Dear [Redacted]-

Thank you for your question. I have listed below a few web links on FDA's web site for your reference:

•   Information about FDA's Office of Good Clinical Practice (OGCP) can be found at the following web link:
http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.htm

•   Information about Clinical Trials and Human Subject Protection can be found at
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.
      o   On this web page, you can sign up to receive GCP/HSP email updates from the FDA.
      o   On this web page, you can see the "In the News" column on the right side of the page that will give you current information about current FDA activities.
      o   There is other helpful information on this web page including resources for you, workshops and meetings, and contacts.
      o   Here you can access a link on the left side of the page to guidance documents (including Information Sheets) and notices.

•   Information about Good Clinical Practice Contacts can be found at
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm.
      o   On this web page, you can find information about how to submit GCP questions to the FDA through our public mailbox at gcp.questions@fda.hhs.gov.
      o   On this page, you can find contact information for the FDA product Centers if you have general product questions.

•   Information about past questions OGCP has received from the public along with a FDA's response at
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm.
      o   On this page you will see redacted past inquires and responses grouped by year (since 2002) by category. You can search these queries and responses to see what other GCP questions have come in over the years.

The 2014 redacted questions and answers will be posted soon in 2015. The information found on that last web link I provided above sounds like the type of information you are looking for. There is a lot of other helpful information that you can find by searching FDA's web site at http://www.fda.gov/default.htm.

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. As I mentioned above, 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

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.

-----Original Message-----
From: [Redacted]
Sent: Thursday, December 25, 2014 8:09 AM
To: OC GCP Questions
Subject: FDA Good Clinical Practice Program question

Hi there,

one of my GCP guidebook refers to "FDA Good Clinical Practice Program". I would really appreciate if you could tell me if there's any website or book I could read more about guidelines or Q&As submitted by FDA in terms of GCP. So far I have only identified guidelines posted on website of Yours, but I'd like to explore more formal responses FDA gave for some questions arisen by site staff and Sponsors.

I'd like to take this opportunity to wish you Merry Christmas and a wonderful New Year!

Many thanks and all the best,

[Redacted]