From: Toth-Allen, Jean
Sent: Friday, February 17, 2006 11:29 AM
To: [purged]
Subject: RE: IND question

Dear [purged]:

Thank you for your follow-up questions and for using the GCP mailbox as requested in my original response to [purged].

When pharmaceutical trials are conducted under an investigator-initiated IND, there are specific regulatory responsibilities for the different parties involved and also legal, contractual arrangements that are made. While FDA does not get involved with the legal contracts, we are interested that contracted responsibilities are correctly outlined in them. It is probably easiest to answer your questions by spelling out the individual regulatory requirements and where FDA recognizes that contractual arrangements may be in place.

Pharmaceuticals used in clinical trials, whether already approved for some indication or completely investigational, must be obtained from a manufacturer. If the manufacturer is sponsoring clinical trials similar to those intended by the sponsor-investigator, they may not want such individual INDs to occur and so may not be willing to entering into a contractual agreement to supply the pharmaceutical for such studies. Assuming that such an agreement is reached and an individual receives a supply of the pharmaceutical, someone must apply for an IND. The applicant can either merely sponsor the trial or actually participate in it, as either an investigator or a sub-investigator. As a sponsor, however, he/she assumes specific responsibilities that include applying to FDA for the IND, making any and all reports to FDA that the regulations require, controlling use of the investigational product, choosing qualified investigators, obtaining the investigators' commitments on a 1572 to comply with the regulation, and monitoring the study and investigator compliance at any and all sites. The actual investigators must sign the 1572 and comply with the appropriate regulations. Investigators may enter into contractual agreements with the study sponsor as well, that might include monetary arrangements or other compensation or support.

You may also consider consulting with the review division in the Center for Drug Evaluation and Research (CDER) for any specific concerns they may have given their experience with sponsor-investigator INDs. The contact number for the Division of Reproductive and Urologic Products (DRUP) in the Office of Drug Evaluation III (ODEIII) is (301) 796-2130.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

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.

From: [purged]
Sent: Tuesday, February 14, 2006 8:33 AM
To: OC GCP Questions
Cc: Toth-Allen, Jean
Subject: RE: IND question

Thank you for your response to [purged]. I am the director/Senior Investigator thus get approached to develop investigator – initiated trials. In doing so, I then assign a junior investigator the lead (PI), myself as a sub. Our regulatory group then submits IND with me as sub and listed on documents as such 1572, protocol, etc. So I interpret the FDA guidelines and your email, this is approved at the agency, thus I am not considered the PI, although may hold the IND. Is the correct? Similar question regarding contracts. The contract appears un my name ,because of similar reason, I am recognized in the field of urologic cancer, thus work initiated, assign PI, stay involved to assist in proper development of young clinical investigator, industry staff understands I will be involved as sub investigator, yet told because not PI cannot hold contract. Not clear to me in FDA guidelines, Can you clarify? Thank you [purged]

From: [purged]
Sent: Monday, February 13, 2006 7:05 PM
To: [purged]
Subject: FW: IND question

[purged]:

Did you get this?

Thanks, M

From: Toth-Allen, Jean [mailto:jean.toth-allen@fda.hhs.gov]
Sent: Mon 2/13/2006 7:15 AM
To: [purged]
Subject: RE: IND question
Dear [purged]:

Thank you for your inquiry regarding sponsors of INDs. Sorry this response is so delayed, but its appearance in my personal GCP inbox appears to have been delayed.

As you note, part 312 does not define a sub-investigator - or co-investigator, or any similar terms - merely investigator, sponsor, and sponsor-investigator. The ICH GCP document, with which FDA concurs as guidance, available at http://www.fda.gov/cder/guidance/959fnl.pdf, does define at 1.56 a sub-investigator as "Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows)." If an individual chooses to submit an IND for a study and will not consider himself/herself as the clinical investigator of the resulting study, but merely a support person or sub-investigator as defined above, that information would need to be included in the submission materials. The regulations do not prohibit such a person from acting as a sponsor and it would be the decision of the reviewing division as to whether his/her role in the resulting study appeared appropriate or not.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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From: [purged]
Sent: Friday, February 03, 2006 3:04 PM
To: gcpquestions@oc.fda.gov
Subject: IND question
To Whom It May Concern:

Can a Sub-Investigator hold an IND and act as the Sponsor of a clinical trial? 21CFR312.3 refers to Sponsor-Investigator but does not mention anything about Sponsor-Sub Investigator.

Thank you,
[purged]