From: OC GCP Questions
To: [redacted]
Subject: PI - Maternity Leave
Date: Wednesday, November 07, 2018 11:37:00 AM
Attachments: [redacted]

Good morning –

If there is a new CI, even temporarily, signs on as a new CI, the CI will be required to sign a 1572 form for drug and biologic studies or an investigator agreement for device studies.

Please find the links below that addresses additional 1572 questions and FDA inspections of CIs.
www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

Please note, FDA regulations refer to the investigator whose name is on the FDA Form 1572 (the 1572) for drug and biologics studies or the investigator agreement for device studies as a clinical investigator (CI) rather than a principal investigator (PI), though we recognize that the industry often uses PI instead. The CI is the person who has responsibility for the conduct of the study at the site. Replacement of the CI at a study site is one of the only reasons a new 1572 is needed (see Q&A #7 in the guidance document). The sponsor must have a signed and dated 1572 before a new CI can participate in the conduct of the study.

The guidance states --

3. When must this form be completed and signed by an investigator?

Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572 before permitting the investigator to begin participation in the clinical investigation (21 CFR 312.53(c)). The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Section #9 of the 1572. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator's brochure (if required), and is familiar with the regulations governing the conduct of clinical studies.

The investigator's signature on this form constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator's written commitment to abide by FDA regulations in the conduct of the clinical investigation.

7. 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.

As stated in your email, for example --If an investigator is to act as the study's clinical investigator (CI) during the maternity leave of the CI who originally signed the study 1572, then the study sponsor needs to approve her replacement. If the study sponsor agrees that her replacement is acceptable to them, then

the new investigator needs to complete and sign a 1572 and return it to the sponsor. One of the purposes of the 1572 is to provide the sponsor with a signed agreement from the CI to comply with the investigational plan, which includes the study protocol, as well as with relevant regulations. While the replacement may be temporary, this new CI is responsible for the conduct of the study during the original CI's maternity leave and therefore needs to acknowledge that by signing a 1572, even if all other information on the form remains unchanged.

The 1572 form is a sponsor form and a change in the PI should be approved or requested by the sponsor. You are stating the central IRB is requiring this change. The changes to the 1572 is up to the sponsor.

If you are the sponsor, I suggest that you contact's FDA regulatory project manager (RPM) of the IND to discuss your situation.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [redacted]
Sent: Tuesday, November 06, 2018 8:56 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: PI - Maternity Leave

Hello,

We have a PI that is going on maternity leave soon, and the central IRB is requiring that a different PI be assigned while the current PI is out (including revising and submitting all documents such as 1572, ICFs, etc), not allowing a sub-I to oversee the study during this time (6 weeks). Is this correct that a different PI must be assigned altogether and the current PI removed from the study during the time she is on leave? It's a lot of paperwork, seemingly unnecessary. I've never experienced this, even with PIs going on extended vacations overseas, where a sub-I oversees the study during that time. Please advise.

Thanks!

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