From: OC GCP Questions
To: [redacted]
Subject: US state specific requirements beyond FDA/GCP/ICH regs.
Date: Tuesday, December 16, 2014 10:56:07 AM

Good morning –

FDA's site only has FDA/GCP/ICH information. You may want to try OHRP or WHO sites. See below. FDA does not have specific information on state requirements.

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WHO | World Health Organization

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, December 16, 2014 7:31 AM
To: OC GCP Questions
Subject: US state specific requirements beyond FDA/GCP/ICH regs.

Dear Sirs and Madams,

I have unsuccessfully tried to locate a list of US state specific requirements (beyond FDA/GCP/ICH requirements) relevant to the planning, conduct and oversight of clinical trials, e.g. such as California Experimental Subjects Bill of Rights.

I was wondering if you could advice where to find this information.

Thanks in advance for your help.

Kind regards,

[redacted]