From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, December 08, 2006 11:18 AM
To: [purged]
Subject: RE: Illegal alien as a subject - is it possible

Attachments: [SUSPECT SPAM] Top SFBC officials Quit Amid Senate Inaquiry
Clinical Trials_ Bloomberg News

Dear [purged],

I have never been asked a question like this. In a nut shell, I don't think it is something you would ever want to do. Let me give you few of the reasons, including the fact that I think that it's against the law to knowingly employ an illegal alien; thus if there is reimbursement involved that could be considered employment. [In this regard, I suggest you contact the Immigration and Naturalization Service; its website on the web is: http://www.uscis.gov .] In any clinical trial, you want a subject population you can reach and follow for safety reasons; illegal aliens would not meet this criteria. You want a population that is appropriate for the trial and not unnecessarily vulnerable. An illegal alien, due to their illegal status, is a particularly vulnerable population and I would be concerned such an individual might to willing to agree to anything regardless of the risks involved. You did not indicate why you would seek out such a population for research. Unless a specific individual required some investigational product and that person was an illegal alien, I cannot imagine targeting that population. Perhaps I need to know more behind your question. As it stands, I would say that one would never want to seek out illegal aliens as subjects. Basically, I believe it would be unethical. There are a series of articles published by Bloomberg on the web in which illegal aliens were recruited for a trial and the problems they faced. I've included one of the write-ups for your information.

If you are asking because this is being done by your company and you want to report the practice, you can do that by sending another email to this address and we can follow-up.

I hope this 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.

From: [purged]
Sent: Friday, December 01, 2006 10:57 AM
To: OC GCP Questions
Subject: Illegal alien as a subject - is it possible

What are the implications and/or requirements for enrollment of illegal aliens in clinical trials in US soil?

Best regards,

[purged]