

From: OC GCP Questions
To: [REDACTED]
Subject: Form FDA 1572 Section 3 vs Section 4
Date: Tuesday, January 10, 2017 12:07:00 PM
Attachments: [REDACTED]

Good afternoon –

Based on the information in your email, it appears the best place to place the Ophthalmology office is in section 4. I also believe that the office should be listed on the 1572 form as the protocol requires that the funduscopy be performed within 90 days.

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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: Tuesday, January 10, 2017 11:34 AM
To: OC GCP Questions
Subject: Form FDA 1572 Section 3 vs Section 4

Good Morning,

We are currently starting a trial that requires a Fundoscopy. Our site does not have the equipment or personnel to complete this procedure so we contract out with a local Ophthalmologist just for the procedure.

A question has arose between us and the Sponsor where we should add the Ophthalmology office on the 1572. After reviewing the information Sheet Guidance for Sponsors, Clinical Investigators and IRBs: FAQs – Statement of Investigator, our site added the Ophthalmology office into box 4 since:

1. The protocol states that if a patient has had a fundus photography/dilated funduscopy have been performed within 90 days prior to next visit and if the results are available at that visit,

then the procedure does not need to be repeated.

2. The funduscopy required by the protocol is not protocol specific and requires nothing additional outside their normal medical practices.
3. The ophthalmologist is not determining subject eligibility by the procedure, their eligibility will be determined by the PI.
4. The ophthalmology office will not provide any other services (i.e. study visits, consenting subjects, recruiting) other than the funduscopy.
5. They are only providing services as a clinical laboratory, etc., as defined by the guidance (28).

We would like to add the Ophthalmology office in box 4 as noted in the guidance provided by the FDA.

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY

28. What qualifies as a clinical laboratory facility for Section #4?

Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

The sponsor has asked us to place the office either in box 3 or remove the ophthalmology office off the 1572 completely. I do not feel comfortable with either option. Can you please provide me with more guidance?

Kind regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]