, details concerning central monitoring and associated training, meetings and procedures

Monitor's Responsibilities

- 3.10 As per PI and MC requirements, the monitor should ensure the study is conducted and documented properly through the following activities (refer to ICH GCP section 5.18.4 for full details):
- 3.10.1 Facilitating communication between the research site and the MC.
 - 3.10.2 Verifying research site personnel, including the qualified investigator and facilities (i.e. pharmacy, laboratory) are adequately qualified to conduct the study (and remain adequate for the duration of the study).
 - 3.10.3 Research site follows study procedures and data collection is carried out in compliance with the study protocol and GCP.
 - 3.10.4 Data is collected and entered into case report forms by appropriately delegated personnel.
 - 3.10.5 Data is free of omissions and is correct.
 - 3.10.6 Confirm each participant has provided written informed consent.
 - 3.10.7 Verifying for the investigational product that:
 - 3.10.7.1 Supplies are sufficient and storage conditions are acceptable.
 - 3.10.7.2 Administration of investigational product follows study procedures (i.e. frequency and dosage).
 - 3.10.7.3 Accountability is performed
 - 3.10.8 Verifying all enrolled participants met eligibility criteria
 - 3.10.9 Verifying that all source documents and other study records, including regulatory documents, are accurate, complete, kept up-to-date and maintained.
 - 3.10.10 Determining whether all adverse events are appropriately reported and within the time frame required by GCP and governing regulations.
 - 3.10.11 Communicating protocol violations/deviations and taking appropriate action to prevent recurrence of the violation/deviation.

- 3.11 A comprehensive list of monitor responsibilities can be found in ICH GCP section 5.18.4.

Monitoring Procedures

- 3.12 The monitor should follow the study specific WI for monitoring a specific study.



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Monitoring Report

3.13 Following the monitoring visit, the monitor should provide the MC (and PI) with a written report.
Written reports should include:

- 3.13.1 Institution, qualified investigator, research site personnel in attendance
- 3.13.2 Date visit conducted, name of monitor
- 3.13.3 Summary of documents the monitor has reviewed, along with a statement of findings, violations/deviations, deficiencies, conclusions, actions taken or recommended.

3.14 Refer to appendix 4.1 for the Site Monitoring Visit Report template.

4. Appendix

4.1 Site Monitoring Visit Report

5. References

5.1 ICH GCP Section 1.38: Monitoring

5.2 ICH GCP section 5.18: Monitoring

5.3 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.010.