From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, April 25, 2002 11:37 AM
To: [purged]
Subject: RE: Consent form changes

[purged],

It is the responsibility of the IRB to ensure that the informed consent document complies with FDA regulations and is written in a way that will be appropriate for the subject population that will be recruited for the study at the clinical site. I believe that it is, therefore, inappropriate for the sponsor to instruct local IRBs in the way that you have described. As to whether the sponsor can "legally" do this, the sponsor can establish whatever criteria it wants to determine what sites it will involve in the Phase IV trial. I think that such a requirement, however, could limit the involvement of most sites with effective IRBs--and would thus be counter-productive to the interests of the sponsor. Perhaps the sponsor wants to send a message to "limit" if possible changes to the form--even that could compromise the integrity of the consent process. While not strictly illegal (I don't think--I'm not a lawyer), it's a bad idea.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Thursday, April 25, 2002 10:11 AM
To: 'gcpquestions@oc.fda.gov'
Subject: Consent form changes

Hello:

I am not sure if this is the right place to ask this question.

I am working with a sponsor who is preparing a protocol for a phase IV study. The sponsor had asked us to use a Central IRB. Sites which cannot use a central IRB, are instructed that they cannot modify or propose any changes to the consent form except for adding the name of the local IRB. Is this legal? Can a sponsor of a phase IV study dictate what can and cannot be changed by an IRB in a consent form?

Thank you.

[purged]