From: OC GCP Questions
To: [redacted]
Subject: Question regarding "over enrollment" in a clinical trial
Date: Monday, January 27, 2014 10:10:39 AM

Good morning –

This office cannot specifically address your over-enrollment question as all studies are different. Sometimes over-enrollment is not advisable. I recommend that you seek advice from the FDA Review Division that you are working with on your specific study (e.g. your assigned FDA Project Manager for the IND). You should also consult your reviewing IRB.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Friday, January 24, 2014 2:00 PM
To: OC GCP Questions
Subject: Question regarding "over enrollment" in a clinical trial

Hi,

The scenario is the potential for over-enrollment in the study was raised as a question whereby as a study is approaching Last Patient, Last Visit, there is the potential for more subjects to be enrolled, however it will bring the total number enrolled over the anticipated number based on initial projections.

Certain areas of the protocol note an approximate number of patients to be enrolled in each phase/part of the study, while other sections of the protocol seem to conflict with this and note a maximum number of patients required and/or does not include the “approximate” language.

It should be noted that this is a Phase 1/2 study, and as such these protocols tend to enroll additional patients based on if a patient is evaluable; while this is certainly common, the protocol language may not provide the flexibility needed for this to occur.

Any thoughts on this matter and whether it is an issue to ‘over enroll’ so to speak, is welcomed.

Thanks!
[Redacted]