From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, April 20, 2004 9:17 AM
To: **[Redacted]**
Subject: RE: IRB Chair Signature Stamps
Dear Ms. **[Redacted]** :

As I said before, because FDA has no regulations or guidance on the use of signature stamps, it is up to the institution and the IRB to determine the circumstances under which using a signature stamp would be allowed, appropriate procedures for its use, and how access to the stamp would be controlled.

Although the use of signature stamps may reduce burdens on staff (e.g., when issuing a large volume of routine or general correspondence), it is difficult for me to imagine circumstances in which a signature stamp on IRB approval correspondence would be justified. In general, the individual responsible for signing a letter to indicate that a study has been approved should really take the time to review the letter and ensure that it accurately reflects the IRB's decision, including any concerns raised during the IRB's deliberations, recommendations for modification of the study, etc. In my opinion, it would be a poor practice to allow uncontrolled use of signature stamps, because that could possibly allow research that had not been actually approved by the IRB to go forward.

Again, as I said before, IRBs need to ensure that they have appropriate controls in place if they decide to allow use of a signature stamp. You can refer to my previous e-mail for examples of such controls.

I hope this answers your question.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857
Phone: 301/827-3340
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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, April 07, 2004 9:27 AM
To: 'OC GCP Questions'
Subject: RE: IRB Chair Signature Stamps
Dear Ms. Hommel-

Thank you for your quick response.
I noticed that your examples for circumstances were general and routine documents.

Would your response be the same for IRB Approval documents?

Kind Regards,
[Redacted]
-----Original Message-----
From: OC GCP Questions [mailto:GCPQuestions@OC.FDA.GOV]
Sent: Wednesday, April 07, 2004 9:23 AM
To: **[Redacted]**
Subject: RE: IRB Chair Signature Stamps
Dear Ms. **[Redacted]** ,

Your question about signature stamps for IRB chairs was forwarded to me for a response.

FDA regulations for Institutional Review Boards (21 CFR 56) and guidance documents are silent regarding signatures of IRB chairs. Because we have no signature requirements, we would not have an official opinion on the use of signature stamps.

IRBs may wish to consult with their institutions to determine if the institution has a policy on signatures, and the use of signature stamps. From a practical standpoint, IRBs might also consider addressing the use of signatures in their SOPs. If a signature stamp were to be employed, the SOPs should address any necessary controls over the stamp, for example, who is authorized to use the stamp, where the stamp is stored and how access to the stamp is controlled, the type(s) of correspondence on which it may be used, and the circumstances for its use (e.g., cover letters providing routine information to clinical investigators regarding the IRB's general procedures or institutional policies).

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
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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-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, April 06, 2004 2:28 PM
To: 'OC GCP Questions'
Subject: RE: IRB Chair Signature Stamps

Hello-

Do you all have an opinion on the use of signature stamps for IRB chairs?

Thanks

[Redacted]