From: Lee, Bonnie
Sent: Friday, June 17, 2005 3:43 PM
To: [Redacted]
Subject: FW: FWA number

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: Lee, Bonnie
Sent: Friday, June 17, 2005 2:57 PM
To: [Redacted]
Subject: FW: FWA number

see below

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: Lee, Bonnie On Behalf Of OC GCP Questions
Sent: Friday, June 17, 2005 1:51 PM
To: [Redacted]
Cc: Chhabra, Renu
Subject: FW: FWA number

Dear [Redacted],

I apologize for the delay in responding to your email below. You asked: If an IRB has a FWA number, is that considered evidence of "GCP Compliance" (as ICH GCP Guidelines request) or is additional documentation needed to show that an IRB with an FWA number also complies with 21 CFR Part 56? (e.g. do they need a "GCP compliance statement" as well as the FWA number?) I think that the answer really depends upon who is doing the asking and what certainty of compliance they want. I believe historically that an FWA number has been shown that the institution is likely to be in compliance with the Common Rule since the FWA number is issued by the Office for Protection from Research Risks at HHS to institutions that assurance their compliance with the HHS regulations at 45 CFR 46. Those regulation to similar, but not identical to FDA's regulations at 21 CFR Part 50 and 56. Some sponsors also want to be advised of the institution's inspection history (that is, whether the IRB has been inspected by FDA and what its findings were). While variability may be the spice of life, it also can add challenges in responding to the question of what evidence is needed. I'm sorry I can't provide an absolute answer.

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

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.

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-----Original Message-----
From: [Redacted]
Sent: Tuesday, May 31, 2005 1:26 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: If an IRB has a FWA number, is that considered evidence of "GCP Compliance" (as ICH GCP Guidelines request) or is additional documentation needed to show that an IRB with an FWA number also complies with 21 CFR Part 56? (e.g. do they need a "GCP compliance statement" as well as the FWA number?)