

Good Clinical Practice Q&A: Focus on Regulators

Citing HIPAA-related privacy standards, some clinical investigators have attempted to deny sponsor-monitors and FDA field inspectors access to study patients' medical records. To what degree, if at all, are such denials of access permissible?

Such denials are not permissible in the context of clinical research. In terms of monitor access, to the extent that monitoring activities are required by the FDA or other regulation or are for purposes related to adverse events, the HIPAA Privacy Rule permits access without an authorization or waiver of authorization.

Likewise, HIPAA privacy standards in no way affect the FDA's access to study-related records. Because it has encountered such situations at some sites, however, the FDA has developed specific language that it uses in response to investigator attempts to use HIPAA concerns to block the agency's access to study records: "The FD&C Act, the FDA-482, and BIMO regulations at CFR 812.145(b), 312.68, and 56.115(b) permit FDA investigators at reasonable times to have access to, copy and verify records. In addition, the subjects' informed consent forms are to 'include a statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained and that notes the possibility that the FDA may inspect the records' [(CFR 50.25(a)(5)]. Additionally, several specific exemptions in the HIPAA privacy rule [45 CFR Parts 160 and 164] expressly permit covered entities to use and disclose protected health information to FDA investigators without the investigator having to sign any kind of agreement. These include uses and disclosures: (1) required by law [45 CFR 164.512(a)]; (2) to a public health authority authorized by law to collect or receive such information [164.512(b) (1)]; and (3) to a health oversight agency for oversight activities, including audits, investigations and inspections [164.512(d)]. HIPAA privacy standards are not intended to affect the access that FDA investigators have previously been afforded."¹

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2011, #4.28 p. 134

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2011," is available for \$45.95 at <http://www.barnettinternational.com> in electronic and paper form.