

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** GCP and Form 1572 Question  
**Date:** Thursday, July 18, 2019 2:27:33 PM  
**Attachments:** [REDACTED]

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Good afternoon –

Please see the FDA 1572 Form guidance. No, there is no need to add the coordinator right away. See below from the guidance.

**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.*

The above statement would include coordinators. The sponsor can accumulate certain change and submit this information to the IND in an information amendment o protocol amendment. Please keep track of when (date) the coordinator started assisting with the study.

Kind regards,

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**From:** [REDACTED]  
**Sent:** Tuesday, July 16, 2019 6:16 PM  
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>  
**Subject:** GCP and Form 1572 Question

Greetings,

I can't find any exact guidance on the following question. When a new study coordinator is added to a study, must they be added to the 1572? I know this is a contract for the PI and the SI but when I researched this matter GCP nor does ACRP mention if it is required for a coordinator to be listed. Please advise.

Kind Regards,

