From: OC GCP Questions
To: [redacted]
Subject: RE: Question on IND holder
Date: Tuesday, December 4, 2018 12:54:00 PM
Attachments: [redacted]

Dear [redacted],

It appears from your inquiry that the sponsor-investigator IND holder is moving from one hospital to another to conduct the study. In general, it is acceptable for the IND holder/sponsor-investigator to change hospitals/study sites and remain the IND holder.

Given your reference to the new hospital as a "sub-site" and his/her role at the new hospital at "the local PI", however, it is not clear whether the study will be continue to be conducted under the supervision of another clinical investigator at the original hospital or elsewhere.

If, in fact, there will be another clinical investigator at another study site participating in the study, the other clinical investigator should complete and sign Form FDA 1572 and submit that form to the sponsor-investigator at your site who holds the IND. In addition to the other sponsor responsibilities found in 21 CFR 56 Subpart D, the sponsor-investigator will be responsible for submitting updated information about the IND to the FDA review division, either by submitting the 1572 or including the updated information in IND progress reports. (21 CFR 312.53(c)).

The FDA guidance called "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" at

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf contains the following information on page six:

> ***When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?***
>
> There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).
>
> If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

You don't mention the issue of IRB review but it is worth thinking about a few issues. Does your hospital have its own IRB or is there a centralized IRB overseeing the study? Depending on the circumstances, you may need to consider whether a cooperative agreement of some sort is needed. Has the prior hospital been informed of the move of the IND holder/sponsor-investigator? Have subjects been enrolled at the previous hospital where the IND holder/sponsor-investigator worked? If so, will they continue in the study and under whose oversight? How will subjects be informed about the changes, including the change in clinical investigator (if that is applicable)? You may want to consult this guidance about IRB transfer issues:
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM307779.pdf

Does the IND holder/sponsor-investigator plan to monitor the former study site at the prior hospital? You email indicates that it is in another state – is it near to your hospital or far away? The distance between sites may affect the ability of the sponsor-investigator to monitor effectively. How does the sponsor-investigator plan to monitor the study at your hospital? You may want to suggest that the sponsor-investigator review this guidance about clinical investigator responsibilities,
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

I hope that these suggestions for issues to consider is helpful to you.

Best Regards,

Karena Cooper
Senior Regulatory Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. 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.

From: [redacted]
Sent: Friday, November 30, 2018 12:25 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; [redacted]
Subject: Question on IND holder

To whom it may concern,

I am writing as the Director of a small investigator initiated cancer group.

I am writing today to clarify my understanding of the sponsor-investigator (312.3) and IND holder roles as we have a new investigator who will be joining in the coming months from a prior hospital.

If an IND holder/sponsor-investigator leaves their institution for another hospital (in a different state), do you foresee an issue with the sponsor/investigator remaining the IND holder after leaving the first institution, if he plans on opening the study at his new hospital as a sub-site (where he will be the local PI). I do understand the sponsor/investigator would remain responsible for all activities of the trial. However, I wanted to confirm if I was maybe missing something in my review of this potential situation.

Thank you
[redacted]

[redacted]

[redacted]

[redacted]