From: OC GCP Questions
To: [redacted]
Subject: GCP Predicate rules
Date: Thursday, March 29, 2018 9:50:00 AM
Attachments: [redacted]

Good morning –

I send you second email to the Center for Drugs (CDER) Office of Medical Policy (OMP) for a response.

Below is OMP's cleared response:

The underlying requirements set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and FDA regulations (in addition to part 11) are referred to as the predicate rules.

That said, a CRO that assumes any obligation of a sponsor must comply with the specific regulations in 21 CFR part 312 that are applicable to this obligation. The CRO is subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to "sponsor" in 21 CFR part 312 applies to a CRO to the extent that it assumes one or more obligations of the sponsor. Please see 21 CFR 312.52 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.52)

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, March 28, 2018 12:16 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: GCP Predicate rules

Hmmm, that is confusing, you quoted "Persons must comply with all applicable predicate rule requirements"… then clarified a predicate rule means underlying requirements. I would like to make sure I comply with predicate rules, since it is clear we are supposed to know these. If they are the underlying requirements, are you saying the predicate rules = guidance requirements? Are they the same thing?

[redacted]

From: OC GCP Questions <gcpquestions@fda.hhs.gov>
Sent: Wednesday, March 28, 2018 8:56 AM
To: [redacted]
Subject: GCP Predicate rules

Good morning –

There is no true listing of predicate rules. See below.

What might be the most relevant reference about which you should become familiar is the part 11 guidance entitled "Guidance for Industry Part 11, Electronic Records, Electronic Signatures- Scope and Application" (http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf) . This guidance explains the agency's current thinking on the application of part 11 to FDA regulated activities that involve the creation, modification, maintenance, archiving, retrieving or transmission of records. Persons must comply with all applicable predicate rule requirements (**where predicate rules mean the underlying requirements set forth in the FD& C Act, the PHS Act, and FDA regulations published in the Title 21 Code of Federal Regulations [Emphasis added)**

Kind regards,

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

From: [redacted]
Sent: Monday, March 26, 2018 4:21 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: GCP Predicate rules

Hello,

I work at a CRO, and we use 21 CFR Part 11 as our guide for compliance. We are a clinical research partner to the pharmaceutical, biotech, and medical device industries, offering biostatistical and data management services (protocol dev, SAPs, analysis and reporting, data mgt.)

I have been training on Part11 and have noticed many references to “following your industry’s predicate rules”, but I don’t know where to find the specific predicate rules for a CRO. On the GCP page, your contact info was listed. Can you help? In a nutshell, what rae the predicate rules for a

CRO in GCP?

In the FDA website information, it doesn't specify, it says:

> "Understanding the predicate rules that apply to your company is key to being compliant with 21 CFR 11 because those rules will determine the corresponding Part 11 controls that apply to your company"

[redacted]

[redacted]