From: OC GCP Questions
To: [redacted]
Subject: Questions regarding clinical trial NCT[redacted]
Date: Friday, October 31, 2014 11:43:39 AM
Attachments: Reporting Complaints Related to FDARegulated.doc

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Good morning –

The costs of the any study related procedures should be outlined in the informed consent document. You may wish to discuss your situation with the reviewing institutional review board or the clinical investigator for further clarification.

Please the FDA's regulation below on charging for investigations drugs under an IND.

21 CFR 312.8 – Charging for investigational drugs under an IND.--

(a)General criteria for charging. (1) A sponsor must meet the applicable requirements in paragraph (b) of this section for charging in a clinical trial or paragraph (c) of this section for charging for expanded access to an investigational drug for treatment use under subpart I of this part, except that sponsors need not fulfill the requirements in this section to charge for an approved drug obtained from another entity not affiliated with the sponsor for use as part of the clinical trial evaluation (e.g., in a clinical trial of a new use of the approved drug, for use of the approved drug as an active control).

(2) A sponsor must justify the amount to be charged in accordance with paragraph (d) of this section.

(3) A sponsor must obtain prior written authorization from FDA to charge for an investigational drug.

(4) FDA will withdraw authorization to charge if it determines that charging is interfering with the development of a drug for marketing approval or that the criteria for the authorization are no longer being met.

(b)Charging in a clinical trial --(1)Charging for a sponsor's drug . A sponsor who wishes to charge for its investigational drug, including investigational use of its approved drug, must:

(i) Provide evidence that the drug has a potential clinical benefit that, if demonstrated in the clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation, or prevention of a disease or condition;

(ii) Demonstrate that the data to be obtained from the clinical trial would be essential to establishing that the drug is effective or safe for the purpose of obtaining initial approval of a drug, or would support a significant change in the labeling of an approved drug (e.g., new indication, inclusion of comparative safety information); and

(iii) Demonstrate that the clinical trial could not be conducted without charging because the cost of the drug is extraordinary to the sponsor. The cost may be extraordinary due to manufacturing complexity, scarcity of a natural resource, the large quantity of drug needed (e.g., due to the size or duration of the trial), or some combination of these or other extraordinary circumstances (e.g., resources available to a sponsor).

(2)Duration of charging in a clinical trial . Unless FDA specifies a shorter period, charging may continue for the length of the clinical trial.

(c)Charging for expanded access to investigational drug for treatment use . (1) A sponsor who wishes to charge for expanded access to an investigational drug for treatment use under subpart I of this part must provide reasonable assurance that charging will not interfere with developing the drug for

marketing approval.

(2) For expanded access under 312.320 (treatment IND or treatment protocol), such assurance must include:

(i) Evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trial(s) will be successfully completed as planned;

(ii) Evidence of adequate progress in the development of the drug for marketing approval; and

(iii) Information submitted under the general investigational plan (312.23(a)(3)(iv)) specifying the drug development milestones the sponsor plans to meet in the next year.

(3) The authorization to charge is limited to the number of patients authorized to receive the drug under the treatment use, if there is a limitation.

(4) Unless FDA specifies a shorter period, charging for expanded access to an investigational drug for treatment use under subpart I of this part may continue for 1 year from the time of FDA authorization. A sponsor may request that FDA reauthorize charging for additional periods.

(d)Costs recoverable when charging for an investigational drug . (1) A sponsor may recover only the direct costs of making its investigational drug available.

(i) Direct costs are costs incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.

(ii) Indirect costs include costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

(2) For expanded access to an investigational drug for treatment use under 312.315 (intermediate-size patient populations) and 312.320 (treatment IND or treatment protocol), in addition to the direct costs described in paragraph (d)(1)(i) of this section, a sponsor may recover the costs of monitoring the expanded access IND or protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access IND.

(3) To support its calculation for cost recovery, a sponsor must provide supporting documentation to show that the calculation is consistent with the requirements of paragraphs (d)(1) and, if applicable, (d)(2) of this section. The documentation must be accompanied by a statement that an independent certified public accountant has reviewed and approved the calculations.

Please also see FDA's Information Sheet for Charging for Investigational Products – link below.

Guidances > Charging for Investigational Products - Information Sheet

I don't know of any company or agency that can assist with the charge. If you would like to file a complaint with FDA, please see the information below.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for additional questions.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, October 31, 2014 10:12 AM
To: OC GCP Questions
Subject: Questions regarding clinical trial NCT[redacted]

Hello! My name is [redacted] and I have two questions specifically regarding the clinical trial NCT[redacted].

1. Is it ethical for them to charge $20,000 to participate in a clinical trial?

2. If so, can you tell me if there are any resources (e.g. a study sponsor, governmental agency) that would help offset the costs?

Thank you,

[redacted]