From: OC GCP Questions
To: [redacted]
Subject: RE: Requirements regarding listing of clinical sites on clinicaltrials.gov
Date: Tuesday, February 03, 2015 2:26:00 PM

Good afternoon,

To try an answer your question, I would point you to the description of the required fields for "applicable clinical trial" registration with ClinicalTrials.gov. These requirements are outlined in section 402(j)(2)(A)(ii)(III)(cc) of the Public Health Service Act (42 U.S.C. § 282(j)). This section requires submission of location and contact information including "the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location may be accessed)." The text of the statute can be found at http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82 .

Please bear in mind that not all trials listed on ClinicalTrials.gov are "applicable clinical trials" and may not be required to submit the information described in the statute. A further description of the definitions related to ClincialTrials.gov submissions can be found on the NIH website at http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf .

Sponsors may not be required to provide you with a list of all sites related to a particular clinical trial. However, I would expect they would provide you with information for sites which are convenient for you. Similarly, you would not be required to provide the sponsor with personal information for which you are not comfortable providing. As an alternative, it may be helpful for a third party (e.g., your physician) to contact the sponsor on your behalf to obtain information related to the clinical trial.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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Office of Good Clinical Practice
Food and Drug Administration

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: Tuesday, February 03, 2015 11:08 AM
To: OC GCP Questions
Subject: Requirements regarding listing of clinical sites on clinicaltrials.gov

To whom it may concern

Can you please advise if sponsors are required to specifically list the sites where their clinical study is being performed?

I have seen several instances where the information on clinicaltrials.gov is very specific about individual sites, their location, and contact information, but I have also seen several instances where the only information available is contact information at the sponsor.

If you contact the sponsor, are they required to provide a listing of sites?

It is somewhat unnerving to have to provide personal information about one's health status and location to a company developing a potential treatment. Since phone numbers and IP addresses are easily tracked, it would seem to me that one's information is easily compromised.

Thanks

[redacted]