From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, May 09, 2005 8:53 AM
To: [Redacted]
Subject: RE: IRB documents and email

Dear [Redacted]:

Your question about the suitability of e-mail for submission and approval of IRB-related documents was forwarded to me for a response.

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."

Assuming that such controls are in place, use of e-mail would appear to be a reasonable and reliable method for submitting information to the IRB, as well as for conveying the IRB's decisions back to the site.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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, May 04, 2005 1:43 PM
To: gcpquestions@oc.fda.gov
Subject: IRB documents and email

Good afternoon!
What is the FDA's stance on an IRB using email for submission and approval of IRB related documents instead of hard signatures?
[Redacted]