From: Lepay, David
Sent: Friday, August 22, 2003 7:34 AM
To: [Redacted]
Subject: RE: FDA question

Dear [Redacted] :
FDA regulations (21 CFR 50.27) require that informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent.

There is no FDA regulatory requirement for the IRB to stamp pages of the informed consent with the approval date and expiration date. However, IRB's do have the authority to implement internal procedures; this may be an example of one such procedure.

Could you convey this information to the correspondent.

Thanks, Dave

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Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs
OSHC, Office of the Commissioner, US 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, August 21, 2003 10:22 AM
To: Lepay, David
Subject: FW: FDA question

Please help me with this email...Thanks....

-----Original Message-----
From: [Redacted]
Sent: Wednesday, August 20, 2003 4:02 PM
To: oracontactus@ora.fda.gov
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

Address:

Phone: [Redacted]

URL:

Comments: Is it an FDA requirement for an IRB to stamp any or all pages of an informed consent form for use in a clinical trial with the approval date and expiration date?