From: [Redacted]
Sent: Monday, February 10, 2003 9:49 AM
To: gcpquestions@oc.fda.gov
Subject: Question regarding to compensation for injury

Good Morning,

My name is [Redacted] and I am [Redacted]. I work in a CRO and at this moment I am participating in
a Irritable bowel syndrome project.

After submitting the Informed Consents to the IRBs I was requested by a [Redacted] IRB to delete a phrase (below) from the text regarding to compensation for injury. I understand that the IRB is right asking for this since it is for patient protection, but the study sponsor do not want to delete this phrase because it was requested only for one IRB and because it is an usual procedure in USA.

My question is if it is really usual in USA Sponsors do not pay for such things and also, I understand that each IRB is independent and has the right to ask changes in the ICF, is it correct? Any idea for managing this situation?

COMPENSATION FOR INJURY

If during the course of this study any injury should occur to you as a direct result from the Investigational treatment, Sponsor will pay all medical expenses necessary to treat such injury provided: a) you follow the study doctor's instructions at all times, b) you promptly report any such injury to the doctor conducting the study, and c) the expenses are not otherwise covered by your insurance. (strikethrough: Financial compensation for such things as lost wages, disability or discomfort due to type of injury is not routinely paid.) By signing this consent form, you will not be waiving any of the legal rights which you otherwise would have as a subject in a research study.

Thanks in advance,
[Redacted]