Compliance & Non- Compliance

Module 7 Topic 6

Definition

- Non-compliance is any failure to comply with GCP or the current study protocol as approved by Ethics Committee, any relevant Regulatory Authority, sponsor and Research Department
- Non-compliances are often technical deviations which do not have a significant impact on the safety or physical or mental integrity of the subjects of the trial or the scientific value of the trial
- More serious non-compliance may constitute research fraud or misconduct or may constitute a serious breach of the trial protocol or GCP

Serious Breach

- A “serious breach” is a serious non-compliance with the protocol or with GCP which is likely to affect to a significant degree
- The safety or physical or mental integrity of the subjects of the trial; or
- the scientific value of the trial.

Reporting of non-compliance

- The Principal Investigator (PI) or other member of the research team identifies that a non-compliance with either GCP or the protocol has occurred
- The member of the research team identifying the non-compliance informs the PI of the non-compliance
- The PI or delegate records the non-compliance on the Non-Compliance Form and makes an initial assessment of whether the non-compliance may constitute a serious breach

Reporting of non-compliance

- Where the PI or delegate suspects that the non-compliance may constitute a serious breach the PI or delegate reports the non-compliance to their R&D Coordinator within 24 hours of becoming aware by faxing the non-compliance form to the Research Department
- The R&D Coordinator notifies the QA Lead and Research Manager immediately of the potential Serious Breach and logs the receipt on the Research Department database

Non Serious Breach

- Where the non-compliance is not considered to be a serious breach the PI or delegate forwards the non-compliance form to the R&D Coordinator either by email or by post
- The R&D Coordinator logs receipt of the non-compliance form on the Research Department database

Non Serious Breach (contd)

- The R&D Coordinator reviews the non-compliance form, taking advice from the QA Lead, Research Manager or delegate where necessary to decide whether the non-compliance could constitute a serious breach
- If the R&D Coordinator suspects that a Serious Breach may have occurred the R&D Coordinator reports their concerns immediately to the QA Lead or Research Manager

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- Non-compliances may also be detected by the Research Department during Monitoring Visits or For Cause Audits. In this case non-compliances will be recorded as findings on the Monitoring Report
- If, as a result of the monitoring visit the R&D Coordinator conducting the visit suspects that a serious breach may have occurred the R&D Coordinator reports their concerns immediately to the QA Lead or Research Manager

Key Role

- Who plays the primary role in assuring research is performed in compliance to the regulations?
- Not the Sponsor; Not the CRO; Not the SMO; Not the Institution or the IRB

THE INVESTIGATOR

Key Role

- If the sponsor's research does not meet compliance standards of the Institution, the IRB, or the Investigator, they can refuse to conduct the research
- If the Investigator's research practices are not in compliance it is more difficult to identify, correct or control in "real time"