

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Protocol update training
Date: Wednesday, July 15, 2020 11:14:41 AM

Good morning -

Thank you for your inquiry. FDA recognizes a need to have study staff adequately knowledgeable of the study requirements should be documented in some manner or there is no evidence that it occurred. However, FDA regulations in this regard are very general. Should a bioresearch monitoring (BIMO) inspection of your site occur for a particular study, FDA investigators will expect to see some evidence that the study staff are qualified (by experience and training) to conduct the study. Since FDA regulations governing the conduct of clinical studies (21 CFR Part 312 for drugs and biologics and 21 CFR Part 812 for devices) do not specifically require maintenance of such records, observation of the fact that such documentation is absent would not be placed on the Form FDA 483 (483), as only observations regarding regulatory requirements are noted there. If a study is clearly well conducted and the study staff prove knowledgeable during the inspection, the lack of documentation may not even be noted in the establishment inspection report (EIR) submitted to the Center that requested the inspection, as the FDA investigator may not even have found it necessary to verify such training. Absence of such documentation becomes an issue when there is evidence the study has problems and inadequately trained staff appears to be at least a contributing factor. Maintaining adequate documentation is a sign of a well-functioning study and is therefore always recommended, even when not specifically required by regulation. While guidance may not be cited as an inspectional observation, it represents FDA's thinking on an area. While other means of fulfilling a regulatory requirement are possible, following FDA guidance on the subject would be considered compliance.

There is not specific FDA regulation that requires signatures for protocol update training. This would be up the sponsor and clinical investigators SOPs. The training as noted about should be well documented, if performed.

Kind regards,

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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: Wednesday, July 15, 2020 8:41 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Protocol update training

Hello,

Is there a FDA regulation that requires sites to document with signatures when the protocol is updated and/ or revised?

We are aware of delegation of authority (DOA Logs) that require investigators to take responsibility of staff performing duties on the study that they are appropriately educated, certified, licensed, and trained on the study protocol, but we are questioning if a regulation has been issued for when there are updates to protocols; does the FDA require signatures?

Thank you

