questionFrom: Hommel, Carolyn - OC
Sent: Thursday, April 07, 2005 10:10 AM
To: [purged]
Subject: RE: question

Hi, [purged],

You might want to start by reviewing the agency's "Application Integrity Policy," webpage. It has some helpful guidance, e.g., "Points to consider for internal reviews and corrective action operating plans," that issued in June 1991. Here's a link to paste into your browser: http://www.fda.gov/ora/compliance_ref/aip_points.html. The Application Integrity page also includes a copy of the Federal Register notice in which FDA articulated its policy on "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," that might also have helpful background for you.

In terms of FDA staff who are knowledgeable in this area, I'd recommend my colleague, Stan Woollen. He was a field investigator for over 20 years, was Deputy Director of CDER's Division of Scientific Investigations for several years, and is (in my opinion) the most knowledgeable person about bioresearch monitoring policy and inspections in the agency. He's given talks in the past on investigator misconduct, and would certainly be worthwhile for you to talk to.

He can be reached at 301/827-3792. I think he may be out of the office today, but should be in tomorrow.

Carolyn

-----Original Message-----
From: [purged]
Sent: Wednesday, April 06, 2005 2:09 PM
To: carolyn.hommel@fda.hhs.gov
Subject: question

Hi Ms. Carolyn;
Inevitably, I assumed this would occur, I have been invited to speak at two large professional groups. One May 1st the other in August and the topic

:Dealing with Discovery of Misconduct during a Clinical Trial: What should you do"
I am wondering, who at the agency would be a good person to speak with briefly as possible, to get the agency perspective on several specific topics.
Personally, these meetings, maybe > 2500 people all together, are opportunities that I hope to make the following points.

It is better to have a preventative quality program in place

When misconduct is suspected, the following actions need to be taken...

Action after confirmation of misconduct should include immediate notification of Food and Drug Administration (FDA)

The Food and Drug Administration (FDA's) position on self-reporting will normally be ....

The items the agency will need to have to make an assessment include...

There is a standard format in which data should be compiled

Finally, it is better to have discussions with the agency prior to submission of reports and prior to undertaking a major audit and or investigation, in order to ensure the agency concurs with your action plan

Thus, it would be a major aid for me, and I suspect the agency, if I could deliver a clear message that is reflective of the agency's views.
Is there a more appropriate person to talk with or would anyone provide the sort of generic information I am seeking.
Thanks, as always, Carolyn. Hope you are having a great spring, thus far.
[purged]

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