

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). It 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,

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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: GYXUM/XQ
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!