From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, September 20, 2005 4:04 PM
To: [Redacted]
Subject: RE: GCP Compliance Question

Dear [Redacted],

I have been asked by Dr. Lepay to respond to your email (below). I understand that you have also spoken with Carolyn Hommel, who provided you with the information I am now providing in writing.

In discussing this issue in the past with others in the agency, we believe that e-mail is a reasonable and reliable method for IRBs to send information (like meeting minutes, research proposals) to IRB members because e-mail systems inherently meet part 11 requirements. E-mail systems, when used properly, have controls that ensure: 1) limited system access through individual user accounts/passwords, 2) the confidentiality of information contained in messages/attachments; and 3) user authentication (i.e., by using e-mail, one is generating an electronic signature and making a statement that, in essence, makes the statement "this is my account and I've prepared this message." Further, the records created by IRBs are generally not "high risk" documents that would require all of the part 11 controls. If one goes back to the "old days", or what happens without e-mail: an IRB creates a document on a typewriter or computer, prints it out and saves a copy in a file. We have never required that these records be signed (although most if not all IRBs do this) or that the word processor program be "validated" by the end user.

The use of e-mail in place of correspondence is common place and efficient and has adequate controls for the types of documents issued by IRBs. The more efficient an IRB is in dealing with its documentation requirements, the more time it will have to address issues that impact on human subject protection--which is really their basic focus and responsibility.

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

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: Wednesday, September 14, 2005 8:58 PM
To: Lepay, David
Cc: [Redacted]
Subject: GCP Compliance Question

Hello Dr. Lepay,

As a new GCP Compliance Auditor with [Redacted], it is one of my responsibilities to consult with our clinical staff for the purpose of providing clarity and guidance to GCP compliance related issues concerning our clinical trials. Recently, a compliance question was presented to me by [Redacted] that I believe requires additional research on my part before responding to them. This email is being sent to you with the hope of obtaining additional insight to this question. In addition, as [Redacted] has communicated with you in the past to gain similar clarity on "grey" areas of GCP compliance, she suggested that I present this question to you.

Background and Question:

A local IRB that provides oversight to a clinical site that we may consider using, currently has a "standard" practice of submitting their IRB approvals via email to the sites.

The IRBs procedures are as follows:

In lieu of sending hardcopy letters to the investigators, they send out, on a routine basis, all official letters to the investigators using their email system. In addition, the IRB official communication of full and expedited review decisions is sent from the email address of either their IRB Coordinator or IRB Administrator. This new practice was "suggested to them by the OHRP" and also "discussed with a FDA representative". (The FDA representative considered this an acceptable policy that currently is not subject to 21 CFR Part 11.)

Is this an acceptable GCP practice and if so, how would one verify that the IRB approvals are coming from the IRB's "Coordinator or Administrator"? What activities should the Sponsor perform, if any, to assure these procedures are verifiable and auditable? Has there been, in your experience, any concerns surrounding this procedure, if this is in fact, an acceptable practice?

I'd greatly appreciate your feedback on this matter.

Regards

[Redacted]

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