From: Beers Block, Patricia
Sent: Tuesday, December 12, 2006 9:40 AM
To: [purged]
Subject: RE: HHS conducted/funded research by FDA

Dear [purged],

Since FDA is part of HHS, and FDA does fund contracts for research at academic settings, you might just want to make reference to "HHS funded or conducted research" in your procedures. By inference, any research that might be FDA funded will be covered by your written procedures.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340

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: Monday, December 11, 2006 11:45 AM
To: OC GCP Questions
Subject: HHS conducted/funded research by FDA

To Whom it may concern,

When looking at the regulations and when it talks about HHS funded or conducted research, the FDA is one of the agencies under HHS. Generally, we do not think of the FDa as funding or conducting research on its own, but supporting the conduct of research by industry and the research enterprise by providing review structure for the IND/IDE process. Does the FDA fund or conduct research in the regular sense of the word? I think someone told me yes once, but I want to be sure for SOPs, as we prepare for AAHRPP.

[purged]