From: OC GCP Questions
To: [redacted]
Subject: Request for copy of FDA Form 3674
Date: Friday, October 12, 2018 11:55:00 AM
Attachments: [redacted]

Good morning,

I'm sorry you are having trouble accessing the Form FDA 3674. We have not previously had issues with users opening the form. I am providing a copy of the form in the hopes that this might do the trick. This copy does open on my system. If it does not open for you, I would suggest that you have your IT staff investigate the issue on your end.

We have had seen some issues with the Adobe Reader opening in a preview mode which could be an issue, especially when using a Mac. Changing the settings could address that but you would need to discuss that with your IT staff. We have noted that trying to open the form from certain web browsers is problematic, particularly Chrome. Switching browsers usually solves the problem (try Internet Explorer), however, we do not normally have any issue with a user opening the pdf after we have sent it to them.

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: [redacted]
Sent: Thursday, October 11, 2018 3:47 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Request for copy of FDA Form 3674

Dear Madam/Sir,

I am a regulatory affairs consultant and I am presently working on a submission for a client. I am having difficulty accessing your Form 3674 and am hoping you can provide me with a fillable copy.

Thank you kindly,

[redacted]