From: OC GCP Questions
To: [redacted]
Subject: RE: Protocol waivers
Date: Thursday, June 19, 2014 1:11:00 PM

Dear [redacted],

FDA considers these to be deviations from the protocol and so expect them to be reported to us in the same way as all deviations in a given study are reported. Unless a deviation is related to a serious adverse effect for a subject, it can be reported as part of the deviations report in the yearly study report.

While we recognize that sponsors do at times grant a clinical investigator (CI) what they consider as a waiver of one or more eligibility criteria, when such individuals are enrolled in a study the ability to pool their data with those enrolled according to the protocol criteria is diminished considerably or even null. Therefore, we try to discourage sponsors from granting such waivers. We suggest instead that sponsors have the CIs who will likely be part of the study assist with the finalization of the protocol to avoid requirements that are either unnecessary or too restrictive. This should avoid requests for such waivers and therefore improve the poolability of data from the entire subject population.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Office of Good Clinical Practice
Office of the Commissioner, US 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: Wednesday, June 18, 2014 8:04 PM
To: OC GCP Questions
Subject: Protocol waivers

I have a question about eligibility waivers for studies conducted under an IND. Does the FDA require advance review or prompt notification of isolated eligibility criteria waivers that are approved by trial Sponsors and site IRB? If an eligibility waiver is approved by Sponsor and IRB, is the Sponsor permitted to report these waivers at IND annual report?

Thank you,

[redacted]