CHICKEN SOUP FOR THE BUSY COORDINATOR

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NHG RQM Common Study Review Finding: Data Collection & Source Documentation

One of the most common study review findings observed by the NHG Research Quality Management (RQM) Unit at study reviews is the lack of reliable, accurate and adequate source documentation.

Scenario:

The NHG RQM conducted a study review of Dr. W., the Principal Investigator (PI) of a clinical research study. This study involves the collection of data (i.e. vital signs and ECG) from research procedures. Data Collection Forms (DCFs) and questionnaires were used to collect these data. During the study review opening meeting, it was informed that source data (ECG and vital signs) were printed out from machines. As the printed copies of the original source data may fade, the study coordinator made copies of them. It was also informed that the questionnaires were administered for some subjects by the clinic nurses who were not study team members.

During the document review, it was noted that completed questionnaires did not capture the signature and date of the study team member who had completed the information. The study coordinator did not initial and date the changes on the DCF. A pencil was used to correct some study documents. Eligibility assessments completed by the study coordinator were not documented in the source documents.

Based on the scenario above, what are considered deficiencies/ findings reportable by NHG RQM Study Reviewers?

1. Non-study team members conducted study related activities.
2. Source data was not attributable as they were printed out from machines, were photocopied and not certified as true copies by the designated staff.
3. Inappropriate correction methods were used to correct the DCF.
4. Completion of the DCFs were not attributable and legible.
5. Documentation of eligibility assessments was not available.

What are the Recommended Corrective Action and Preventive Action (CAPA)?

1. Report a non-compliance to the NHG DSRB as non-study team members were involved in study activities.
2. As source data are printed out from machines will be photocopied, to certify them as true copies by the designated staff and file it in the investigator file.
3. Create a "Note-to-file", to explain who had made the corrections and documentations on the questionnaires (for items 3 and 4).
4. Create a "Note-to-file" to explain who had conducted the eligibility assessments and provide an explanation for all subjects' eligibility assessment/recruitment process.
5. Moving forward, the PI and study team should ensure that the research study information is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

References:

1. NHG Proper Conduct of Research SOP:
501-A02: Responsibilities of the Research Team & 501-B05: Documentation
2. NHG Proper Conduct of Research Template: 507-006 Note to File Template

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