Q on non-english-speaking subjectsFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, February 01, 2006 5:10 PM
To: [purged]
Subject: RE: Question

Hi [purged],

FDA has no specific guidance on the issue. FDA regulations require that the investigator follow the protocol (and any requirements that the protocol imposes re: inclusion/exclusion criteria and including required washout periods between trials). To me, it's somewhat like asking whether we have guidance about adultery or stealing. We don't, but that doesn't make them right. Sorry, but beyond expecting people to follow our regulations and act conscientiously and with integrity, I'm not sure what to suggest. Nothing is 100 percent. I hope this is helpful to you.
Bonnie
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-----Original Message-----
From: [purged]
Sent: Friday, January 27, 2006 4:15 PM
To: OC GCP Questions
Subject: Question

Hi all,

Would appreciate your input on the question below.

Q. In a recent press article, several clinical trial subjects interviewed spoke openly about how they worked around controls meant to limit a subject's participation to one study at a time (e.g., lying to site personnel, using fake documents, and enrolling in studies in rapid succession), and how common such practices were. Some Phase 1 units spoke about their efforts, including fingerprinting study subjects, to limit

such practices, but conceded that tracking study participation was impossible without a central clearinghouse. What are FDA's expectations, if any, of study sites in ensuring against a subject's participation in multiple trials? Also, have agency officials discussed this issue and, if so, what possible solutions has it considered/is it considering?

Thanks and best regards,

[purged]