From: OC GCP Questions
To: [redacted] OC GCP Questions
Cc: Kalb, Soma
Subject: RE: Compassionate Use - Question regarding process
Date: Thursday, June 25, 2015 8:12:00 AM
Attachments: [redacted]

Dear [redacted],
Responses are below each of your questions. For investigational device studies, you may also direct questions to Dr. Soma Kalb, IDE Director at soma.kalb@fda.hhs.gov .

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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Office of Special Medical Programs, Food and Drug Administration

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Wednesday, June 24, 2015 1:22 PM
To: OC GCP Questions
Subject: Compassionate Use - Question regarding process

To Whom It May Concern,

I would like some clarification on 2 topics related to compassionate use approval of a device:

01) For a device study that has already been reviewed and approved by the institutional IRB, if a physician seeks and receives approval from the FDA for a protocol deviation under the compassionate use provision, is the site also required to submit a protocol deviation report to the IRB? I have been told that since the FDA has approved the deviation, the variance does not meet criteria of a reportable protocol deviation to the IRB.
Compassionate use requests that have been approved by FDA prior to the use of the device would not be reportable as a *protocol deviation* to the IRB, but the compassionate use request does have to be reported to the IRB or Chair, and either Board approval or IRB Chair concurrence granted prior to using the device (per your facility's SOPs). See response to question #2 below.

02) Regarding the IRB review, my understanding is that if the device has already been reviewed and approved the institutional IRB, the only approval needed from the institutional IRB to

include the patient in the study under the compassionate use provision, is IRB Chair Concurrence. Is this correct?

FDA requires only IRB Chair concurrence; the level of IRB review needed depends on your facility's SOP and any state or local laws. Your SOP may require either Chair concurrence, a sub-committee review or review by an expert in the patient's disease/condition in addition to IRB Chair concurrence, or your SOP may full Board review. Please follow your institution's SOP. If you don't have an SOP for compassionate use, IRB Chair concurrence for device studies is sufficient from FDA's regulatory requirements, but please check with your legal counsel to be sure there are no overriding state or local requirements.

Your assistance is truly appreciated.

Kind Regards,

[redacted]