From: OC GCP Questions
Sent: Thursday, February 06, 2014 8:16 AM
To: [redacted]
Subject: RE: Psychiatry Trials - source documentation

Dear [Redacted],

FDA has the authority to review relevant records that provide needed background information about a study participant when that participant's data are used in support of a marketing or research permit submitted to FDA. For psychiatric patients who become participants in a clinical investigation, a heightened concern about privacy and confidentiality is understandable.

FDA drug and device regulations in this regard require broadly that study records be adequate and accurate (see 21 CFR 312.62 and 812.140). This regulatory flexibility allows sponsors and clinical investigators to establish procedures best suited to their circumstances. Since a sponsor's monitors and auditors are tasked with ensuring the integrity of the data in the same way FDA investigators are, they too need access to the original source documents to verify essential information is accurate and complete. Before including a site in a study, a sponsor should verify that study monitors will be allowed access to all pertinent source documents.

When the regulations were written, capture of information regarding study participants was expected to mimic how physicians record patient information during routine medical visits. That is, it was expected that notes would be entered into a subject's chart, with information specific to case report form (CRF) data transcribed to the CRF at a later time. Since some information and a number of testing procedures (e.g., quality of life surveys, pain scale determinations) may be study-specific information, many sponsors/study sites choose to enter this information directly on a CRF. This method has the advantage of eliminating transcription errors, which can be numerous for studies that collect large amounts of data.

While this means there is no other source that can be used to verify information captured only on the CRF, FDA has not forbidden this practice. If a sponsor chooses to do this, the study protocol should specifically spell out which data are directly entered onto CRFs and therefore have no corroborating documentation. This will allow for consistency across study sites and inform FDA BIMO investigators of this fact, if there's a BIMO inspection.

Oftentimes, clinical investigators maintain copies of certain records in their study files; for example, records from a hospital or other institution that must maintain the originals. FDA refers to these as shadow files. While it is acceptable to keep shadow files in the study records, an FDA investigator conducting a bioresearch monitoring (BIMO) inspection of the study would expect to review at least a portion of the original source documents for those shadow files to verify their authenticity (even if the copies in the shadow files are certified as authentic copies).

For additional information, please see the International Conference on Harmonization (ICH) Guidance for Industry – E6 Good Clinical Practice: Consolidated Guidance (available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf). Section 4.9 contains certain recommendations regarding investigator records and reports. For example, data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained (see paragraph 4.9.2).

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
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Office of Good Clinical Practice
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WO32/5129
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From: [Redacted]
Sent: Wednesday, February 05, 2014 1:33 PM
To: OC GCP Questions
Subject: Psychiatry Trials - source documentation

Good Afternoon,

I'm wondering if Psychiatric clinical trials have different guidelines for source documentation requirements? Many psychiatrist's practices do not have access to patient medical records (electronic or paper) because of the location of the practice and because psychiatric records often require a different level of access than regular medical records, so are kept separately from the standard medical record. When clinical trials involve collecting data, other than from the psychiatrist's own patient records/notes, (past medical history, lab tests, etc…) is source documentation considered adequate if it's derived from a patient interview and the investigator/psychiatrist dictates the information into a signed and dated note? Or, as with other medical disciples, the source is where the information was originally recorded? If this is the case, it would seem appropriate to ask for the patient/subject to provide a copy of pertinent information from their medical record for the clinical trial.

Thank you very much,
[Redacted]