From: OC GCP Questions
To: [redacted]
Subject: 1572s and Foreign Sites
Date: Friday, August 21, 2015 8:52:19 AM

Good morning –

Please see FDA's web page that discusses INDs.

Investigational New Drug (IND) Application

Please also see the guidance documents below that describe an IND.

http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

If I have not adequately answered your question, you may contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov. They generally answer IND specific questions.

Kind regards,

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Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, August 20, 2015 1:49 PM
To: OC GCP Questions
Subject: 1572s and Foreign Sites

Hi GCP Questions -

An ex-US colleague has provided their interpretation of the FDA Guidance entitled *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBS: Frequently Asked Questions - Statement of Investigator (Form FDA 1572) (Guidance)* along with their stance with submitting 1572s for ex-US sites.

Their stance is that 1572s do not have to be collected, since in their view a study is

not conducted under an IND if a protocol has been submitted through a CTA. Even though the same protocol has also been submitted under an IND. I understand that the Guidance addresses foreign sites in questions 9 - 15.

Without going into detail about my situation, how do you define "conducted under an IND"?

If you can provide an answer to my question, I believe it can clarify my situation well.

Thank you!

[redacted]