From: OC GCP Questions
To: [redacted]
Subject: RE: Form FDA 3674
Date: Tuesday, February 06, 2018 7:36:00 AM
Attachments: [redacted]

Good morning,

FDA's guidance document related to Form FDA 3674 lists the applications and submissions which FDA recommends being accompanied by the form. This list does not include an Investigational Device Exemption (IDE). This guidance may be found at https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm

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.
Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. Food and 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: Monday, February 05, 2018 4:13 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Form FDA 3674

Hello,

My name is [redacted]. I am wondering if form 3674 is needed for a Feasibility IDE application?

Thank you.

[redacted]