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Good Clinical Practice Q&A: Focus on Subject Diaries

If study coordinators transcribe data from diaries onto a case report form, should the site retain copies of the diaries? And are diaries source documents? How would eDiary data be retained?

When diaries are used to record the first observations of a subject's clinical status while on study — even though the subject and not the investigator or site staff make these observations — they should be considered source documents. When diary data must be transcribed onto a case report form, the site must retain the diaries just as any other source documents would be retained. Monitors should review the case report forms against the diaries to check for inconsistencies and/or data omissions. The direct integration of eDiary information to a Clinical Data Management System or to an eCRF will eliminate this step, both as a task for the site, as well as a potential for the secondary introduction of data entry errors. When an eDiary is in use, whether integrated or not, the eDiary data should be maintained in a database and ultimately in an archive that is fully accessible to the appropriate site personnel. Site personnel should be able to generate copies of the eDiary data upon request.

Source

"Good Clinical Practice: A Question & Answer Reference Guide," Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.