From: OC GCP Questions
To: [redacted]
Subject: FDA regulated clinical trials
Date: Thursday, September 07, 2017 11:27:00 AM

Good morning –

If the study is FDA-regulated and also federally conducted or supported/funded, then the regulations at 21 CFR (FDA) and 45 CFR 46 both apply. When both sets of regulations apply to a study, then both sets of regulations must be followed. In situations where the regulations differ, the more stringent regulations apply.

The "Common Rule" refers to the Department of Health and Human Services' (DHHS') regulations that pertain to the institutional review and protection of human subjects who participate in federally funded or federally sponsored studies.

Again The DHHS regulations are found in 45 CFR 46 (OHRP). If a federally funded or federally sponsored study involves an FDA-regulated product, then both sets of regulations would apply.

While this may seem confusing, the regulations at 45 CFR 46 and FDA's regulations for informed consent and IRBs are fairly congruent, with only a few differences, centered primarily on the regulations' applicability. For example: -FDA is responsible for overseeing research involving FDA regulated products, whereas the HHS regulations cover biomedical, behavioral, and social research.

You may also contact the Office for Human Research Protections (OHRP)

Telephone: (866) 447-4777

Telephone: (240) 453-6900

E-mail: OHRP@hhs.gov

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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From: [redacted]
Sent: Thursday, September 07, 2017 9:16 AM
To: OC GCP Questions
Subject: FDA regulated clinical trials

My understanding is that FDA regulated clinical trials are not subject to the Common Rule 45 CFR 46 because FDA rules trump the Common Rule. However, could funding change this? For instance, if a FDA regulated trial is federally funded, would it then by subject to the Common Rule?

Thanks

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