From: OC GCP Questions
To: [redacted]
Subject: Compassionate Use IND
Date: Wednesday, February 14, 2018 8:49:00 AM

Good morning –

Please see FDA website on Compassionate Use. Expanded Access (Compassionate Use). Also, please see FDA guidance on Expanded Access https://www.fda.gov/downloads/drugs/guidances/ucm351261.pdf OGCP cannot specifically answer your questions. We suggest you contact Center for Drugs (CDER) directly at druginfo@fda.hhs.gov

Kind regards,

The OGCP Group

From: [redacted]
Sent: Tuesday, February 13, 2018 9:23 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Compassionate Use IND

Dear GCP:

I have been approached about an expanded access situation and am trying to navigate the expanded access world. I read all the information FDA has put out on the issue, but what I have read does not appear to fit the instance at hand. With that, I was wondering whether you could direct me to published information or impart on me your FDA regulatory knowledge regarding the following scenario.
A physician notifies his local IRB about an expanded access situation one year after he treated his patient with an expanded access product, a vaccine. The physician sought and received the investigational product from the [redacted] via a [redacted] compassionate use IND. The physician called the [redacted] and was subsequently provided the product. (Per the documents I reviewed it appears that the physician did not satisfy all of the FDA regulatory criteria, e.g., never received written confirmation from an uninvolved physician that the patient provided with the vaccine was eligible for treatment with the expanded access product.) The [redacted] informed the physician that he could treat his patient under a standing [redacted] IRB protocol instead of going to his own local IRB; this in fact is what the physician did using a [redacted] IRB approved informed consent form. Thus, the reason for not contacting his local IRB at the time of treatment use.

What I am trying to figure out is what steps the physician needed to take prior to treating his patient regardless of the holder of the compassionate use IND. In other words, are there different regulatory requirements for physicians treating patients under a compassionate use IND held by the [redacted]? If so, can you tell me what those requirements are? Alternatively, if the requirements are the same regardless of IND holder status can you list the requirements here for me or direct me to where I can find this information, e.g., the FDA expanded access guidance document?

Lastly, may an IND holder also have a standing IRB approved protocol to cover possible future treatment uses of a product covered by its own compassionate use IND? I raise this as it appears to be a possible COI.

Any assistance would be greatly appreciated.

[redacted]

[redacted]