From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, February 16, 2005 2:12 PM
To: [redacted]
Subject: RE: Part 11 Compliance of open systems

Dear [redacted],

Your inquiry was referred to our office for a direct reply. Actually, there are no regulatory requirements for encrypting clinical trial data. What is required by the regulations is that IRBs approve studies that have adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, where appropriate. [see 21 CFR 56.111(a)(7)]

It is quite understandable that, when transmitting data from one system to another (especially one outside of your system), one might want to encrypt data to make ensure confidentiality of the data. When it comes to storing data on your hard drive, it is more important that controls be in place that limit access to the data to authorized persons only. This type of control can be accomplished in ways other than through data encryption. For example, requiring that data be entered and accessed through password protected, individual user accounts is a reasonable way to address subject confidentiality issues.

When it comes to controlling access to records, I look at electronic records in the same way I do paper records when it comes to issues related to access. It's not necessary to keep clinical trial records in "locked" file cabinets, but it is a good idea to keep records in a filing system that ensures record accountability and that the records are available to staff on as "as needed basis". Similar controls need to be used for electronic records; namely one needs to employ controls that ensure that only those people who are authorized to enter and access clinical trial data in e-records do, in fact, have access to them. Likewise, there need to be controls in place that "capture" information about who entered/accessed data, what data they entered/changed, and when they entered the data.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]

Sent: Sunday, January 16, 2005 5:21 AM
To: [redacted]
Subject: Part 11 Compliance of open systems

Dear Sir or Madam,

If I am working with an open system, and want to be Part 11 compliant, do I need to encrypt all my clinical data from my clinical trials (saved data) that sits on my hard drive, or just encrypt all network traffic to and from the server.

Thank you in advance,
[redacted]