From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, April 25, 2006 4:10 PM
To: [Redacted]
Cc: [Redacted]
Subject: RE: Policy on charging patients

Dear [Redacted],

I have reviewed your questions below and conclude that it would NOT be ethically justified to charge subjects in either of your examples. In the first, you stated that the "baseline CT scan" would be conducted "in a study"; as such it is part of the study and should be paid by the resarcher, not the subjects. In the second, the subjects in the control arm are receiving the standard of care in order to be controls in the study, presumably undergoing various examinations and, again because this is clearly part of the resarch, it should be paid by the researcher, not the subjects. In each case, I think youi need to ask whether the research could be conducted if the subjects were to say that they did not want to pay for the procedure or intervention. If they did not have the procedure or intervention could the researcher conduct the research without it?--That is, is it necessary for the conduct of the research or not? If it is necessary for the conduct of the research, it should be paid by the researcher or whomever is funding the study.

We do have an old information sheet on the topic of charging for investigational products--a slightly different topic from the question you asked. However, I have appended its contents below for your information; it is also available on the web at: http://www.fda.gov/oc/ohrt/irbs/toc4.html#products.

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Note new email address: Bonnie.Lee@FDA.HHS.GOV

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.

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Charging for Investigational Products

This information sheet discusses FDA policy on allowing charges for the test articles in clinical investigations.

Decisions concerning charging subjects for investigational products are guided by professional ethics, institutional policies, and FDA regulations. The FDA informed consent regulations require the consent document to include a description of any additional costs to the subject that may result from participation in the research [21 CFR 50.25(b)(3)]. IRBs should ensure that the informed consent documents outline any additional costs that will be billed to study subjects or their insurance company as a result of participation in the

study. IRBs should also ensure that any such charges are appropriate and equitable.

Because the regulations governing drugs and biologics vary from those governing medical devices, the Agency's position on charging for the test articles will be discussed separately. FDA does not prohibit charging the subjects for related treatment or for services.

1. Charging for Investigational Medical Devices and Radiological Health Products

The Investigational Device Exemption (IDE) regulations allow sponsors to charge for an investigational device, however, the charge should not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device [21 CFR 812.7(b)]. A sponsor justifies the proposed charges for the device in the IDE application, states the amount to be charged, and explains why the charge does not constitute commercialization [21 CFR 812.20(b)(8)]. FDA generally allows sponsors to charge investigators for investigational devices, and this cost usually is passed on to the subjects.

2. Charging for Investigational Drugs and Biologics

The Investigational New Drug (IND) regulations [21 CFR 312.7(d)] permit a sponsor to charge for an investigational drug or biologic that has not been approved for marketing, only under the conditions outlined below. In both a clinical trial and a treatment IND, the charge should not exceed an amount that is necessary to recover the costs associated with the manufacture, research, development, and handling of the investigational drug or biologic. FDA may withdraw authorization to charge if the Agency finds that the conditions underlying the authorization are no longer satisfied.

(i) Clinical Trials Under an IND

A sponsor may not charge for an investigational drug or biologic in a clinical trial under an IND without the Agency's prior written approval. In requesting such approval, the sponsor must explain why a charge is necessary, i.e., why providing the product without charge should not be considered part of the normal cost of conducting a clinical trial [21 CFR 312.7(d)(1)].

(ii) Treatment Protocol or Treatment IND

A sponsor or investigator may charge for an investigational drug or biologic for a treatment use under a treatment protocol or treatment IND, as outlined in 21 CFR 312.34 and 312.35, provided: (1) there is adequate enrollment in the ongoing clinical investigations under the authorized IND; (2) charging does not constitute commercial marketing of a new drug for which a marketing application has not been approved; (3) the drug or biologic is not being commercially promoted or advertised; and (4) the sponsor is actively pursuing marketing approval with due diligence. FDA must be notified in writing prior to commencing any such charges. Authorization for charging goes into effect automatically 30 days after receipt of the information by FDA, unless FDA notifies the sponsor to the contrary [21 CFR 312.7(d)(2)].

There is no specific regulatory requirement that the Investigator's Brochure be submitted to the IRB. There are regulatory requirements for submission of information which normally is included in the Investigator's Brochure. It is common that the Investigator's Brochure is submitted to the IRB, and the IRB may establish written procedures which require its submission. Investigator's

Brochures may be part of the investigational plan that the IRB reviews when reviewing medical device studies.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, April 11, 2006 10:19 AM
To: OC GCP Questions
Cc: [Redacted]
Subject: Policy on charging patients

Dear Sir,

I am a [Redacted]. I have the following queries regarding the accepted policy for charging patients who participate in a clinical trial. The queries are the following:

1. Is it ethically justified to charge patients for services that would have been accepted as `routine care' had the patient not participated in the clinical trial? For e.g. can the patient be justifiably charged for a baseline CT scan [Redacted] in a study that compares a novel drug combination to an accepted standard [Redacted] regimen for [Redacted]?

2. In phase III randomized studies of [Redacted] that compare a new [Redacted] regimen to the standard of care, can the participants in the control (standard) arm be charged for the standard regimen, provided this information has been given to them as part of the informed consent process?

I would appreciate if you could refer me to published guidelines with regard to the above.

Thank you,

Sincerely,

[Redacted]