From: OC GCP Questions
To: [redacted]
Subject: RE: Questions concerning FDA Form 3674
Date: Tuesday, October 27, 2015 7:14:00 AM

Good morning,

FDA has certain responsibilities related to information required to be submitted to the ClinicalTrials.gov databank. A description of these responsibilities can be found on the FDA website at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/FDAsRoleClinicalTrials.govInformation/default.htm .

The certification requirement went into effect on December 26, 2007 and I believe Form FDA 3674 was available in early 2008. FDA has a guidance document related to this form which is available at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM164819.pdf . The discussion of the requirements for submitting certifications to an IND start on page 6.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Monday, October 26, 2015 3:30 PM
To: OC GCP Questions
Subject: Questions concerning FDA Form 3674

Dear Staff:

I recently became aware of FDA Form 3674, Certification of Compliance. When was this form instituted and when is it to be used? Are currently enrolling studies required to complete this form and send it in with a protocol amendment or is it to be used with new submissions only as of a certain date? Please advise. Any light you can shed on FDA Form 3674 would be most appreciated.

Thanks in advance for your time and attention to my question.

[redacted]