From: OC GCP Questions
To: [redacted]
Subject: RE: Scope of Good Clinical Practice
Date: Thursday, March 16, 2017 11:22:07 AM
Attachments: [redacted]

Dear [redacted],

Thank you for your question. If I understand your question correctly, I think you are asking how Good Clinical Practice (GCP) is reflected in both the FDA regulations and guidance. So I have provided a response based on this assumption.

I want to make sure that you understand that there are regulations and there is also guidance, and that there is a difference between these two. When Congress enacts laws affecting FDA-regulated products, FDA can be required to develop regulations to implement the law. A good way to think about it is that FDA regulations establish legally enforceable responsibilities and must be followed. When you read regulations, you will usually see the use of the word shall or must. This means something is required.

FDA may also issue guidance, which is different from regulation. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidance means that something is recommended or suggested, but not required. Guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

I hope this helps to distinguish regulations from guidance.

GCPs are referred to as a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. GCPs include things such as review and approval (or provision of a favorable opinion) by an institutional review board (IRB)/independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IRB/IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study.

GCP standards are reflected in FDA's regulations found throughout Title 21 of the Code of Federal Regulations – see the FDA web page for a list of the FDA Regulations Relating to Good Clinical Practice and Clinical Trials at https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm114928.htm.

There may be times when FDA will adopt a guidance document that has been issued by another group as is the case with ICH E6, which FDA adopted as guidance in 1997 (see https://www.gpo.gov/fdsys/pkg/FR-1997-05-09/pdf/97-12138.pdf). So, FDA recognizes the ICH E6 guidance document as FDA guidance.

Together, the FDA regulations and FDA guidance, including the ICH E6 guidance, reflect GCPs and the standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

You may want to consult others within your institution such as the legal department, the IRB, and training department to get more information about GCPs that may be helpful to you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

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From: [redacted]
Sent: Wednesday, March 15, 2017 10:39 AM
To: OC GCP Questions
Subject: Scope of Good Clinical Practice

Hello -

Could you clarify a couple of questions I have about the scope of GCP:

- ✓ A reference to Good Clinical Practices is specifically tied to the International Conference on Harmonisation's GCP?
- ✓ The FDA does not adopt its own set of GCP standards nor does any other federal agency? There are federal regulation addressing GCP topics however the federal government is not producing its own set of GCP standards?
- ✓ The FDA relies on the ICH's GCP for guidance - while not adopted into U.S. law - how is guidance applied?

With appreciation - [redacted]

[redacted]