From: OC GCP Questions
To: [redacted]
Subject: RE: Interpretation question
Date: Tuesday, March 11, 2014 10:54:00 AM
Attachments:

Dear [Redacted]-

Thank you for your question. Your interpretation of the words "shall" and "should" as they appear in regulations and guidance is on target. A good way to think about it is to remember 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 by the regulations.

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 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, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Monday, March 10, 2014 3:37 PM
To: OC GCP Questions
Subject: Interpretation question

To FDA representative:
I have a question about interpretation of guidelines/regulations. Would you please define the words "should" and "shall"? GCP and ICH tend to use the word "should" often, and I take that to mean "not mandatory", while "shall" means "mandatory".
Is this an accurate interpretation? Would you please enlighten me?

Thank you,
[Redacted]