From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 29, 2004 12:15 PM
To: [Redacted]
Subject: RE: Sub-Investigators
Dear [Redacted] , I apologize for the delay in responding to your question. FDA regulations do not specify who needs to be listed on the consent form from the clinical staff. Rather, 21 CFR 50.27(b)(2) requires a "short form" to be signed by a witness to the consent as well as by the person actually obtaining informed consent. If an IRB requires additional names or signatures, then FDA would expect those names or signatures to be on the form--however, that would be fulfilling an IRB requirement (and in some cases an ICH requirement), not necessarily FDA's informed consent regulation requirements. I hope this is helpful to you. Happy new year.

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: Wednesday, December 08, 2004 11:25 AM
To: gcpquestions@oc.fda.gov
Subject: Sub-Investigators
Would you please provide clarification on the following issue concerning the listing of every staff member involved with a study on the Informed Consent.

It is my understanding that on the Informed Consent the only staff that has to be identified is the PI and the other physicians participating in the study. The study coordinators, lab staff and pharmacy sign the site signature logs therefore, it is not necessary to list them on the consent. Thank you for your assistance.