From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, August 18, 2005 11:54 AM
To: [Redacted]
Subject: IRB Review of Written Info Given to Subjects

Dear [Redacted], Your email below and one sent August 9 on the same topic were both referred to me for response. Certain information that may be given to subjects (such as how to collect a "clean" urine sample) is standard information whether it is in the medical or research context. It seems to me that the written information given to subjects that the IRB should review (based on 3.1.2) is that information related to the specific study. That being said, however, if the IRB wanted to review any and all information that would be given to subjects, there is nothing in our regulations that would prevent the IRB from doing so. One could read ICH 6, 3.1.2. to be limited to (1)documents obtained by the IRB (2) in order to fulfill its responsibilities. I think it would be hard to rationalize that an IRB would need to review directions for how to collect a "clean" urine sample unless the study involved subjects with some anomaly that caused an unusual collection system.

I'm sorry that I can't be more helpful. Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

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.

-----Original Message-----
From: CDER DRUGINFO
Sent: Thursday, August 04, 2005 1:22 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Thursday, August 04, 2005 12:17 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Regarding ICH Guideline E6 3.1.2 "The IRB/IEC should obtain the following: written information to be provided to subjects..."
1). I realize these are just guidelines but I try to follow them as best as I can and am wondering if we have to submit "any" written information given to the subjects to the IRB?

2). Does it matter if it is study specific or not?

3). Would a document, for example, that explains how a subject should collect their urine samples in a "clean" manner need IRB approval?

Thanks in advance for your time,
[Redacted]