From: Lee, Bonnie
Sent: Monday, February 07, 2005 2:12 PM
To: [Redacted]
Subject: RE: IRB Waiver

[Redacted],

Although we believe that cooperative review agreements (or delegated review agreements) should be documented, we don't specify the form, content, or format of the agreement. It may be that an institution wants to use an FWA agreement form if the institution has an FWA and uses that form for its other studies that are supported or conducted by HHS. However, from FDA's perspective, there is no requirement from FDA that the institution use that form. It is also possible that if the institution has agreed to apply the FWA to all research conducted at its institution regardless of the source of funding, it may feel that it needs to use the same agreement forms for all studies. The only thing I can say for sure is that we do not require that you use the FWA form; however, we would expect that there be some form of documentation. I hope that this answers your question and that it's helpful to you.

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.

-----Original Message-----
From: [Redacted]
Sent: Monday, February 07, 2005 10:00 AM
To: 'BLee@OC.FDA.GOV'
Subject: IRB Waiver

Bonnie-
This question may be out of your realm however, you have been helpful with your responses in the past and I'm hoping you can clarify an issue for us again.
We are establishing a new facility for conducting trials which is associated with a hospital that presently has an IRB. This facility's IRB will be waiving review to the different central IRB's that are used for each of the trials we are conducting. The authorization agreement form they have submitted to us is the one used with a FWA (Federal Wide Assurance). To my knowledge, this form is typically only used for government supported trials. Is it required that we use that form if we are not conducting govt. sponsored trials?
Any information you may have is appreciated.
Thank you in advance.

[Redacted]