

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Research Personnel Printing, signing and d dating their own name  
**Date:** Wednesday, December 06, 2017 1:26:00 PM  
**Attachments:** [REDACTED]  
**Importance:** High

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Good afternoon --

There isn't any specific regulatory citation in 21 CFR 312 related to signing and dating documents, except for 21 CFR 312.62(b): "An investigator is required to prepare and maintain ADEQUATE AND ACCURATE case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, SIGNED AND DATED CONSENT FORMS AND MEDICAL RECORDS including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study." [Emphasis added.]

In general, the date should reflect when an individual actually signs a document. Documents should not be "pre-dated" or "post-dated, or pre-signed" and it's poor practice to do so. Simply put, "pre-dated" or "post-dated" records are not accurate. If pre-dating and/or post-dating an pre-signing is done routinely, it could be considered repeated and deliberate non-compliance.

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.

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**From:** [REDACTED]  
**Sent:** Wednesday, December 06, 2017 12:48 PM  
**To:** OC GCP Questions <gcp.questions@fda.hhs.gov>  
**Subject:** Research Personnel Printing, signing and d dating their own name  
**Importance:** High

Hello,

Can you please clarify if it is acceptable to have an Investigators name pre-printed and possibly pre-dated on a central lab print out, a training log, any document that has a section printed name, signature, and date (informed consent?)?

Thanks in advance for any guidance you can provide!

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