From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Thursday, February 03, 2005 5:19 PM
To: [purged]
Subject: RE: FDA 1572 form completion

Dear Ms. [purged],
Thank you for the thorough explanation of the ethics approval system in the UK. In the situation you describe it sounds as if the MREC alone can be listed on the 1572. Perhaps the best advice I can give in helping you to decide whether to list the LREC or the MREC is to refer you to U.S. regulations for IRBs. They are available on the web at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56. You can then determine which body would best meet these requirements. You should also have a look at our informed consent regulations at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

You are probably wondering why I am referring you to US regulations as they obviously don't apply to ethics committees in the UK. Unfortunately, this is the dilemma sponsors face when using the 1572 for non-US studies that are conducted under an IND. The 1572 form of course is intended primarily for use in the U.S. for studies conducted under an IND. However, the 1572 is often used voluntarily abroad and is mandatory for studies being conducted under an FDA IND regardless of where the trial is located. It's use outside the US can be problematic for IND studies, particularly regarding human subject protection commitments. This is because by signing the 1572 (see item 9 on the form) the investigator is technically agreeing the study will be reviewed by an IRB and consent will be obtained in compliance with the US regulations I referenced above.

Fortunately there is a provision in our IND regulations that permits sponsors to ask for a waiver of any IND requirement if they can explain why compliance can't be achieved and describe and alternative way to satisfy the purpose of the requirement being waived. Sponsors who conduct IND studies abroad often take advantage of this waiver provision.

In recognition of this problem and the increasing number of studies conducted globally, we are currently considering revision of our regulations on acceptance of foreign data to address this issue. I probably told you more than you want or need to know, but I hope this is helpful. If we can be of further assistance, don't hesitate to contact us at this e-mail address.

Sincerely yours,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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 judgement 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: [purged]
Sent: Tuesday, February 01, 2005 5:59 AM
To: 'gcpquestions@oc.fda.gov'
Subject: FDA 1572 form completion

Dear Sir/Madam,

[purged] is frequently requested to complete 1572s for studies in addition to satisfying local regulatory requirements. I would appreciate some advice regarding completion of the FDA 1572 form for investigational sites in the UK. To give some background, until recently, approval was required from both the Multicentre Research Ethics Committee (MREC) and also the Local Research Ethics Committee (LREC) for the site before an investigator could participate in a clinical trial. The procedure has now changed, and the MREC alone gives documented ethical approval for UK sites. The LREC is still involved in that it must agree the participation of the investigator following site assessment, and its agreement triggers MREC approval of that site. It does not approve the study itself.

I would be most grateful if you could advise whether the FDA expects details of both the MREC and LREC to be completed on the FDA 1572 forms, or whether it is sufficient for just the MREC details to be included.

Thank you in anticipation.
Yours faithfully,

[purged]

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