From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, June 25, 2002 4:18 PM
To: [purged]
Subject: RE: informed consent

Dear [purged],

Your institutional IRB needs to establish a policy as to how it will interact with (or accept the review of) central IRBs. While most institutional IRBs do retain at least some jurisdiction over all studies conducted within their institution, some IRBs, for certain types of studies enter into formal agreements whereby they will accept the review of the central IRB. If that is done, then you avoid some of the problems that you have identified. If that is not done, then let me try to address each of your specific concerns in turn:

(1) FDA regulations, at 21 CFR 50.25(a)(5), state that the consent form must include "A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records." A general statement, such as you have suggested, would not be in accordance with these regulations if the research was subject to FDA regulations. We believe that because we commonly access records during an FDA inspection that it is important for subjects to explicitly understand that FDA may be looking at their records.

(2) You certainly want your patients/subjects to understand information that is provided to them either orally or in a written informed consent document. However, many have objected to the phrase "I understand" because a subject may have been told something, may think that they understand what has been told to them, but, in fact, have totally misunderstood the information. Therefore, we believe that it is more appropriate to say "I have been informed" rather than "I understand" in a consent document.

(3) I am not too sure if I understand your question. Hopefully, this is responsive. Generally, there is "local" information that is included in the consent form relating to: whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; and an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. A centralized IRB can be used if it specifies precisely the "local" information that must be inserted into the IRB-approved consent form and the IRB receives and approves the completed form.

I hope this information is helpful to you.

My best,

Bonnie

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-----Original Message-----
From: [purged]
Sent: Monday, June 24, 2002 10:58 AM
To: gcpquestions@oc.fda.gov
Subject: informed consent

I am trying to understand the discrepancies in interpretation for informed consent. Our institutional IRB is having problems with central IRBs. As you are aware pharmaceutical companies are doing more phase 4 post-marketing trials using large numbers of sites each recruiting small numbers of patients. In most of these "trials" there is low, if any risk, to the patient.

Our institutional IRB is refusing to use central IRB forms for several of the following reasons:

1) they say that the FDA must have the right to look at the patients information. I would point out that the sentralized IRB states that "The personal information obtained about you during the course of this study will remain as confidential as poosible under local, state and federal law. ..." If federal law allows the FDA access to individual patient records then this item is fullfilled by this statement.

2) Our institutional IRB states that the words "I understand" cannot be used in an IRB as declared by the FDA. I have read the information concerning informed consent available through the FDA's web sites and do not see any statement preventing the use of this term. Do we not want our patients to understand?

3) They say that every informed consent must have the institutional policy within it. This would then mean that no centralized IRBs can ever be used.

Could someone please help clarify these issues. We are turning down safe multicenter trials because of these issues.

Thank-you for your help.

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