From: OC GCP Questions
To: [redacted]
Subject: Inclusion of Sub-investigators on 1572
Date: Tuesday, May 13, 2014 11:08:11 AM

Good morning –

Based on the limited information in your email, it appears that the ophthalmologists should be listed on the 1572 as they are performing study related activities.

Kind regards,

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

From: [Redacted]
Sent: Tuesday, May 13, 2014 10:05 AM
To: OC GCP Questions
Subject: Inclusion of Sub-investigators on 1572

[Redacted] is currently initiating a clinical trial site and is seeking clarity after review of the guidance document on the need to include certain clinical staff on the 1572 as sub-investigators.

- It is a Phase I trial of new oncology drug that has been shown to have ophthalmologic effect in dogs in GLP toxicology studies.
- The protocol includes an ophthalmologic exam for all patient both before and after treatment as part of the safety evaluation schema.
- Some of the centers have in house ophthalmologist and other centers are contracting with outside physicians to perform these evaluations.

  Per the guidance it is our view that these physicians are independently carrying out study evaluations and should be included on the 1572 as sub-investigators as the ophthalmologist will be responsible for a key safety evaluation. It is the sites opinion that it is not necessary to include the ophthalmologist on the 1572. Can you please clarify if the ophthalmologist should be included on the 1572 as a sub-investigator.

  Thank you in advance for your help with our question.
  Best regards

[Redacted]