From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Thursday, September 04, 2003 6:05 PM
To: [redacted]
Subject: RE: Specific guidance with regards to Investigator qualification

Dear [redacted],

As you correctly observe there is much room for interpretation of regulations by various sponsors. Each sponsor may decide for itself what level of documentation it may require to be satisfied that selected investigators are appropriately qualified. However with respect to what the regulations require as evidence of a clinical investigator's qualifications, I would refer you to 21 CFR 312.53 (c)(2) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=312.53 which requires the sponsor to obtain
"A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation." There is no regulatory requirement for a sponsor to obtain a copy of the medical license. I hope this is helpful in answering your question.

Sincerely,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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: Friday, August 29, 2003 2:51 PM
To: GCPQuestions@OC.FDA.GOV
Subject: Specific guidance with regards to Investigator qualification

Hello,

I'm looking for some specific guidance regarding sponsor verification of investigator qualifications to conduct a trial. According to the Guideline for GCPs, it is the Sponsor's responsibility to verify an investigator's qualification by education, training and experience to conduct/participate in a clinical trial by reviewing an investigator's "up-to-date" CV. The PI also shares this burden of ensuring the appropriate training and qualification of his staff. Is there a need, or requirement, to go beyond the CV and collect the medical license too? The practice of collecting the medical license seems to me to be an un-necessary and burdensome practice.

Like so many things, this is open to interpretation and individuals in the Pharma/CRO industry take a draconian approach to even the simplest of tasks. What is sufficient to verify.

Thanks so much,

[redacted]