From: Lee, Bonnie
Sent: Friday, February 18, 2005 11:21 AM
To: [Redacted]
Subject: RE: Electronic approvals/correspondence

Dear [Redacted],

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 that you've suggested. 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.

I note that one of your concerns is about how the IRB protects patient confidentiality; because the IRB rarely receives patient names or records, I don't believe that this is a concern related to the IRB as much as it is of the investigator.

I do think that your questions go beyond what we would expect. If you apply an industry standard to IRBs, my concern, in part, would be that you could force IRBs to abandon the use of technology (to avoid Part 11, for example), resulting in inefficiencies and less protections to research subjects. 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.

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: Thursday, February 17, 2005 3:22 PM
To: 'blee@oc.fda.gov'

Subject: Electronic approvals/corespondence

Hi Bonnie,

Thanks for returning my call.

I initially contacted you because some IRBs are handling all correspondence via email, this includes approvals and acknowledgement of safety events. When we asked about confidentiality issues and document integrity, the IRB's response was that FDA is okay with email and it isn't subject to part 11. This is contrary to my understanding of industry standards for electronic records.

For sites with IRBs that rely solely on electronic correspondence, I believe a sponsor must be sure certain conditions are met. I have proposed that we ask the following questions:

- has the IRB met part 11 requirements for validation of their system to assure that use of the system doesn't impact the accuracy, reliability, integrity, availability, and authenticity of required records and signatures? If the system has been validated, is documentation available to explain the validation process?

- how does the IRB protect patient confidentiality?

- if approval is sent electronically, does it have an electronic signature that meets part 11 requirements?

- are electronic documents sent via a secure line, closed environment (for example, secure study web site), or is an approved encryption system in place?

- does the IRB have SOPs for maintenance of their system, change control, audit trails?

- does the IRB have SOPs that explain how the electronic documents are generated, transmitted, retained/archived and who is responsible for each of these functions?

My goal is to assure that [Redacted] has documentation which will withstand regulatory scrutiny. Do you think these questions go beyond what is necessary to achieve this goal? Any guidance that you can provide on FDA expectations would be greatly appreciated.

Thanks,

[Redacted]