CHICKEN SOUP FOR THE BUSY COORDINATOR

January 2018

BEST PRACTICES ON DATA MANAGEMENT

Scenario:

Professor T conducted an investigator initiated trial (IIT) with his group of research team members evaluating the effects of Vaccine A on patients diagnosed with disease Z. The participants were inpatients of the hospital, and the Computerised Patient Support System (CPSS) acted as the source documents.

The information was later transcribed onto the paper Case Report Form (CRF) before being entered into the electronic data collection form (eDCF). Dr Y, the co-investigator later highlighted that the result was wrongly reported due to a technical reason. The paper CRF and source documents of all the 100 enrolled patients in the CSPP were later being updated with the correct data by the team members. However, the eDCF was being overlooked.

What should have been done to ensure data accuracy prior to using data for research

Professor T should:

- Include plans and/or standard operating procedures on how data/information collected should be reviewed and sign off; to signify their completeness and accuracy.
- Queries should be addressed as soon as possible.
- Ensure all that study team members are adequately trained in good data-management practices.

Some useful pointers/ considerations for good data management

- Professor T should state clearly in the Study Responsibility Log whom in the research team is responsible for data management activities such as transcription of data to CRFs, data entry and analysis (where applicable).
- Recording should be done as soon as possible after data are collected.
- Set aside some budget to engage someone/agent to conduct frequent monitoring for the study as regular monitoring can help to ensure data completeness and accuracy.
- Using best practices through all stages of a research project will ensure the accessibility and longevity of resulting data.
- For electronic data (if used), the archival processes of these documents must adhere to the following principles:
    - All research information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.
    - The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with applicable regulatory requirements.
    - Systems with procedures that assure quality of every aspect of the research should be implemented.

References:

1) NHG Proper Conduct of Research Standard Operating Procedures 501-B05: Documentation & 501-B08: Data Collection and Handling

Additional reading:

1) NHG Proper Conduct of Research Standard Operating Procedures 501-B09: Study Completion Activities
2) NHG Responsible Conduct of Research Chapter 5. Data Management Practices

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