From: OC GCP Questions
To: [redacted]
Subject: RE: handwritten dates on regulatory documents
Date: Friday, September 29, 2017 10:01:50 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. From the limited information provided, it isn't clear what type of document you are referring to, or the scenario in question, but I provide the following thoughts.

There may be any number of essential documents for the conduct of a clinical trial that, for various reasons, may require a signature and a date. If, for example, the document you are referring to is an informed consent form for an FDA-regulated study, you should consult the regulations at 21 CFR 50.27(a) copied here:

> Sec. 50.27 Documentation of informed consent.
>
> (a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

As stated in the regulation, the consent form is signed and dated at the time of consent. Pre-dating informed consent forms would not appear to meet this requirement.

Also, you may find information in the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance - you can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) helpful to you regarding documentation.

Section 1.24 of the guidance defines Good Clinical Practice (GCP):

> 1.24 Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Section 2.10 of the guidance states:

> 2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.

Section 4.8.8 of the guidance states:

> 4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

Section 4.9.3 of the guidance states:

> 4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections (see section 5.18.4(n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

Many sponsors, CROs, investigators/sites, and IRBs have SOPs regarding documentation requirements, and best documentation

practices, so you should consult these groups with your documentation question. The process for signing and dating documents, including what a signature is attesting to on any given document, may be addressed in an SOP. You may also want to consult legal counsel at your institution to ensure that you are aware of expectations about documentation.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

[redacted]

[redacted]

From: [redacted]
Sent: Tuesday, September 26, 2017 1:04 PM
To: OC GCP Questions
Subject: handwritten dates on regulatory documents

If a date is typed into a document and then staff hand writes their signature, does that signature attest to the date that was typed in?

[redacted]