From: OC GCP Questions
To: [redacted]
Subject: Question on text in ICF disclosing treatment or dose after trial is over
Date: Monday, April 14, 2014 2:25:22 PM

Good afternoon –

I am sorry I don't recall receiving your initial email in our queries box last week.

When we speak of double-blinded studies we mean that both the study subject and the clinical investigator (CI) are blinded to the assignment of the product. (A single-blinded study meaning study subjects do not know what they receive but the CI does.)

Any combination of blinding is possible if it is spelled out in the study protocol. It seems that a rationale for whatever scheme is chosen would be there as well so the reviewing IRBs understand why it is being imposed on the study.

To answer your question, there is no standard practice or requirement to inform the subjects. This would be up to the sponsor, the reviewing IRB, and the nature of the research and investigational product.

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

From: [Redacted]
Sent: Monday, April 14, 2014 11:36 AM
To: OC GCP Questions
Subject: FW: Question on text in ICF disclosing treatment or dose after trial is over

Dear FDA Associate,

I wondered if my e-mail message was lost "in the wires."

If someone could respond to my question (forwarded below), I would appreciate it.

Kind regards,
[Redacted]

From: [Redacted]
Sent: Friday, April 04, 2014 11:24 AM
To: 'gcp.questions@FDA.HHS.gov'
Subject: Question on text in ICF disclosing treatment or dose after trial is over

Dear FDA representative,

When preparing an ICF for a double-blind clinical trial with an active drug and placebo (or even an open-label trial with multiple doses of an active drug), is there a requirement, or a standard practice, to include the text stating that after the trial is over the subject will be told which treatment or dose the subject received during the trial?

I've seen this text in some ICFs and not in others. After trials were complete, I've also known investigators to tell subjects which treatment the subject received, even though the ICF did not specifically state that this would be disclosed.

Kind regards,
[Redacted]