From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Tuesday, May 24, 2005 10:59 AM
To: [purged]
Subject: RE: Inquiry

Dear [purged],
Your question, about how to prepare a site for inspection, is a bit subjective, and my answer might not be what you would expect. I'm sure your question is focusing what to do after the site has completed the study and the sponsor has been informed that it will be inspected. However, in my opinion the preparation for regulatory inspection should occur before, during and after the study is conducted.

Preparation should start at the beginning of the study with the selection and qualification of the sites and investigators. Investigators and study staff should be fully informed of their responsibilities under regulations and be told to expect that FDA or other appropriate regulatory authorities may visit their site to inspect their records and verify that the study was performed in accordance with the regulations and protocol. They should understand the protocol requirements completely, especially with regards as to inclusion/exclusion criteria, tests and observations to be made, and what study documentation is to be kept. If the study is done under an IND, the investigator and his staff should carefully read block #9 on the back of the 1572 and understand each of the commitments the CI is making when he signs the form.

During the conduct of the study. The sponsor should provide adequate monitoring to ensure that the above requirements are being met and that the study is being conducted in accordance with the protocol, regulations, and that all study activities are meticulously documented. Records should be kept up to date, complete, accurate and organized for ready retrieval and access. Any noncompliance with the regulations or other problems with study conduct observed by the monitor should be reported to the clinical investigator and/or sponsor as warranted. These observations as well as their correction should be documented in monitoring reports. If the monitoring detects serious continuing noncompliance and correction cannot be secured the sponsor should be informed and take appropriate action as required by 21 CFR 312.56(b)

After the study has been completed the clinical investigator should again be reminded of the possibility that they may be contacted by FDA to arrange an inspection of their performance of the study. This will include interviews with the investigator and study staff as well as an in-depth review of the study files. All study records must be retained in accordance with the regulations and be available for inspection. If the investigator is interested in exactly what will be covered during a site inspection he should be referred to FDA's compliance program covering clinical investigator inspections. This is available on our website. He should specifically note Part III of the program which identifies the areas FDA inspectors will covered see http://www.fda.gov/ora/compliance_ref/bimo/7348_811/48-811-3.html

I suspect your question probably was aimed at what the sponsor should do to prepare the site for inspection after they learn or suspect that a site will be inspected. If all of the above steps have been taken during the entire course of the study, there is very little for the sponsor to do, at this point. It might be helpful to visit the site to ensure that all of the required study documentation has been retained and is organized and available for inspection and that direct access to records can be assured.

I hope this is helpful. Sorry for the lengthy reply but I did want to make the point that it's virtually impossible to prepare a site for a successful inspection visit after the fact if the study site has not been prepared all along.

Sincerely,
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 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:[purged]
Sent: Tuesday, May 17, 2005 11:23 AM
To: gcpquestions@oc.fda.gov
Subject: Inquiry

1. What is the best way to prepare an investigator
site for a regulatory inspection?

Do you Yahoo!?
Yahoo! Small Business - Try our new resources site!
http://smallbusiness.yahoo.com/resources/