From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, August 18, 2005 1:44 PM
To: REDACTED
Subject: RE: IRB question

Dear REDACTED,

Normally, as part of the continuing review process, the IRB asks for a copy of the consent form currently in use in the study. This allows the IRB to review the consent form against the one it approved earlier to ensure that they are the same. If it isn't, then the IRB would need to consider appropriate corrective action and report the finding of non-compliance to FDA, the institution, and sponsor. It is unusual (if I understand what you are saying correctly) for an IRB to get copies of signed forms--most IRBs are concerned about compromising the subjects' privacy or confidentiality of the data. 21 CFR 56.109(f) states that An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

The regulations also address your question indirectly in: 21 CFR 56.109(b) An IRB shall require that information given to subjects...is in accordance with 50.25; (c) An IRB shall require documentation of informed consent in accordance with 50.27; 56.111(a)(4) informed consent will be sought from each....subject...in accordance with and to the extent required by part 50; (5) Informed consent will be appropriately documents...; (6) ...the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Each IRB can make its own policies as long as they are consistent with the regulations (or don't contradict them). I can understand why your investigators are balking. It could be disruptive to be providing confidential documents at random times "whenever you want" when other procedures could serve the same function. For example, at the time of approval of the study, you could require the submission of a sample consent form annually (at the time of continuing review), biannually, quarterly, or at some other interval which would make the reporting predictable, confidential (since the sample form would not be signed), and less burdensome. 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

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: REDACTED
Sent: Thursday, August 18, 2005 11:08 AM
To: OC GCP Questions
Subject: RE: IRB question

Many thanks, that is helpful. One other questions, is there a policy for the IRB to ensure that its investigators are using the consents that were approved by the IRB. I have been asking for copies of the consents to ensure compliance, but some of our investigators are balking. It is my understanding that it is their responsibility to keep copies and that I can ask for them to ensure compliance whenever I want. But is this written anywhere so I can refer to it?

Thanks in advance for your help with this.

Best regards,
REDACTED

-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]**On Behalf Of** OC GCP Questions
Sent: Thursday, August 18, 2005 10:05 AM
To: REDACTED
Subject: RE: IRB question

Dear REDACTED,

The IRB does need to review the sponsor's plans to provide these gifts to ensure that they would
not be coercive to the subject. I will say (as one cancer patient) that it sounds like a lovely idea and assuming that these gifts are for breast cancer subjects, they seem not only reasonable, but also "pick-me-ups" that could boost their spirits--but that's a decision for your IRB who would have better knowledge of the patient population to be involved..

I hope this is helpful to you.

Bonnie

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

-----Original Message-----
From: REDACTED
Sent: Monday, August 08, 2005 1:10 PM
To: gcpquestions@oc.fda.gov
Subject: IRB question

Are sponsors allowed to provide patients with gift bags? We have a sponsor for an IRB study who wants to give patients who enroll:

- a t-shirt w/breast cancer logo
- a pink rubber bracelet
- a pin
- gel pack
- nail/spa gift certificate

Can they do this? Does the IRB have to approve.

Please advise as soon as possible.

Thanks,
REDACTED