From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 21, 2005 2:21 PM
To: [Redacted]
Subject: RE: IRB Question

Dear [Redacted],

I will admit that no one has ever asked us a question like this. While you could ask the IRB what it thinks, I would think that the IRB would only need to know that the hospital inpatient menu would be used in the study as you described--it would not need a copy of the menu. I do wonder, however, about relying on the subject to record the quantity eaten (or not) depending upon the subject's condition. Further, I know from personal experience, that you don't always get what you order--you may want some verification from the subject on that. Basically, the IRB needs to review the protocol and plan; unless it thinks that it needs to see the actual menu, I don't think the menu needs to be submitted to the IRB.

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Friday, October 21, 2005 10:55 AM
To: 'gcpquestions@oc.fda.gov'
Subject: IRB Question

Hi Carol,

We are trying to determine the most accurate and efficient way of collecting information regarding the diet consumed over the 24 hour period of study. The subjects will be admitted to the hospital for this 24 hour period and if we give them a diary to complete while in the hospital, this diary will need to be reviewed and approved by the IRB/EC. Another idea is to have the subjects mark up the hospital menu (many hospitals in the US (I don't know about other countries provide printed menus for the subject to chose what they want from the menu)with what they ordered and how much of it they actually ate. The menu should have the subject's name and room number on it. This would also be very reliable.
This is kind of a gray area, because the hospital menu would not normally need to the submitted to the IRB/EC, but if we use it for the study and

retain the completed menu in the subject's chart, would we need to submit the menu to the IRB/EC for review?
Would you please let us know your thoughts?

Thanks,

[Redacted]

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