

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Subject Enrollment Question
Date: Tuesday, January 27, 2015 8:35:10 AM

Good morning -

I don't believe this is a protocol deviation as you state the cancer was discovered after enrollment. Since the subject now meets exclusion criteria there is a good chance he will need to be terminated from the study. A note to file regarding the situation, follow-up and decision-making is advisable. Please consult your sponsor for direction and it is best to notify your reviewing IRB. The sponsor can always consult the project manager of the IND in CDER to discuss options for this subject.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

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From: [REDACTED]
Sent: Monday, January 26, 2015 7:06 PM
To: OC GCP Questions
Subject: Subject Enrollment Question

To Whom it May Concern:

A subject was consented and screened for a study. During the office visit the patient was referred for a dermatology consult stating, "He has a non-healing ulcer on the helix of his left ear. This may be non-healing due to his diagnosis of lymphoma. It does not appear to be a malignant finding or a new skin cancer. However, he was recommended evaluation by a dermatologist for a more definite diagnosis. This finding is not a contraindication for initiating the clinical trial."

The Investigator proceeded to randomize the study subject and treat per protocol. A few days later the Investigator was notified that the subject went to see the dermatologist and a biopsy of the ulcer was taken. The biopsy results were basal cell carcinoma. One of the Exclusion Criteria for the protocol states...

7. Current or previous other malignancy within 2 years prior to randomization. Subjects who have been free of malignancy for at least 2 years, or have a history of completely resected non-melanoma skin cancer or successfully treated carcinoma in situ, are eligible.

Is this considered a protocol deviation even though the diagnosis wasn't made until after the subject was treated? Could you please advise as to how this should be handled.

Thank you,

[REDACTED]