AlfredHealth

Research Governance Update – ICH GCP E6 (R2)

A new addendum has been created in response to compliance issues with GCP (data management, documentation and monitoring). It is effective as of November 2016.

The main compliance issues include: inadequate record keeping and storage of records, protocol deviations, poorly documented training, inappropriate delegation of authority, lack of source documentation and poor informed consent processes.

The addendum covers changes to data management, investigator responsibilities and sponsor responsibilities.

For investigators (and this means Principal Investigators) the focus is on i) adequate resourcing and ii) reporting and recording trial data. The key points are as follows:

i) Adequate resourcing

- The investigator is responsible for supervising anyone they have delegated tasks to. Supervision is throughout the life of the trial, not just the commencement.
- The investigator is responsible for the delegation log, ensuring this is kept up to date and that those delegated tasks are appropriately qualified to perform those tasks. The delegation log now has to cover third party providers (such as outsourcing testing to a private provider) and recommends a service agreement be in place for external providers. Resource centre declarations should be in place for use of health service departments.
- Investigators should keep a training log and include training in protocol amendments.
- Investigators should keep a record of team meetings and the topics discussed.

ii) Reporting and recording of trial data

- Investigators should keep adequate source documentation and trial records. Source documents should clearly identify the person who made the entry and be legible, contemporaneous, original, accurate and complete. Templates may be helpful for collecting source data.
- Sites should discuss data management with the trial sponsor up front and be mindful of what is agreed to in the clinical trial research agreement.
- Investigators should retain a record (list) of all locations where source documentation is held as not all source information is in the patient medical record.

For sponsors the focus is on developing and implementing monitoring plans. The monitoring plan should use a risk based monitoring approach. The sponsor should develop SOPs on data collection and electronic data capture. Sponsors are also responsible for developing corrective and preventative actions when non-compliance with GCP is identified. Sponsors can now terminate a site's participation in a trial, under GCP, for serious or continual non compliance of the protocol or GCP.

For more information or a copy of the addendum go to
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf