From: OC GCP Questions
To: [redacted]
Subject: Version Numbers In Informed Consents
Date: Wednesday, March 05, 2014 9:29:02 AM

Good morning –

FDA regulations do not specifically address how the ICD version control should be maintained. When the regulations are silent, IRBs are free to develop their own standard operating procedures (SOPs) to address a specific situation or issue.

It might be helpful to look over the guidance document below.

Guidances > A Guide to Informed Consent - Information Sheet It states –

Revision of Consent Documents during the study
Study protocols are often changed during the course of the study. When these changes require revision of the informed consent document, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. While not required by FDA regulations, some IRBs stamp the final copy of the consent document with the approval date. The investigator then photocopies the consent document for use.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Friday, February 28, 2014 3:32 PM
To: OC GCP Questions
Subject: Version Numbers In Informed Consents

To whom it may concern,

I have been asked to verify if the FDA mandates that consents contain version numbers. Is a version date by itself not sufficient?

Many thanks in advance for your assistance.

Best regards,

[Redacted]