From: OC GCP Questions
To: [redacted]
Subject: 21 CFR 56.103 Question
Date: Thursday, October 01, 2015 6:38:28 AM

Good morning –

In the 2015 CFRs 813 is not listed so I believe it has been removed. The CFR lists 812 and skips to 814. Please see below that describes what "reserved" means.

Where is the [Reserved] material?

"[Reserved]" is a term used as a place holder within the Code of Federal Regulations. An agency uses "[Reserved]" to simply indicate that it may insert regulatory information into this location some time in the future. Occasionally "[Reserved]" is used to indicate that a portion of the CFR was intentionally left empty and not accidentally dropped due to a printing or computer error

If I have not adequately answered your question, you can contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov This Center oversees the 800 regulations.

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: Wednesday, September 30, 2015 4:48 PM
To: OC GCP Questions
Subject: 21 CFR 56.103 Question

We are revising our policies and need clarification for the information in 21 CFR 56.103 Circumstances in which IRB review is required, item (a)—see highlighted reference and question below.

> **§56.103 Circumstances in which IRB review is required.**
> (a) Except as provided in §§56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

Question: The CFRs show "813" as "[RESER
VED]." Has this reference been removed or changed? If the latter, please provide the new subpart.