

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: time elapse between consent signing and pt registration
Date: Thursday, January 11, 2018 12:38:00 PM
Attachments: [REDACTED]

Good afternoon --

FDA does not have a "30-day" rule. In fact, FDA regulations do not really address your question directly. We require IRB review of research (including the consent form) to occur according to the degree of risk, but at least annually. That does not mean that the consent form will change annually, or that subjects must provide consent on an annual basis. (Although, if the consent form were to change and that change was relevant to subjects enrolled in the study, then those subjects should be provided the new informed consent document.) However, because the IRB is responsible for reviewing the consent process, it would seem reasonable to ask the IRB if they have policies in this regard.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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From: [REDACTED]
Sent: Thursday, January 11, 2018 10:53 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: time elapse between consent signing and pt registration

I work at a research site. We would like to know if there is a regulation that addresses a time limit between the time the patient signs consent and the when they are registered on the clinical trial. If there has been no changes/revisions to the study or the informed consent can more than 30 days elapse between the time the patient signed the consent document and the time they are registered to the trial?

Thank you.

[REDACTED]