From: OC GCP Questions
To: [redacted]
Subject: Form 3674 - New version?
Date: Wednesday, March 07, 2018 10:56:00 AM
Attachments: [redacted]

Good morning –

The new version of the form is still under review by the Office of Budget and Management. Therefore, it is okay to use the expired form.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Zar[redacted]
Sent: Wednesday, March 07, 2018 10:31 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Form 3674 - New version?

Dear Sirs,

I am contacting you regarding Form 3674. The version available on FDA webpage (https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm?Page=10) expired last 02/28/2018 and we need it to complete a submission to an IND.

Could you please advise how we should proceed?

Thank you.

Kind regards,

[redacted]