From: Lepay, David on behalf of OC GCP Questions
Sent: Friday, February 28, 2003 11:17 AM
To: [Redacted]
Subject: RE: Clarification on NDA

Dear Ms. [Redacted]:
You are quite correct. FDA does not "approve" informed consent documents. FDA regulations under 21 CFR 56.109 describe IRB review of research: In particular, 21 CFR 56.109(a) states: "An IRB shall review and have authority to approve, require modification in (to secure approval), or disapprove all research activities covered by these regulations." And 21 CFR 56.109(b) states: "An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects." You can access these regulations from our GCP website (www.fda.gov/oc/gcp through the "Regulations" link).

FDA regulations for medical devices require submission by the sponsor of "copies of all forms and informational materials to be provided to subjects to obtain informed consent" as part of the IDE submission (21 CFR 812.20). However, IND regulations (for drugs and biologics) are silent on the submission of informed consent materials to FDA.

Sincerely,
David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: [Redacted]
Sent: Friday, February 28, 2003 10:55 AM
To: gcpquestions@oc.fda.gov
Subject: Clarification on NDA

Good morning!

We have a new coordinator who wants to know why the local IRB requires the sponsor's "FDA Approved" informed consent to be changed to fit our requirements. I am not completely certain but I don't think that the FDA approves the sponsor's informed consent document although if I remember correctly, it is submitted as part of the NDA. Does the FDA approve a sponsor's informed consent for multicenter trials and if so, does the local IRB have the right to request changes, modifications, etc., to the document?

Thank you and I look forward to your response.
[Redacted]