From: OC GCP Questions
To: [redacted]
Subject: Applicability of FDA regulation to and ICH GCP to public health intervention studies
Date: Tuesday, June 23, 2015 12:20:05 PM

Good afternoon –

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP. FDA regulations apply when research is being conducted with an FDA-regulated product.
(Drugs, biologics, and devices). The regulations can be found at the link below. For drugs and biologics, please see CRF 21 Part 312, for devices please see CFR 21 Part 812. Please see CDR 21 Part 50 for protection of human subjects and CFR 21 Part 56 for institutional review boards. The link below also discusses preambles to GCP regulations. Additionally there are a number of other useful links on this webpage.

Clinical Trials and Human Subject Protection > Regulations

ICH E- 6, Good clinical practice guidance is used as a guide for international ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Guidance Documents (Including Information Sheets) and Notices > ICH Guidance Documents

If the clinical trial is being conducted with a FDA-regulated product under the investigational new drug (IND) for drugs and biologics or investigational device exemption (IDE) for devices FDA regulations must be followed. Device Advice: Investigational Device Exemption (IDE); Investigational New Drug (IND) Application.

Please see the guidance document that discusses determining whether human research studies can be conducted without an IND.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

Lastly please see the link below for the guidance that discusses protecting the rights, safety, and welfare of study subjects.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
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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: Saturday, June 20, 2015 12:21 PM
To: OC GCP Questions
Subject: Applicability of FDA regulation to and ICH GCP to public health intervention studies

To whom it concerns,

I am currently working on a master thesis describing the FDA and international regulation for data management in clinical trials.

My understanding is that FDA regulations, such as FDA 21 CFR Part 11 and the international guidance ICH GCP only apply to clinical trials where data is being generated to submit to the regulatory authorities, i.e. pharmaceuticals or medical devices submitted for marketing approval.

What is the rule for experimental studies in humans intending to define best practices, for example comparing MRI tests to CT scans for diagnosing certain diseases? Would these studies be subjected to FDA and/or ICH GCP regulation?

What is the applicabiltity of those regulations to public health intervention studies, such as a randomized controlled trial assessing the effectiveness of new paper documentation form for health records? Must these studies be conducted in accordance with the regulations (FDA and ICH Gcp)?

If so, are there documents where this applicability is explicitly stated for such cases?

Many thanks in advance for your time.

Kind regards,

[redacted]