From: OC GCP Questions
To: [redacted]
Subject: IND Exempt Required Regulatory Documents
Date: Thursday, July 24, 2014 1:58:23 PM

Good afternoon --

We consulted the Center for Drugs (CDER) for an answer. If a study is exempt from the IND requirements per 21 CFR 312.2(b), FDA does not have any regulatory record keeping requirements for studies not under an IND (exempt). If is advisable that if you received an IND exemption letter you probably would want to keep this letter on file as a reference for the future.

Kind regards,

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

From: [redacted]
Sent: Thursday, July 24, 2014 1:07 PM
To: OC GCP Questions
Subject: IND Exempt Required Regulatory Documents

Good Afternoon,

We have been asked to work on a project with an Investigator/Sponsor of a single site for which he has been given an IND exemption for his pilot study (approved drug/different indication). Can you please let us know which regulatory documents you would expect to see in the regulatory files for an IND exemption like this?

Thank you!