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When Is a Medical Record Not a Source Document?

By Paul R Latimer

Increasingly, site monitors ask investigative sites for access to a study subject's entire medical record. In the case of psychiatric trials, the medical record includes notes on everything the patient has discussed confidentially, whether or not it is relevant to the trial. Psychiatric medical records often include embarrassing information and might even disclose criminal activity.

Site monitors are seldom able to explain why they want access to the entire record or specifically what they are looking for. The author has actually been told, "I don't know, but I'll know it when I see it." This is a fishing expedition, not a scientific inquiry. A site monitor should be able to say what they are looking for and why, so the relevant records can then be provided.

An investigator should not give a site monitor access to a subject's complete medical records — without adequate justification — for the following reasons:

- Unlimited access constitutes an unwarranted invasion of a subject's privacy, prohibited by ethics and often regulation.
- Unlimited access raises issues related to the time and cost required, proper delegation of authority to the investigator, and the investigator/sponsor relationship.
- Unlimited access unfairly discriminates against some study subjects just because their medical records are available.

Subject Privacy

Although subjects are aware that strangers will view some of their medical history, they generally assume it will only be information that is relevant to the clinical trial in which they are participating. It is thus unethical for a physician to give *carte blanche* access to a subject's medical history, unless the information is directly relevant to the clinical trial and the subject has given informed consent to the extent of the disclosure.

U.S. Federal regulations and the FDA's "Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance" (GCP) give site monitors access to medical records for specific purposes, subject to limits that protect subject privacy.[1]

GCP defines source data and documents as follows:

> **Source Data.** All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). (GCP 1.51)
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> **Source Documents.** Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, X-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). (GCP 1.52)

GCP states that, "the sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit *trial-related monitoring*, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents." (GCP 6.10, italics added) GCP sets no explicit limits on source document access when it states that the purpose of source documents is: "To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject." (GCP 8.3.13) However, based on the author's experience in psychiatric clinical research, "trial-related monitoring" is often interpreted as unlimited access, which is overly broad and creates significant privacy issues, unnecessary burdens on the investigator and site personnel, and inefficient processes for both site and sponsor.

U.S. Federal regulations state that an investigational new drug application must include "a description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and *to minimize risk*." (21 CFR 312.23 (a)(6)(iii)(g), italics added) They also state that, "the IRB shall determine that…there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." (21 CFR 56.111) They further state that the essential elements of informed consent include "a description of any reasonably foreseeable risks or discomforts to the subject" and "statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." (21 CFR 50.25) While disclosure to *unauthorized* persons is of primary regulatory concern, limiting the amount of disclosure to *authorized* persons is also important to reduce both the risk of disclosure to unauthorized persons and also because many study subjects would want to limit disclosure of their sensitive information even to authorized persons. The HIPAA Privacy Rule thus states that "…a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request." (45 CFR 164.502(b)

Clearly, access to a study subject's private medical records should be minimized, in respect to who has access and also to which specific documents can be accessed. The informed consent form and/or HIPAA authorization should state the extent of access, particularly to sensitive information. A bland, open-ended statement about access is insufficient; if site and sponsor personnel will have *carte blanche* access to a subject's medical records in their entirety — including sensitive information irrelevant to the study's objectives— the investigator must ensure that the subject clearly understands the scope of the disclosure he or she is authorizing.

While a subject's identity may be concealed in study documents by the use of initials and numbers, his or her full name is readily available on the signed consent form, so anonymization is ineffective for anyone who has access to both consent form and medical records.

Site monitors need complete access to consent forms and source documents that directly support the case report forms (CRFs). They also need access to documents required to ensure adequate monitoring. This access extends to relevant medical records, but not to medical records in their entirety. For example, in a psychiatric study, medical records pertaining to sexually transmitted disease is probably irrelevant. If investigator fraud or incompetence is suspected, broader access might be warranted.

Practical Issues

A study sponsor delegates conduct of a study to an investigator who is "qualified by education, training and experience to assume responsibility for the proper conduct of the trial." (GCP 4.1.1) The "sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted

and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)." (GCP 5.1.1) In other words, the investigator conducts the study according to the protocol, and the sponsor ensures that the investigator conducts it properly. If the sponsor wants the investigator to conduct the study in a particular way, it should provide the appropriate instructions in the protocol, not attempt to take on the investigator's role.

The protocol should include "a detailed description of the objectives and the purpose of the trial." (GCP 6.3) It should also include "subject inclusion criteria" (GCP 6.5.1), "subject exclusion criteria" (GCP 6.5.2), and "the methods and timing for assessing, recording and analyzing safety parameters." (GCP 6.8.2) Although GCP does not connect the dots explicitly, the protocol should state what data and documents from the subject's medical record are relevant to the protocol's objectives, eligibility criteria, and safety monitoring, so the investigator can conduct the study correctly. Given that medical records contain the study subject's private information, the protocol should not permit the investigator, site personnel, or sponsor personnel to invade the subject's privacy more than necessary to accomplish these objectives.

Unlimited access to medical records by site monitors (and other sponsor personnel) can raise practical issues, such as the following:

- It is time consuming to generate paper copies of medical records. Site personnel have to request, review, copy and certify the records. Alternatively, giving a site monitor access to electronic health records typically requires full-time participation by a study coordinator. Obtaining records from other health care providers can be especially costly and problematic.
- Many site monitors do not have the medical training necessary to correctly interpret medical records, so time-consuming explanations can be required. Medical monitors can overrule correct decisions.
- Medical records are often ambiguous, e.g., if a patient's diagnosis has changed over time. A previous physician might have made a different diagnosis because he or she used different diagnostic criteria or because the patient presented differently at that time, e.g., with bipolar disease. A physician might have employed an incorrect diagnostic code to obtain insurance coverage for the patient for an expensive treatment or procedure.
- Patients with extensive medical histories are less likely to participate in clinical trials, provided they understand the extent of the intrusion into their privacy. From a scientific and safety perspective, these are the preferred subjects for clinical trials.
- Second-guessing the investigator's medical judgment or honesty can corrode his or her vital relationship with the sponsor. It also encourages investigators to rely on the sponsor for quality management.

Fairness

A subject who has been the investigator's patient for many years is likely to have extensive medical records available, while a subject referred by another physician may have only an extract or summary available, and a subject who responded to an advertisement might have no medical records available at all. It seems unfair to intrude on the privacy of long-time patients more than that of complete strangers, especially since the investigator's judgment about his or her patients is likely to be much more accurate than about complete strangers. In addition, a close examination of a long-time patient's records implies that the investigator is less competent or honest than a referring physician, or no physician at all.

Recommendations

Diligent site and medical monitoring certainly finds mistakes, some very serious, made by investigators and site personnel. However, there should be reasonable bounds on the information provided by the site, consistent with regulations, ethics, practical issues, and fairness. The following steps could be implemented:

- The Institutional Review Board (IRB) or Privacy Board should ask the sponsor to specify and justify the bounds of medical records access in its initial application, with special attention to sensitive and noncontemporaneous material.
- The sponsors should request only those medical records directly related to data in the CRFs and adverse event records.
- If the sponsor needs additional medical records, e.g., to ensure proper site monitoring, it should request only that data and clearly explain why they are needed. In the case of a serious adverse event or suspicion of investigator fraud or incompetence, the monitor can "break the glass" to access more information.
- Access by site study personnel to medical records should be on a need-to-know basis, which becomes more practical with the adoption of suitable electronic medical records systems.
- Informed consent forms and/or HIPAA authorization forms should clearly explain which medical records would be made available to whom and for what reason.

Reference

1. Based on International Conference on Harmonisation "Guideline for Good Clinical Practice E6(R1)," 1996

Author

Paul Latimer, MD, PhD, FRCP(C) is a psychiatrist and President of Okanagan Clinical Trials in Kelowna, BC. Contact him at 1.250.862.8141 or dr@okanaganclinicaltrials.com.

