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What Does the Investigator's Signature Mean?

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Over the past decade, clinical research sponsors have steadily increased their requests for principal investigator (PI) signatures on more and more pages of the source documents. This increase may reflect growing sponsor concerns about "ghost" investigators. No doubt, there are PIs who abdicate their responsibilities to inexperienced study coordinators and, days after the event, hastily sign the source documents for subjects barely remembered from the initial visit. However, at the opposite extreme, there are diligent PIs who are physically present or readily available during study visits and who closely supervise and train their staff on protocol specifics. Precisely because the PI is already closely involved in the study, he/she may not feel the need to immediately countersign every routine visit encounter, electrocardiogram (ECG), chest film, or lab data report.

The PI's dated signature indicates that he/she has accepted responsibility for reviewing the information in the document. However, it says nothing about whether the PI was actually present at all or part of the visit and, if present, what part of the visit's activities he/she personally performed or supervised. To accomplish these objectives, more detail is required. If the visit is routine, there are no apparent adverse events, and a future audit is unlikely, the PI may not want to make the extra effort to document these details. However, once there is an unexpected event or an audit or FDA inspection occurs a year or two later, the detailed extent of the PI's supervision and personal conduct of the trial may become a very important question. The PI may now wish that there had been more documentation.

Scenario One: "Diligent PI"

"Diligent PI" is present for a Friday visit. He talks with the subject and reviews the ECG, lab data, etc. Everything is normal and routine. Because the visit does not require a physician assessment, Diligent PI does not write anything in the source documents; he does not track down and sign the lab reports that he reviewed during the visit a few minutes ago but are now on the coordinator's desk. Monday arrives. The coordinator gives Diligent PI the chart with the source documents and reports in place for his signature. Although Diligent PI actually saw the patient and reviewed the data on Friday, he correctly signs the required source document visit and lab report sheets with today's (Monday's) date. To document his presence and review of lab data at the Friday visit, Diligent PI could take the extra time to write a note, or "late entry" but he doesn't see the need, so he simply signs and dates the required pages. (Diligent PI does not even consider "backdating" the signature to Friday since a false date could be viewed as fraud.) The study proceeds to completion uneventfully.

The FDA arrives for an inspection a year later. There are some issues – minor, but issues none the less – about the extent of Diligent PI's supervision. Nobody can remember whether Diligent PI was present at the Friday visit. The documentation (nursing assessment, lab reports, etc.) was signed three days after the visit date, suggesting that Diligent PI was not there. Also, on several other visits, Diligent PI's signatures were dated several days after the actual visit date. There were no protocol violations to alarm the FDA. Nor, during the three days between the study visits and PI signatures, were there any serious adverse outcomes (e.g., heart attacks or strokes) to provide fodder for potential negligence claims . That is fortunate, because the FDA or the subject's attorney could easily have concluded

that there was a pattern of negligence when, in fact, Diligent PI was doing an outstanding job.

Scenario Two: "Casual PI"

During the Friday visit, "Casual PI" is out of the office as usual and makes no effort to be available by telephone. The coordinator, accustomed to proceeding on her own, performs the visit assessments, ECG, etc., and does not notice an abnormal lab test (T wave changes on the ECG). She puts the source document paperwork in Casual PI's signature box. Casual PI has learned the value of dotting the i's and crossing the t's. He therefore comes into the office late that Friday night on his way home. There is an impressive stack of paper in his inbox. Since the coordinator has not flagged any of the reports, Casual PI overlooks the abnormal ECG and rapidly signs the required pages with the correct (Friday) date. Luckily, the study proceeds to completion uneventfully.

The FDA arrives for an inspection a year later. It appears that Casual PI was present at the visit and doing a good job since all the other visits and lab reports were apparently signed on time and Casual PI simply missed the abnormal lab data due to "human error". The subject did not have a heart attack, which would have given his attorneys a field day claiming negligent review of the ECG. Perversely, Casual PI looks good when, in fact, he was doing a poor job.

The Solution

A negligent investigator may prefer to leave the question of his/her presence and role ambiguous, but a diligent investigator benefits from accurate documentation. Extensive handwritten progress notes are overly burdensome, but there is an easier alternative: a checklist progress note form, completed during the visit that documents the PI's role in the visit.

An example form developed by Spartanburg Medical Research (SMR) is at http://www.firstclinical.com/journal/2006/0609_Present_Form.pdf. In addition to documenting the extent of PI involvement for the visit, this form also gathers together key items such as reminding the subject about the next appointment, ascertaining if there is a need to communicate with other physicians who may be seeing the subject, and having the subject sign for any reimbursement. Most importantly, taking just a few extra seconds, the coordinator documents the PI's involvement in the visit. The PI may also comment on trends, adverse events, etc., as indicated. Including all of these items on one form reduces the likelihood of overlooking anything important.

Asking the coordinator to document PI involvement on this form raises the question: Who is the best person to document the PI's involvement – the PI or the coordinator? With all due respect to PIs, there are good reasons to rely on the coordinator:

- The study is the primary focus of the coordinator. He/she is less likely to be distracted by conflicting tasks.
- Documentation is a large part of the coordinator's job. It is a secondary priority, at best, for physicians.
- If there is any innuendo of fraud or misrepresentation, contemporaneous documentation by one person for another is most credible.
- The precedent has been established elsewhere in the healthcare system (e.g., hospitals) for nurses to document in their progress notes when physicians arrive on the floor.

Use of the progress note form at SMR has substantially contributed to the quality of the service provided and, on balance, saved time. Because everyone knows they are "on camera," issues never arise about "tattle-telling." Unlike selective documentation, which can appear self-serving, routine documentation holds up better in FDA inspections and subject injury litigation. SMR's progress note form presents the facts in an objective manner, while handwritten documentation may inadvertently cast an event in a negative light. Positive comments by sponsors and the absence of any questions as to the extent of PI involvement in four FDA audits (but no subject injury litigation) suggest that the effort has been worthwhile.

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