From: Toth-Allen, Jean
Sent: Thursday, January 19, 2006 8:06 AM
To: **[Redacted]**
Subject: RE: Regulatory Requirements for External Physicians

Dear Ms. **[Redacted]**:

Thank you for your inquiry regarding FDA Form 1572.

One of the main purposes of the 1572 is to provide the study **sponsor** with information about the clinical site and potential investigator(s), to enable the sponsor to determine whether the investigator(s) and site are qualified to participate in a given study. If the investigator at your site holds the IND then he/she is the sponsor of the study and information about individuals participating in the study is relevant to him/her. Individuals to be listed as sub-investigators on the 1572, specifically in section 6, are **those who make a direct and significant contribution to the data** - i.e., those who will play a key role in the collection and interpretation of data and/or in the conduct of the study itself. If physicians outside of your site are administrating the investigational drug to study participants, they are participating in the conduct of the study and therefore should be included on the 1572. Any and all information pertinent to the qualifications of these individuals, which would include their CVs and copies of the current medical license, should likewise be maintained.

Hope this information is helpful.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: Thursday, January 12, 2006 2:45 PM
To: gcpquestions@oc.fda.gov
Subject: Regulatory Requirements for External Physicians

Dear Sir or Madam:

I would like to request regulatory guidance for the following scenario:

1. The PI for the protocol is one of our physicians and he/she also holds an IND for the study

2. The patient receives their initial treatment at **[Redacted]**. Subsequent doses of study medication would be given by their own physician or a physician at a site outside of **[Redacted]**

We would appreciate guidance on:

1. Are we required to add these physicians to our 1572 form for the study?

2. Are we required to keep copies of the physicians CVs and medical licenses on file at our site?

3. Any other regulatory guidance from a GCP perspective would be greatly appreciated.

I can be reached at the number below if you have questions.

Thank you in advance,
[Redacted]